Environmental Policy and Public Health

Second Edition

Barry L. Johnson and Maureen Y. Lichtveld

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About the Cover

The authors of this book intend the cover to speak about the book's contents. The centerpiece of the cover is planet Earth, as presented by a striking image from the National Aeronautics and Space Administration (NASA). Earth's resources provide the basic essentials to sustain life on the planet: air, water, land, and energy. Further, human life on our planet depends on healthful air, potable water, and safe sources of food. Unfortunately, humankind has not always appreciated the essential nature of Earth's sustainable resources. Arrayed on the cover are examples from the text of humankind's mismanagement of air, water, and food resources, together with other environmental conditions that can affect human and ecosystem health. The images arrayed around planet Earth pertain to climate change (polar bears), air pollution in a major Asian city, a point source of water pollution, devices for inhalation of tobacco products, food waste, plastic waste in the Pacific Ocean, the mosquito that carries the Zika virus, and an American bald eagle, a species saved from extinction, These images on the cover presage the book's description of specific environmental hazards and policies and practices purposed to prevent or diminish their deleterious effects on the residents of planet Earth.

Dedication

This book is dedicated to those policymakers, scientists, medical investigators, environmental and public health agencies, nongovernmental organizations, and individuals who have advocated science-based environmental health policies that have led to human and ecosystem health protections and improvements in environmental quality. Absent their dedicated efforts, our planet and its living organisms would be fewer in number and poorer in well-being.

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Preface

Ten years have passed since this book's first edition was published. Quoting from the Foreword in that edition, "We all benefit from potable water, clean air, food safe to consume, and sanitary disposal of wastes, all environmental conditions that were goals of our ancestors." Although a decade has passed, these goals remain since they are intimately linked to human survival and well-being. But the passage of a decade has resulted in considerable changes, issues, and challenges that may attend the well-being of humankind, indeed, attend the very survival of our planet. These rather dramatic changes have necessitated a second edition of *Environmental Policy and Public Health*.

As with the first edition, this second edition describes how environmental health policies are developed, the statutes and other policies that have evolved to address public health concerns associated with specific environmental hazards, and the public health foundations of the policies. This edition describes policies for what we consider the major environmental physical hazards to human health. Specifically, we describe hazards from air, water, food, hazardous substances, and wastes. To this list we have added the additional concerns from climate change, tobacco products, genetically modified organisms, environment-related diseases, energy production, biodiversity and species endangerment, and the built environment. And as with the first edition, we describe histories of policymaking for specific environmental hazards. Our experience has shown us that knowledge of history gives a vital perspective on how various societies have developed policies to protect against specific environmental hazards. History imparts wisdom, and in absence of wisdom, we all have to struggle.

This edition differs from its antecedent in three significant themes. First, environmental hazards and their consequences are a global issue and concern. We have therefore added global perspectives to chapters that describe specific environmental hazards, e.g., air pollution. Second, we acknowledge that humankind exists in a complex ecosystem. We therefore provide narrative material wherever possible on the consequences of environmental hazards on both human and ecosystem health. Moreover, we consider it essential to link human and ecosystem health as fundamental branches of the same tree of well-being and sustainability. Third, we have added material about interventions that policymakers and individuals can consider in mitigating or preventing specific environmental hazards.

This work can be grouped into five sections. The first section comprises five chapters that provide basic information and data on policymaking basics, policy foundations, and resources for policymaking. The second section describes policies, issues, and health foundations for specific, known environmental hazards, including chapters on climate change, tobacco products, air quality, water quality and security, food safety and security, hazardous chemical substances, waste generation and management, and environment-related infectious diseases. The third section comprises four chapters that are emerging areas of relevance to environmental health: energy production, genetically modified organisms, biodiversity and endangered species, and the built environment. The fourth section contains policy impacts of environmental justice, policy impacts of risk assessment, and lessons learned and the authors' reflection. The fifth section comprises a set of abbreviations, relevant websites, and a glossary of key terms. An index is provided as the terminus.

We intend this work to be useful to students in academic programs of public health, environmental science, and environmental policy and to persons concerned about environmental hazards and policymaking. Moreover, we consider it important to have an appreciation of the history of environmental health's evolution and legislative development. Policies and actions that help protect the public from the adverse consequences of environmental hazards did not appear without a considerable struggle; knowing this history is vital if the protections they bring are to be maintained.

We have used many published sources that have contributed to the content of this book, but some content represents the experiences and views of its authors, whose public health careers in environmental and occupational health provide experienced perspective for understanding policymaking and associated efforts.

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The authors express their sincere appreciation to several persons who reviewed drafts of the first edition and who made significant improvements in its content. In particular, we express our appreciation to several graduate students at the Rollins School of Public Health, Emory University, who provided editorial comments. Similarly, environmental health students at the Morehouse School of Medicine and Georgia State University provided helpful editorial suggestions for the first edition. The authors further acknowledge the involvement of two faculty colleagues at the Department of Global Environmental Health Sciences, Tulane University: Dr. Christopher Mundorf for his significant contribution to the chapters on energy and the built environment and Dr. Diana Hamer for lending her expertise to the infectious disease chapter. We also acknowledge Dr. Seth Ebersviller, University of Findlay, for his contributions to the air quality chapter on air monitoring in the context of policy. We also acknowledge the contributions of Morris L. Maslia, Senior Environmental/Water Resources Engineer, Agency for Toxic Substances and Disease Registry, for his contributions to the preparation of select graphics in this book. The authors also appreciate the thoughtful feedback on the policy questions provided by Carlo Basilio, Shayna Goldfine, Rebecca Timmons, and Imani White, students of environmental policy in the Department of Global Environmental Health Sciences, Tulane University.

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Section I

Policymaking Basics, Foundations, and Resources

1 Fundamentals of Environmental Health Policymaking

1.1 INTRODUCTION

Humankind's journey through the ages has been difficult. Our primordial ancestors faced threats to their survival in a hostile environment. Wild carnivorous animals abounded and natural disasters such as forest fires and floods surely presented grievous challenges to our ancestors. Over time the nature of the environmental hazards changed as humans passed from a nomadic, tribal existence to a more communal lifestyle in small villages and, later, large cites. As humans huddled together in increasingly larger numbers, health problems magnified in both numbers and severity of disease. Perhaps no greater health calamity has befallen humankind than the bubonic plague (also called the Black Death). There were three major pandemics of the plague, occurring in the sixth, fourteenth, and seventeenth centuries. The death toll approximated 137 million victims. The pandemic of the fourteenth century was particularly devastating, causing the death of 25 million people. Ultimately, the plague killed about one-third of Europe's population over a 5-year period, beginning in the year 1347. The plague was eventually found to be caused by the bacterium *Yersinia pestis*, which is spread by fleas that infest animals such as the black rat [1]. The plague, an example of an extreme environmental health problem, illustrates the importance of environmental hazards as a public health concern.

Policy: A definite course or method of action selected from among alternatives and in light of given conditions to guide and determine present and future directions [2].

A healthy environment promotes healthful conditions necessary to sustain living creatures. While this observation seems obvious, in practice, societies that have developed vigorous agricultural and industrial bases have found that pollution became a consequence of those activities. Air quality deteriorated, water purity diminished, and lands became fouled by chemical and other hazardous substances. As biomedical research on the effects of environmental hazards progressed, it became evident that environmental degradation was associated with adverse effects on the health of human populations and ecosystems.* Before proceeding, two definitions are important: hazard and risk. As we will discuss in Chapter 19, the U.S. Environmental Protection Agency (EPA) defines "hazard" and "risk" as shown herein. Although similar definitions are available elsewhere, the cited definitions are purposeful for use in this book.

Hazard: Potential for radiation, a chemical or other pollutant to cause human illness or injury [3].

Risk: A measure of the probability that damage to life, health, property, and/or the environment will occur as a result of a given hazard [3].

In response to concerns about environmental hazards, the federal, state, territorial, and local governments in the U.S. have enacted various statutes meant to conserve the natural environment, assure environmental quality, and protect human and ecological health. Underpinning this effort are policies that shape the intent and implementation of the statutes. This chapter presents an overview of key fundamentals that shape the development of environmental policy. Included in this chapter are a summary of how environmental health has evolved, the fundamentals of public health, the role of government in environmental health, and public policies of relevance to environmental health. Moreover, how environmental policies have emerged in the U.S. and other countries relevant to the practice of public health is also the focus of this book.

1.2 ENVIRONMENTAL HEALTH POLICY FRAMEWORK

Environmental health policy comprises actions that are intended to eliminate the effects of exposure to environmental hazards. One way to consider this kind of policy is to consider its uses, users, and nonusers, yielding the following five considerations.†

Directness. Some policies directly address environmental health. Examples include the EPA‡ standards that regulate the levels of a contaminant in an environmental medium, e.g., levels of air pollutants in outdoor, ambient air. Other policies are primarily environmental policies, without a health focus, but they indirectly affect human health or environmental quality. An example would include the National Environmental Policy Act, discussed in Chapter 4, wherein a national policy of environmental protection is articulated. And still other policies are not even environmental, but they incidentally have a

* Ecosystem—The interacting system of a biological community and its nonliving environmental surroundings [3].

† The authors express their gratitude to Dr. Howard Frumkin, while at Rollins School of Public Health, Emory University, for this contribution.

‡ Lists of key definitions and abbreviations are found at the end of this book, as is a glossary.

major impact on environmental health. For example, national energy policy has an impact on which motor vehicles and heating fuels are used, which, in turn, can affect air quality and therefore human health. This book primarily addresses those environmental health policies that most directly affect human and ecosystem health, since they present a direct course of action in controlling the adverse consequences of environmental hazards.

Level of government. Environmental health policies span the full spectrum of government. This book gives emphasis to U.S. federal government policies, e.g., the Clean Water Act and its attendant policies on controlling emissions of contaminants into bodies of water in the U.S. However, state and local governments also develop environmental health policies and to enact legislation that addresses issues specific to a state's environmental conditions. States enact statutes that are necessary to comply with federal statutes and regulations. For instance, states will enact statutes and provide resources to meet the provisions of the federal Clean Air Act (CAAct), which stipulates specific requirements of states. And local governments establish environmental health policies through ordinances, such as prohibitions on smoking of tobacco products in public facilities. In general, environmental health policies become more specific and targeted as they transition from federal to state to local government.

The federal preemption doctrine is important when issues of disagreement occur between federal and state policymakers, leading to seemingly conflicting policies. These disagreements usually find their way into the province of the judicial system. The preemption doctrine derives from the Supremacy Clause of the Constitution, Article VI, which states that the "Constitution and the laws of the United States […] shall be the supreme law of the land […] anything in the constitutions or laws of any State to the contrary notwithstanding." This means, of course, that any federal law—even a regulation of a federal agency—trumps any conflicting state law. Despite the efforts of some states, even today, to "nullify" federal laws of which they disapprove, few things in constitutional law are any clearer than the fact that any such efforts by states are grossly unconstitutional. What remains as a much more difficult question under Article VI is when a state law or action, which is at least arguably consistent with federal law, in fact creates sufficient conflict so as to justify finding it "preempted" [4].

Preemption can be either expressed or implied. When Congress chooses to expressly preempt state law, the only question for courts becomes one of determining whether the challenged state law is one that the federal law is intended to preempt. Implied preemption presents more difficult issues to courts, at least when the state law in question does not directly conflict with the federal law. The court then looks beyond the express language of federal statutes to determine whether Congress has "occupied the field" in which the state is attempting to regulate, or whether a state law directly conflicts with the federal law, or whether enforcement of the state law might frustrate federal purposes. The matter of implied preemption can be a thorny issue for courts to decide.

Primary strategy. Policymakers such as legislators and government officials have implemented several primary strategies into environmental health policy. Some strategies directly aim to reduce the effects of hazards—some in a prospective manner (e.g., air pollution regulations), whereas others through retrospective action (e.g., cleanups of uncontrolled hazardous waste sites). Other policies do not directly regulate a hazard, but provide information to the public about the hazard, in effect relying on individuals to make informed health decisions. This is a kind of laissez-faire approach to controlling the effects of some environmental hazards. Examples include health warnings on tobacco products; the Toxics Release Inventory, a public database compiled by the EPA on the composition and amounts of pollution released from industrial facilities; and workers' right-to-know communications under the Occupational Safety and Health Act (OSHA), wherein employers must provide employees with information on workplace hazards.

The prime actor in the policy. There can be several prime actors in the development of environmental health policies. While this chapter emphasizes the role of government as the prime actor, private parties can also play a significant role. For example, the American Conference of Industrial Hygienists (ACGIH), a professional society, develops recommended exposure limits for substances found in workplaces. Private industry uses the ACGIH exposure limits as voluntary guidelines for workplace controls when government standards are not in effect. Similarly, the International Standards Organization develops recommended guidelines that industry and some government agencies adopt. As discussed later in this chapter, individuals can be prime actors in helping establish an environmental health policy through litigation against a government agency or a business. Consider the example of a person who litigated a restaurant chain when a cup of very hot coffee spilled on her legs while driving. The coffee's temperature was sufficiently high to cause severe burns. Litigation compensated the woman for her injuries and also contributed to the restaurant chain's voluntary decease in the temperature of the coffee served throughout the restaurant chain. As a consequence, one person's litigation contributed to control of an environmental hazard that was potentially faced by millions of people.

What does not get regulated. This chapter focuses on policies that relate to regulations and standards as the primary means to control environmental hazards. Not described are important environmental issues for which regulatory policies do not exist. Examples of nonregulated environmental hazards include indoor air of domiciles, which is not covered under the federal CAAct and tobacco products for which product labeling is required, but product safety (i.e., sales of tobacco products) is not regulated. These examples illustrate that unregulated environmental hazards can present deleterious impacts on the public's health.

Developing policy, according to our chosen definition, must involve the identification of alternatives that might be applied to specific situations. From the alternatives, policymakers involve the affected public to determine the best

alternative, communicate their decision to interested parties, and apply the policy when future circumstances arise where a response must be based on policy.

1.3 KEY DEFINITIONS

In order to understand and appreciate the complexities of establishing and maintaining environmental health policy, we need to have a common understanding of words and phrases. A common vocabulary is essential if communication and debate over environmental health policies are to occur in any productive manner. Some might say that meanings of words and phrases such as *policy*, *health*, *public health, environment*, ecology and ecosystem, *environmental health*, and *politics* are obvious and well known. This is not the case, however, because meanings of words reside in individuals themselves, not in any inherent properties of words themselves. Differences in how people understand words occur because of variations in individuals' cultural backgrounds, educational levels, home and business environments, and situational-specific settings. As aids to understanding meanings of words, dictionaries help us achieve partial common agreement on words' meanings, but even they must use more words in order to define meanings of specific words.

Meanings of words reside in people, not in any inherent property of words themselves.

We can approach a common understanding of a word or phrase by accepting a definition chosen from a credible source (e.g., a dictionary) and then discussing the definition within the group needing a common definition (e.g., a group of students). With this approach in mind, the definitions are proposed for key words and phrases pertinent to discussions of environmental health policy.

1.3.1 Policy

Policy: *A definite course or method of action selected from among alternatives and in light of given conditions to guide and determine present and future directions* [2]. More to the point of this book, policy is also defined as a plan that embraces the general goals and acceptable procedures in governmental action [2]. Effective policymaking normally will require choices among alternatives and will be based on conditions at hand. In a sense, making environmental health policy is no different from making family or business policies. Many families choose as a matter of policy to budget their expenditures. For businesses, some adopt a policy to service all customer complaints within a specified period of time. In both examples, alternatives were surely considered and a course selected to guide future actions.

Developing policy, according to our chosen definition, must involve the identification of alternatives that might be applied to specific situations. From the alternatives, policymakers (e.g., a legislative body, tribal council, or parent) determine the best (applying stated criteria) alternative, communicate their decision to interested parties, and apply the policy when future circumstances arise whose response must be based on policy.

1.3.2 Health

Health: *A state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity* [5]. This definition comes from the widely respected World Health Organization (WHO), headquartered in Geneva, Switzerland. WHO is a component of the United Nations (UN) and its research, reports, and services are widely accepted by health agencies worldwide. It provides technical assistance and resources globally on programs of human health, including preventing the spread of AIDS, polio, and infectious diseases. Among its many contributions to global human health, WHO led the campaign against smallpox as a global scourge to human health, announcing in 1981 that the disease had been eradicated globally.

By the WHO's definition, a healthy individual, group, or population is free of physical and mental disease and infirmity, as well as being in a state of social well-being. As individuals, the absence of conditions such as bodily injury, cancer, heart disease, depression, or paranoia either is obvious or can be diagnosed by a medical provider. Less obvious in WHO's definition of health is what is meant by *social well-being*, certainly an altruistic component of the definition. But what might be intended by WHO? Several examples reflective of social well-being could include adequate housing, education, income, and living conditions; freedom from war, malnutrition, political abuse, and poverty; and ability to participate in political systems and public policymaking.

The fundamental principle of public health is the prevention of disease and disability.

1.3.3 Public Health

Public health: *The process of mobilizing local, state, national, and international resources to solve the major health problems affecting communities* [6]. This definition, one of several in existence, is appealing for use in a text on environmental health policy. This is because environmental hazards and problems are often community-based, increasingly global, and due to their complexity require multiple resources for risk management and problem solution. Moreover, this definition of public health implies that major health problems must take priority over those of lesser consequence. Increasingly, risk assessment,* as described in Chapter 19, is a tool used by environmental health specialists to separate major hazards to human and ecological health from those of lesser importance.

Public health can be understood as meaning "the public's health." Unfortunately, the U.S. public has an unclear concept

* *Risk assessment*—Qualitative and quantitative evaluation of the risk posed to human health and/or the environment by the actual or potential presence and/or use of specific pollutants [3].

of what public health agencies do and what their programs accomplish, and often associate the term *public health* primarily as being health services for indigent persons. In reality, the spectrum of U.S. public health programs and services encompasses such efforts as global vaccination and other programs, national programs of childhood immunization, cancer research, mental health programs, lead exposure prevention, disease surveillance, medical education, and funding for local health centers. Local health departments conduct such programs as restaurant inspections, vector* control, sanitation programs, immunizations, and activities to prevent the spread of infectious and chronic diseases. From these examples, one can appreciate the broad impact of public health programs on the U.S. public.

1.3.4 Environment

Environment: *The circumstances, objects, and conditions by which one is surrounded* [2]. As an example, consider a student's classroom environment. Circumstances of a student's environment could include an assigned seat in the classroom, thus placing the student in the same location for all class sessions. Another circumstance could be whether the class was required or optional, which could determine which classroom the student occupies. Objects in a student's classroom environment could include other students, desks, tables, video equipment, and such. Conditions of the environment could include ambient air temperature, barometric pressure, relative humidity, lighting intensity, and noise levels.

1.3.5 Ecology and Ecosystem

Ecology: *The relationship of living things to one another and their environment, or the study of such relationships. Ecosystem*: *The interacting system of a biological community and its non-living environmental surroundings* [3]. An example of an ecosystem would be the interacting system of students, faculty, administrative personnel, trees, streams, wildlife, and other biological communities within a college campus. On a larger scale, the Great Lakes region can be defined and administered as an ecosystem.

1.3.6 Environmental Health

Environmental health: *Comprises of those aspects of human health, including quality of life, that are determined by physical, chemical, biological, social and psychosocial factors in the environment. It refers also to the theory and practice of assessing, correcting, controlling, and preventing those factors in the environment that can potentially affect adversely the health of present and future generations* [7]. This verbose definition is no doubt the product of a committee. However, it bears the imprimatur of the WHO, which adds credibility and importance to the definition. Note that this definition is specific to human health and, like WHO's definition of health, includes mention of physical, chemical, and social factors. The second half of WHO's definition expresses the elements of both hazard assessment and risk management. Noteworthy in the definition is mention of *quality of life*, a subjective term. But given the overall environmental context of the definition, *quality of life* could include examples such as the adverse psychological consequences of living near a foul-smelling industrial facility or by living in a metropolitan area where a major highway has been constructed through a formerly well-established neighborhood, thereby exposing residents to more noise and air pollutants and fracturing social relationships due to neighbors' relocation.

Remarkably, the WHO's definition is but one of many existing definitions of environmental health. One source collected 26 different definitions [8], which suggests insufficient effort has been given to achieving a consensus definition for use by environmental health specialists. Given increasing global commitment to reducing the impact of environmental hazards (e.g., the Kyoto Protocol to reduce greenhouse gases (Chapter 6), which are chemicals that have the potential to increase global warming), a plea for a common definition needs action.

There is an alternative definition for the phrase *environmental health* that gives emphasis to the word *environmental* [9]. In this definition, environmental health refers to the health of the environment, that is, considerations of environmental quality, ecosystems' well-being, and conservation of natural resources. For example, in this context, one could speak about the environmental health of equatorial ecosystems as affected by deforestation and human population growth.

1.3.7 Politics

Politics: *(a) The art or science of government, (b) political affairs or business, (c) the total complex of relations between people living in society* [2]. Although most people associate politics with politicians and government, in fact, politics occur within families, businesses, civic organizations, schools, and other societal structures. In all of these examples, politics must incorporate dialog, debate, negotiation, and, ultimately, compromise among the interested parties.

Politics permeates the development and execution of environmental health policy. Some persons may have a negative opinion of politics and politicians because the practice of politics necessarily involves negotiation and compromise, and some politicians have been poor examples of ethical behavior. Thus, to associate a somewhat unwholesome opinion of politics with an altruistic image of public health might seem contradictory to some persons. Moreover, if public health is about preventing disease and disabilities in human populations, should not something so important "be above" politics? The answer, of course, is no. Politics involve relationships among people, and the core of public health rests with people. How public health departments reach out to the public is a matter of politics, involving communication, negotiation, and compromise. Further, government public health organizations must

* Vectors are living organisms that can transmit infectious diseases between humans or from animals to humans.

All successful politics must include discussion, negotiation, and, ultimately, compromise.

compete with other government programs for budgets, personnel allocations, and operational authorities—all of which necessitates political acumen and wisdom.

This collection of definitions of *policy, health, public health*, *environment*, ecology and ecosystem, *environmental health, hazard*, *risk*, *hazard evaluation*, *risk assessment*, and *politics* will help us better understand the development of environmental health policy in the U.S. and attendant actions resulting from specific policies.

1.4 EVOLUTION OF ENVIRONMENTAL HEALTH

An understanding of the evolution of environmental health is necessary for an appreciation of modern environmental policy. After all, as the Spanish-American philosopher George Santayana [10] commented, "Those who cannot remember history are condemned to repeat it." As discussed in this section, humankind long ago learned the importance of potable water and proper disposal of human wastes, perhaps dating to the time of the Neolithic Revolution, which occurred during the period 8000–7000 BCE [11]. During this period humankind began changing from a hunter-gatherer society to a society that relied on agriculture and domesticated animals, forming small tribal settlements in the process. In fact, it can be asserted that modern public health has its historic roots in what we now call *environmental health*. Later, as human populations increased, clean air and safer food supplies were added to the environmental health agenda. Much of modern environmental health policy and practice in the U.S. has roots in nineteenth century Europe, as will be subsequently discussed.

1.4.1 Historical Environmental Hazards

The struggle by humans to overcome environmental problems is certainly not new. Archaeological research has revealed that some ancient civilizations developed ways to dispose of human wastes and to provide water to their expanding cities. As described by the public health historian George Rosen [11], archaeologists have found ancient ruins where bathrooms, flushing toilets, and water gutters were present (Table 1.1), some dating to 2100 BCE. The geographical diversity of these ruins is impressive—extending from northern India to the Incas in South America. Notable is the presence of water supply systems developed by the two major early European cultures: Greek and Roman. Both civilizations built elaborate systems of aqueducts and canals to bring water to the expanding cities of Athens and Rome, respectively.

The environmental health resources listed in Table 1.1 illustrate humankind's search for more healthful living conditions. Such conditions, then and now, include living with an ample, potable supply of water to meet daily needs and for sanitary disposal of human wastes. Maintaining these systems of water supply and waste disposal are constant challenges to modern policymakers because of increases in human populations and global climate change. The former puts added pressure on water resources and sewage systems; the latter will change geographic patterns of rainfall and land use.

1.4.2 Necessities for Survival

Humankind's prosperity over the ages can be attributed to many factors, but surely meeting basic human survival needs must be the foremost factor. For human life to exist there must be healthful air, potable water, and secure food. Absence of any of these three is a death sentence. Another survival need is the sanitary disposal of human wastes, since improper management connotes disease and illness. Moreover, the environment must be sustainable if survival is to continue. The following sections overview the evolution of humankind's means to address these five basic survival challenges, presented in order of their likely historic development.

1.4.2.1 Sanitary Waste Management

There is, of course, no precise date in antiquity that demarcates humankind's awakening to the health hazards of their environment. But there were certainly environmental

TABLE 1.1
Environmental Health Resources before the Common Era

Location	Period	Environmental Health Resource
India: Indus Valley and Punjab	2100 BCE	Bathrooms and drains found in excavated buildings
Egypt: Middle Kingdom	2100–1700 BCE	Water gutters found in excavated city
Troy	2000 BCE	Water supply system
Crete	2000 BCE	Flushing toilets found in excavated palace
Incas	—	Sewage systems
Greece	600 BCE	Water supply system
Rome	312 BCE	Aqueduct to Rome

Source: Rosen, G., *A History of Public Health: Expanded Edition*, The Johns Hopkins University Press, Baltimore, MD, 1993.

BCE, before Common Era.

challenges faced by cave dwellers and other prehistoric peoples. Carnivorous animals, natural disasters, and emerging human diseases all surely took their toll on our earliest ancestors. However, one could postulate that diseases produced by unsanitary environmental practices and humankind's management of them could be called our first environmental health experience. More specifically, improved sanitation management of human wastes was a most important environmental health advancement as encampments grew into villages and then into cities. Too often human wastes were deposited into the residential environment, contaminating drinking water supplies. Cholera and dysentery were grievous outcomes of consumption of impure water.

Attempts to improve basic sanitation practices began during the middle ages in Europe. In the early middle ages, sanitary household practices were primitive to say the least. According to one source [11], "In much of medieval Europe, sanitation legislation consisted of an ordinance requiring homeowners to shout, 'Look out below!' three times before dumping a full chamber pot into the street." Because many houses were multistoried, dumping chamber pots literally caused a rain of human wastes on persons on the streets below. There the waste lay until rain washed it away to be deposited in lower lying areas or waterways. Later, larger cities began building sewers and reducing human wastes left on streets. Practices in China probably preceded anything done elsewhere. For instance, in rural China, "night wastes" have for centuries been routinely collected and used as fertilizer for crops and land, resulting in top soil thickness measured in feet, not inches as in the U.S. As to the earliest environmental health intervention, some public health historians might attribute that to John Snow's removal of a pump handle in London, thereby preventing public access to a community water well contaminated with fecal coliform bacteria, which Snow associated with an ongoing cholera epidemic [12].

In more modern times, the U.S. has enacted federal statutes that control the levels of contaminants that can be released into water supplies and for management of human wastes. These are described in Chapters 9 and 12.

1.4.2.2 Potable Water

Water quality was, and remains, an environmental health problem of great concern to many human populations. Over time, exposure to human wastes found in water gradually decreased by moving latrines, public toilets, and isolated privies away from such water supplies as wells, springs, lakes, and flowing streams. Some of these changes occurred when armies formed themselves into encampments. Military leaders knew the health importance of constructing latrines and requiring their use by troops. As a consequence, one can imagine troops returning to small villages with some experience on how to better manage the disposal of human wastes.

In the U.S., as migration of immigrants increased in numbers, villages and cities sought better ways to protect their water supplies. In contrast, persons who lived on farms and in rural areas had to depend on wells, springs, and surface waters as sources of drinking water. For both urban and rural dwellers, avoidance of biologically contaminated water certainly was of concern, but without the population knowing how to protect themselves. Indeed, as discussed in Chapter 9, sanitary practices and water contamination first came within the province of public health authorities in the early part of the twentieth century. Local sanitation authorities became involved with construction of sanitary sewers and location of waste facilities. The emergence of city and county health departments occurred in the twentieth century. Sanitarians soon became integral members of local health departments.

1.4.2.3 Healthful Air Quality

As cities grew in size and complexity, air pollution resulting from burning coal for industrial purposes and for home heating became another environmental problem. In Europe and the U.S., coal burning created huge amounts of carbonaceous particulates that darkened the environment, fouled the air, and lowered the quality of life. The consequences of air pollution on environmental quality and public health are described in Chapter 8. Suffice it to say here that death to residents of Donora, Pennsylvania, in 1948 and London, England, in 1952 from exposure to episodes of highly polluted air had a major influence on enactment of U.S. federal clean air legislation. In more recent times, emissions from industrial plants and from motor vehicles powered by internal combustion engines have become of public health concern, as described in Chapter 8, where other adverse public health effects of air contaminants are discussed.

1.4.2.4 Food Security

Food, of course, is vital for human survival. In Colonial America and well into the twentieth century, food was produced by farmers and ranchers. In villages and cities, food was purchased at local markets and prepared at home for consumption. Foodborne illness was primarily the responsibility of those who prepared food. As the U.S. passed from an agrarian society into an industrial economy, food was increasingly produced by large agricultural enterprises, and imported supplies of food increased in volume and variety. As food sources became less familiar to consumers, food safety concerns increased.

Perishable food was a special problem for consumers. Methods were developed for canning vegetables, fruits, and some meat products. Canning involved placing cooked food into sterile, sealed containers, a process that killed microorganisms, thereby lessening the possibility of food poisoning. Other preservation methods included sun drying of some foods and the use of preservatives such as salt and the smoke from wood fires. These methods reduced the amount of moisture in the treated foods and thereby inhibited the growth of microorganisms. But technological breakthrough needed to occur before perishable foods could be stored in large quantities for appreciable lengths of time. The invention of refrigeration equipment and its widespread distribution were responsible for increasing food safety. Beginning in the 1930s, perishable food could now be shipped in refrigerated trucks, stored in refrigerated warehouses, and sold to stores and restaurants for

placement in freezers and other refrigerated equipment. The public's health was improved by this technology. However, as will be discussed in Chapter 10, food safety and security concerns remain a major public health problem, given the large number of foodborne illnesses that occur annually in the U.S. and globally.

1.4.2.5 Sustainable Environment

Having access to adequate sources of air, water, food, and methods of waste disposal is necessary for survival, but access itself does not guarantee long-term survival if the access is not sustainable. Sustainability is the ability to continue a defined behavior indefinitely. In this instance, the defined behavior is survival. Consider the defined behavior of animals that rely on only one source of food. If the sole food source disappears, so must those that depend on its availability. The giant panda, whose sole food source is bamboo, and koala, whose only food source is eucalyptus trees, can exist only as long as the sustainability of sources of bamboo and eucalyptus trees, respectively. Humankind's survival ultimately also relies on a sustainable environment. Herman Daly, one of the early pioneers of ecological sustainability, looked at the problem from the perspective of maintenance of natural capital. He proposed in 1990 that:

1. For renewable resources, the rate of harvest should not exceed the rate of regeneration (sustainable yield);
2. [For pollution] The rates of waste generation from projects should not exceed the assimilative capacity of the environment (sustainable waste disposal); and
3. For nonrenewable resources the depletion of the nonrenewable resources should require comparable development of renewable substitutes for that resource [13].

Daly's list gives emphasis to the importance of humankind's management of both resources as well as waste disposal. Chapter 2 will discuss sustainable development, a policy with a focus different from that of sustainable environment.

1.4.3 European Roots

Modern environmental health systems and practices in the U.S. generally derive from those developed in mid-nineteenth-century Europe, although this attribution may wrongly be based on of our lack of knowledge about conditions in other parts of the world. The evaluation of public health awareness and the sanitary movement in Europe in the early to mid-1800s had common roots: industrialization, unsafe and unhealthful working conditions, inadequate sanitation in crowded cities, and persons of vision who were committed to improving the public's health. These conditions were most evident in England, France, and Germany.

One source asserts that the devastating bubonic plague (also called the Black Death) that ravaged the globe during the mid-fourteenth century gave rise to the initial development of public health [14]. He notes, "The Black Death also played a major role in the birth of public health. One early innovation in the field was the municipal health board, such as those in Florence and Venice established in 1348 to oversee sanitation and the burial of the dead. Later the boards would grow more sophisticated. In 1377 Venice established the first public quarantine in its Adriatic colony of Ragusa (modern day Dubrovnik)." It is interesting to note that to some extent what we now call public health has some of its roots in humankind's struggle with a notorious pandemic plague.

In early nineteenth century England, the enclosure of common lands had the deleterious social consequence of creating huge numbers of rural poor. Their numbers exceeded the capacity of the country's existing relief system for the poor. These newly impoverished families migrated to the nascent emerging industrial cities, where work, often hazardous and exploitive of children, was available [11]. Whole families were often crammed into dank basements and cellars, with inadequate or nonexistent sanitary facilities.

As workplace and community living conditions in England continued to worsen, social and health reformers emerged. Principal among them was Edwin Chadwick. The New Poor Law Act of 1834 created a new labor market, facilitating the immigration of the rural laboring poor into the harsh reality of urban factory work [11]. Chadwick had been a primary author of the 1834 act. Later, in 1842, he and colleagues published the influential *Report on the Sanitary Conditions of the Labouring Population of Great Britain*. The report became the seminal work that reformed public health in England. Chadwick and others were convinced that prevention of epidemic disease, e.g., cholera, was less costly to the English economy than treating the consequences of unabated disease. The English model of disease prevention through improved living conditions and sanitary reforms found favor in France and Germany and later also influenced public health policy in the U.S.

In France, during the reign of Louis Philippe (1830–1848), the country's economy began to change from agriculture to industrialization. This change continued until the 1870s, according to Rosen [11]. The French public health movement evolved during this roughly 40-year span. Terrible working conditions were mimicked by equally horrible living conditions, especially in rapidly expanding industrial cities. Overcrowded living conditions were but one symptom of urban distress. Lack of sanitary facilities, poor quality drinking water, and epidemic disease were the companions of impoverished communities.

Commencing in 1841, with the passage of labor legislation regulating child labor in factories, a body of law and sentiment gradually emerged in support of a public health system in France. The outstanding figure in the French public health movement was Louis René Villermé, known for his study of textile workers' health, who aroused public opinion about hazardous workplace conditions [11]. Earlier, in 1828, Villermé had published a report showing that mortality and morbidity rates were closely related to living conditions across social classes. Later, in 1848, a French law created a network of local

public health councils. These councils were not particularly effective, but did serve the purpose of committing the government to a national program of public health.

The public health movement in Germany emerged later than those in England and France. This was due in part to the fact that the modern German nation did not exist until late in the nineteenth century, when the Prussian leader Otto von Bismarck unified the German states into a nation. Similar to England and France, industrialization within the German states was evident by 1848, producing patterns of workplace hazards and unhealthful urban communities. Rosen [11] observes that two health reformers, Rudolph Virchow and Solomon Neumann, were leaders in shaping the German public health evolution. In 1848, Virchow advocated that government programs should provide public medical care for indigent persons. Although this and other social reform proposals foundered, the decades afterward led to a program of limited sanitary reform. During the 1860s and 70s public health reform again emerged. Focused efforts to improve sanitary conditions in Berlin and Munich contributed to the creation in 1873 of the Reich Health Office, the start of a unified, national public health system in Germany [11].

1.4.4 Recent Trends

Environmental factors play a central role in human development, health, and disease. Broadly defined, the environment, including infectious agents, is one of three primary factors that affect human health. The other two are genetic factors and personal behavior. Human exposures to hazardous agents in the air, water, soil, and food and to physical hazards in the environment are major contributors worldwide to disease, disability, and death. Furthermore, deterioration of environmental conditions in many parts of the world slows economic and social development. Poor environmental quality is estimated to be directly responsible for approximately 25% of all preventable ill health in the world, with diarrheal diseases and respiratory infections heading the list [15]. As discussed in Chapter 13, ill health resulting from poor environmental quality varies considerably among countries. Poor environmental quality has its greatest impact on people whose health status already may be at risk.

Because the effects of the environment on human health are so great, protecting the public from exposure to environmental hazards has been a mainstay of U.S. public health practice, dating, perhaps to 1798 [16]. In that year, Congress enacted An Act for the Relief of Sick and Disabled Seamen, which established a loose network of marine hospitals, mainly in Atlantic seaboard port cities for the purpose of providing care for sick and disabled mariners [16]. This care included issues of vessel sanitation and shipboard vermin. Subsequent federal legislation, the Public Health Service Act (PHSAct) of 1912, made more specific the link between federal public health responsibilities and protection from environmental hazards. In particular, the act specified, "The Public Health Service may study and investigate the diseases of man and conditions influencing the propagation and spread thereof, including sanitation and sewage and the pollution either directly or indirectly of the navigable streams and lakes of the U.S., and it may from time to time issue information in the form of publications for the use of the public" [17]. Subsequent amendments to the PHSAct increased and broadened the environmental health responsibilities of the U.S. Public Health Service.

National, tribal, state, and local efforts to ensure clean air and safe supplies of food and water, to manage sewage and municipal wastes, and to control or eliminate vector-borne diseases have contributed significantly to improvements in public health in the U.S. However, the public's awareness of the threat posed by chemical substances in the environment as a matter of public health is more recent. Events such as the publication in 1962 of Rachel Carson's book *Silent Spring*, in which the threat of pesticides to birds, with implications for human health, awakened the U.S. public to a new health concern. Another example of an event that raised public awareness was the well-publicized discovery that residents of Love Canal, Niagara Falls, in western New York, were being exposed to hazardous substances in their homes, which had been built over an abandoned chemical waste dump. Seepage of hazardous waste into local residents' homes brought national focus to a hitherto unrecognized threat to public health. A result of these and other similar events was an expanded environmental movement, which has led to the introduction into everyday life of such terms as Superfund sites, water quality, clean air, ozone, urban sprawl, and agricultural runoff [18].

As we begin humankind's journey through the twenty-first century, there may be the temptation to look smugly and confidently at our prospects. Global wars have not occurred for more than 70 years (which is not even a blink of an eye in human history), scientific knowledge has proliferated (90% of all the scientists that the world has produced are alive now), life spans have lengthened for some groups in developed countries; and national economies and political stability have generally improved globally. There is, indeed, some basis for optimism that humankind will experience a better twenty-first century than the ones preceding it.

Yet, there are already signs that the twenty-first century could be a century of environmentally caused turmoil and hardship. Increases in human population will continue to strain at or deplete natural resources—access to potable water and food supplies are examples. Technological solutions (e.g., cost-effective desalination of sea water) as well as tough societal decisions (e.g., policy choices about urban development and water restrictions) will force tough policy choices. In this regard, the most daunting policy decision will be how to respond to global climate change and how to mitigate the effects (Chapter 6). How these policy decisions are made in ways to share fewer and lesser amounts of natural resources will challenge democratic institutions and promote disharmony unless carefully managed.

How policy decisions are made in ways to share fewer and lesser amounts of natural resources will challenge democratic institutions and promote disharmony unless carefully managed.

The potential for environmental grief in the twenty-first century is real and potentially catastrophic. Already, bacteria and pests have evolved that are resistant to some chemical pesticides and therapeutic drugs. The result has been the reemergence of cholera, tuberculosis, malaria, and other diseases as public health concerns. Moreover, chemical pollutants in air, water, and food remain as public health challenges. Given these conjectures about the twenty-first century, it is important to have a sense of public health fundamentals and government structure. Because public health programs are primarily government in nature, the structure of government in the U.S. is important to understand and will be discussed in Chapter 4.

1.5 NEXUS BETWEEN HUMAN AND ECOLOGICAL HEALTH

An ecosystem is defined as the interacting system of a biological community and its nonliving environmental surroundings. In 1975, James Lovelock, a British atmospheric chemist, and Lynn Margulis, a U.S. microbiologist, proposed that Earth be viewed as one enormous, complex ecosystem, which they called Gaia, after the Greek goddess of the Earth, and that humans constitute cells in a tissue of this supraorganism [19]. This has become known as The Gaia Hypothesis. Further, as commented by EPA, "Ecosystem goods and services are the many life-sustaining benefits we receive from nature—clean air and water, fertile soil for crop production, pollination, and flood control. These ecosystem services are important to environmental and human health and well-being, yet they are limited and often taken for granted" [20]. Humans interact, indeed depend, on complex interactions with soil, water, air, and other living creatures, such as bacteria, feral animals, plants, forests. Our oceans, lakes, rivers, wetlands, forests, arable soil, and atmosphere all support our needs for food, shelter, water, air, and clothing. The nexus between human health and ecosystem health is the common denominator of life.

Human health is therefore intertwined with the health of our local, regional, and global ecosystems. As will be described for each of the physical hazards that constitute environmental health, it is important that we understand the impacts of these hazards on not only human but also ecosystem health. Public health specialists and policymakers should be aware of the nexus between human and ecosystem health. As but one example, climate change, with its increase in global temperature, will change the distribution of pests, food sources, natural disasters, and disease patterns. Each of these changes will affect the health and well-being of human populations. Put in different words, each of these impacts on ecosystems will have human health consequences.

1.6 FUNDAMENTALS OF PUBLIC HEALTH

The fundamental principle of public health is the prevention of disease and disability. Prevention is as fundamental to public health practice as physiology and anatomy are to the practice of medicine. Preventing disease and disability brings with it elements of both idealism and practicality. Prevention is idealistic in the sense of altruistic conduct by persons concerned about the health and well-being of others. Disease and disability connote human suffering; prevention of suffering is an altruistic act, and an element of most religious beliefs and practices. What individual doesn't feel a sense of satisfaction when helping alleviate the suffering of another person? Moreover, some would consider prevention of suffering a necessary characteristic of what constitutes humanity.

Public health practitioners have developed several structures (i.e., models, paradigms) for preventing disease and disability. The elements of two models are shown in Table 1.2. The Disease Prevention Model consists of the five elements listed below [21]. The application of the model to prevention of childhood lead intoxication is shown in parentheses as an example.

- *Surveillance* for patterns of morbidity and mortality in at-risk populations (blood lead reporting systems administered by state or municipal health departments);
- *Evaluation* of the factors underlying the observed patterns of morbidity and mortality (assessment by health officials to determine when reported blood lead levels exceed health-based guidelines);
- *Interventions* or control strategies, including health education and risk communication (follow-up visits to homes of children with elevated blood lead levels to identify sources of exposure to lead);
- *Infrastructure* at the federal, state, and local levels to implement interventions (grants from federal agencies to states and local health departments);
- *Impact assessment* to assure that the interventions undertaken have been effective (evaluation by health officials to determine if blood lead levels have decreased in children at risk).

The Industrial Hygiene Model [22] (Table 1.2) differs in some important respects from the Disease Prevention Model. Its four elements consist of the following:

- *Anticipation*—Have in place mechanisms such as prospective risk assessment, basic research, surveillance systems that can identify potential morbidity or mortality.

TABLE 1.2
Two Public Health Models for Prevention of Disease and Disability

Disease Prevention Model	Industrial Hygiene Model
Surveillance	Anticipation
Evaluation	Recognition
Intervention	Evaluation
Infrastructure	Control
Impact	Assessment

- *Recognition*—Identify specific patterns or instances of excess morbidity or mortality.
- *Evaluation*—Assess the casual factors that account for the observed excess morbidity or mortality
- *Control*—Implement strategies and actions that will reduce or prevent the identified patters of excess morbidity or mortality.

The Industrial Hygiene Model includes *Anticipation* as one of its elements, whereas the Disease Prevention Model does not explicitly mention anticipation, although some anticipation must be inherent in the latter model's *Surveillance* element in order to provide a focus for surveillance. In contrast, the Disease Prevention Model contains the elements *Infrastructure* and *Impact Assessment*, which are absent in the Industrial Hygiene Model. However, both models serve useful purposes for protecting populations at risk of adverse health effects.

Any system of disease and disability prevention will founder if the system is not well planned and maintained. Dr. William Foege, former Director, Centers for Disease Control and Prevention, identified what he called three enemies of prevention [22], to which a fourth element, *Ignorance*, was added by the authors. Shown in Table 1.3 are four enemies of disease/disability prevention: Time (e.g., diseases that have a long latency, loss of public health resolve, atrophy of funding), Distance (e.g., locally originating diseases can be transported to parts of the world that lack prevention programs, such as AIDS), Greed (e.g., tobacco companies continue to market a product that kills its users), and Ignorance (e.g., lack of knowledge of a disease or disability's causal factors make prevention a challenge).

"Children are the main sufferers of environmental hazards. It is unacceptable from every point of view that the most vulnerable members of a society should be the ones who pay the price for failures to protect health from environmental dangers."
Dr. Lee Jong-wook, WHO Director-General [23].

In addition to the altruistic aspect of prevention of disease and disability, there is also a practical aspect in the sense of economic considerations and societal survival. As to economic considerations, persons who are sick or disabled are no longer contributing to family and other incomes. Tax bases are lessened when persons are unable to work, and monies spent on curative medicine are lost to other potential expenditures that impact national economies. Consider the horrific situation of the AIDS pandemic that has ravaged populations and national economies in certain African countries and elsewhere. Deaths from AIDS in such countries have removed potential new workers from contributing to national economies and industrial and agricultural development. Prevention of the spread of AIDS would have had obvious economic benefits. Left unchecked, disease pandemics have the potential to put at risk the survival of humans as a species. As to societal survival, national and local security can be compromised when defenders are sick or lost to death.

TABLE 1.3
Enemies of Prevention of Disease and Disability

Time
Distance
Greed
Ignorance

In a different perspective, long before modern public health programs were implemented in the U.S. for prevention of childhood diseases, families in colonial times through approximately the first third of the twentieth century experienced the death of many children lost to disease. Diphtheria, pertussis, measles, and polio all took their toll on children. Visit any old cemetery and observe the ages of those interred there. Many families chose to have large numbers of children, knowing that some would be victims of childhood diseases. This cycle of death was finally broken in many parts of the world through public health practices that included large-scale vaccination programs and improvements in sanitation practices and water quality. Unfortunately, these improvements in public health remain quite unevenly distributed across nations. For example, WHO reports that polluted air and water in addition to other environment-related hazards annually kill more than 3 million children under the age of 5 years, further observing that although just 10% of the world's population is under the age of 5 years, 40% of the environment-related disease burden falls on children in this age category [23]. Moreover, WHO elaborated on the global impact of environmental hazards by observing that

- Unclean water causes diarrhea, which kills an estimated 1.8 million people worldwide annually, 1.6 million of whom are children under five. It's also responsible for many diseases including cholera, dysentery, guinea worm, typhoid and intestinal worms.
- 86% of all urban wastewater in Latin America and the Caribbean, and 65% of all wastewater in Asia, is discharged untreated into rivers, lakes and oceans.
- Nearly one million children die annually from diseases caused by air pollution inside their own homes. More than 75% of households in most Asian and African countries cook with solid fuels, such as wood, dung, coal or crop waste, which produce a black smoke that, when inhaled, may give rise to, or worsen pneumonia and other respiratory infections [23].

These grim data on children's health illustrate the fact that saying "prevention of disease and disability is the keystone of public health" is an easy statement to make. How to make prevention a reality is a tough challenge, which leads one to a consideration of public health practice. Fortunately, the concept and practice of public health have benefitted from thoughtful, dedicated, energetic practitioners. With the passage of time

and from lessons learned, we now have guidelines that serve to drive modern public health practice. The following section discusses key elements of modern public health practice.

1.6.1 Public Health Practice

Modern public health practice has evolved to include the components shown in Figure 1.1, which was developed by the Centers for Disease Control and Prevention (CDC). The pyramid shown in this figure illustrates infrastructure components at the bottom, supporting scientific and technical capabilities in the middle tier, and public health programs in the apex [24]. The infrastructure shown in Figure 1.1 will depend on other existing social infrastructures. These include form of governance, communication systems, transportation, technology available, health care system, and people and economic resources. As a consequence, the public health infrastructure in the U.S. could differ somewhat from that in Great Britain. Although this diagram was developed by the CDC, the contents of this diagram also apply to U.S. state and local public health agencies; however, the levels of investment of resources in a particular area (e.g., surveillance) will vary between governmental public health agencies. The elements in Figure 1.1 are described in the sections that follow.

1.6.1.1 Organizational Capacity

This element represents the authority of an organization (e.g., EPA, CDC, Missouri Department of Health; Carroll County, Kentucky, Health Department) to receive and expend public monies. Legislative bodies such as the U.S. Congress and state legislatures are authorized by constitutional mechanisms to create organizational entities (e.g., a new public health agency), raise public funds through taxes and other means, and appropriate funds to governmental agencies. The created government organizations are structured into functional components (e.g., offices, divisions) and programs, based on authorizing legislation. Authorizing legislation at the federal level includes generic legislative acts, such as the PHSAct, which authorizes broad-based federal public health activities, as well as targeted legislative acts such as the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLAct) (Chapter 12), which authorized the remediation of uncontrolled hazardous sites, emergency responding, and the creation of the Agency for Toxic Substances and Disease Registry, a federal public health agency.

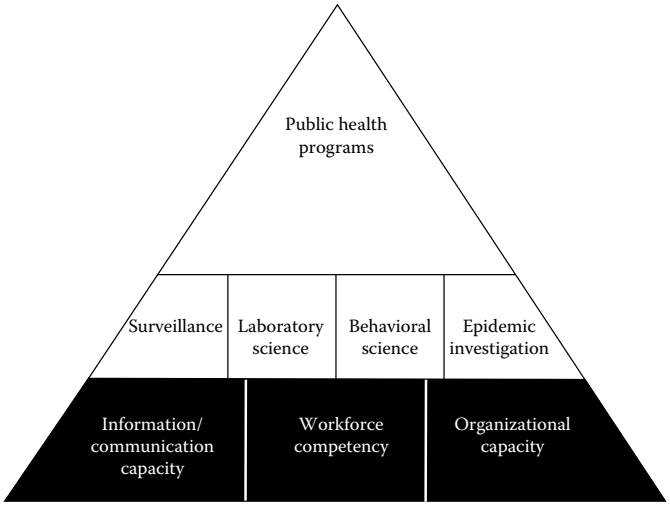

FIGURE 1.1 Elements of public health practice. (Adapted from Lichtveld, M. Y., Personal communication, Tulane University, Department of Environmental Health, New Orleans, LA, 2005.)

1.6.1.2 Workforce Competency

Organizational capacity is for naught if the workforce populating the organization is inadequate to do the tasks of the organization. The workforce of a public health organization must be adequate both in terms of numbers of persons as well as being professionally competent. The number of people within any organization depends on the organization's budget, which is appropriated by a legislative body. Also, some federal and state statutes stipulate ceiling levels that specify the maximum number of agency employees. Another determinant of numbers of persons is how the organization executes its authorizing legislation. For example, some organizations are legislated to process and oversee grants awarded to academic institutions and individual researchers. The numbers of persons required to manage an agency's grants program are generally fewer than what is required to operate a heavily laboratory-oriented program.

Workforce competency also pertains to assuring that an organization's staff is well trained and professionally up to date. This obvious statement assumes that workforce competency spans the whole of an organization's workforce. For instance, professionalism in office administration is as important as professionalism in epidemiology in terms of the overall well-being of a public health organization. Maintaining workforce competency begins with hiring competent workers and proceeds through programs of internal and external training and performance reviews. Unfortunately, some organizations during periods of tight, constrained budgets will decrease or eliminate the funds directed to workforce training and development. This is a recipe for the downward spiral of an agency's effectiveness and performance. If workforce training is abandoned by an organization, long-term relevance of the organization will eventually be questioned by legislative bodies, the agency's parent organization, or the public, leading to questions of an organization's need to exist.

Workforce training and development programs are offered by various federal public health agencies, such as CDC and the Food and Drug Administration (FDA), state health departments, and private sector health providers. State health departments often provide training to county and municipal health departments and health care providers. In turn, local health departments offer training and other education opportunities for their own staff and members of the public that they serve. Another significant source of workforce training is provided by professional societies such as the American Medical Association, the American Public Health Association, the

Society of Toxicology, and many others. These kinds of professional societies also serve an important purpose of credentialing those members who meet conditions of continuous education and testing.

1.6.1.3 Information/Communication Capacity

Silence or ineffective communication on important matters of public health is poisonous to the practice of public health. Given that prevention of disease and disability is the essence of public health, inability to communicate risks to health and well-being means that preventions will not occur. Even if organizational capacity and workforce competency are in place within a public health organization, lack of information and communication capacity will disserve these other two infrastructure elements.

A public health agency derives its communications to the public from science-based research findings and translated by communication specialists into effective public health messages. Public health communicators can range from an individual health care provider (e.g., attending physician) to large offices of media relations found in some federal public health agencies. For example, several federal, state, and local health departments actively outreach to the general public and populations at risk of contracting HIV. These programs of outreach and education have been credited with reducing the spread of HIV infection in the U.S. population. In an environmental context, EPA has effectively communicated the cancer risk of exposure to radon gas formed by the natural decay of uranium that is found in nearly all soils. Homeowners are advised to check for radon gas in their indoor ambient air, basements, and crawl spaces under houses.

A public health agency derives its communications to the public from science-based research findings and translated by communication specialists into effective public health messages.

1.6.1.4 Surveillance

Surveillance can be defined as a data collection system that monitors the occurrence of disease (disease surveillance) or the distribution of hazard (hazard surveillance). Such systems are the eyes and ears of public health practice. Surveillance systems typically collect data from individual health care providers, hospitals, and entities such as health maintenance organizations. For example, state-based surveillance of birth defects and reproductive disorders has emerged, principally by way of federal grants. Other examples include surveillance of blood lead levels in children and, in some states, workers. These kinds of birth defects and blood lead data are typically collected by county and municipal health departments, reported to them by individual physicians, hospitals, and other health care providers.

Evaluation of surveillance data can reveal early, unusual patterns of disease or disability. In the case of disease outbreaks (and other health events), physicians' detection and reporting of sentinel cases is of great importance. Early detection provides public health agencies with an edge in developing and implementing targeted prevention programs. For example, identification of an unusual type of cancer, Kaposi's sarcoma, led to the identification of what subsequently became known as acquired immunity deficiency syndrome (AIDS). The appearance of a rare cancer in numbers exceeding normal expectations was an alert that a possible health problem was emerging. In time, programs of disease prevention evolved. Without an active disease surveillance system, the AIDS epidemic could have spread more quickly and with even more devastating effects on the public's health.

1.6.1.5 Epidemic Investigation

Referring again to Figure 1.1, epidemic investigation of suspicious patterns of disease or disability surfaced by surveillance systems is a key element of public health practice, whether at a federal, state, or local health department level. Epidemiologists are sleuths who examine patterns of morbidity or mortality and attempt to relate them to likely or plausible risk factors. Examples of epidemic investigations include those specific to risk factors in heart disease (e.g., the role of high density lipids in blood), Legionnaire's Disease, occupational injuries, mortality attributable to use of handguns, patterns of suicide in adolescents, and the spread of West Nile Fever through mosquito bites.

From epidemic investigations that identify specific risk factors (e.g., cholesterol levels or mosquito bites) can flow such prevention activities as public education efforts, vaccination programs, workplace redesign, and personal lifestyle changes (e.g., cessation of tobacco usage or choosing to reside in an area distant from sources of pollution). Findings from epidemic investigations, if of sufficient gravity for public health, can lead to legislative actions, which in turn, provide public health organizations with authorities and resources. A case in point is the legislative response to the AIDS epidemic, a response that has led to appropriating budgets and authorizing AIDS research, surveillance, and public education programs on AIDS prevention.

1.6.1.6 Laboratory Science

Laboratory science is defined here as those activities comprising laboratory research and laboratory practice. Bearing in mind that prevention is the central thesis of public health practice, findings from laboratory research can serve as powerful anticipatory data for prevention responses. While surveillance data are vital and indispensable to public health practice, such data nevertheless represent public health outcomes that have already occurred. In distinction, findings from laboratory research can sometimes serve as predictors of possible adverse health outcomes if interdictions are not taken. An example would be the laboratory testing for toxicity of new chemicals intended for use in consumer products, prior to introducing them

Bearing in mind that prevention of disease and disability is the central thesis of public health practice, findings from laboratory research can serve as powerful sentinel data for prevention responses.

into general commerce. Should toxicity be evident under laboratory conditions, appropriate interdictions could include abandoning the product or reformulating it and then retesting the modified substance or product.

Laboratory practice, as distinguished here from laboratory research,* is the establishment and application of laboratory services in support of public health programs to prevent disease and disability. Laboratory services can include measurement of toxicants in body tissues such as blood, bacterial levels in environmental media such as water supplies, viruses in human tissues and feral animals, and reference standards against which other laboratories can compare for accrediting purposes. In particular, the importance of laboratory practices as a means to help characterize exposure to chemical and biological agents cannot be overemphasized. Exposure characterization substantially strengthens epidemic investigations and surveillance programs. Moreover, exposure data can be used to hone public health prevention efforts. For example, measurements of blood lead levels in young children can aid public health interventions. Higher lead levels carry an urgency of medical intervention, while lower blood levels can trigger monitoring programs in order to identify and eliminate sources of children's contact with lead in the environment.

1.6.1.7 Behavioral Science

A relatively new element of public health practice is behavioral science. Traditional public health programs have relied on surveillance, laboratory science, and epidemic investigations, all of which have been used to build a data-based platform for specific public health prevention actions. Prevention efforts were largely focused on populations at risk of disease or disability. Individuals within the populations were given less attention, mostly because of how surveillance systems and epidemic investigations yield their results. However, primarily from the public health experience in preventing the spread of HIV, public health agencies gradually recognized that too little was known about the personal behaviors of persons at risk of adverse health effects. For example, what are the personal determinants of why individuals choose to smoke cigarettes? Why do individuals still choose to smoke, given the overwhelming evidence of adverse health problems that are a consequence of smoking? Knowing answers to these kinds of question provides data for further refinement of antismoking public health endeavors. The addition of psychologists, sociologists, and behavioral scientists to the workforce of public health agencies brings the promise of better understanding individuals' risk-taking behaviors and subsequent refinement of prevention programs.

1.6.1.8 Public Health Programs

Categorical public health programs are at the apex of the public health practice pyramid developed by the CDC [25]. These programs are the culmination of both legislated mandates as well as agency-determined public health needs. In both cases, funding must come from funds appropriated by a legislative body such as Congress or a state legislature. Categorical programs, as suggested by Figure 1.1, are built upon core public health infrastructure (the base of the pyramid) and supporting scientific and technical capacities (the pyramid's middle level). Which categorical public health programs are expressed and exercised by a specific public health organization depends on the organization's authorities. This leads to differences in categorical programs between federal public health agencies, state health departments, and local health agencies.

As an example, categorical public health programs at the CDC include programs in immunization, sexually transmitted diseases, environmental health, chronic disease, birth defects, infectious diseases, bioterrorism, and injury prevention and control. These programs involve, at different levels of resources, surveillance, laboratory science, epidemic investigation, and behavioral science. State health departments' categorical health programs often mirror those of the CDC, since the federal agency is a primary funding source for state and local health programs.

1.6.2 Comparing Public Health Practice and Medical Practice

While public health practice largely focuses on populations at risk of adverse health effects, and medical practice pertains largely to curing individual patients, this distinction should not be considered absolute. To elaborate, any public health practitioner must always remember that populations necessarily involve individuals. How an individual within a population will respond to a particular public health intervention (e.g., vaccination programs) must be of great importance to public health officials. Similarly, health care providers who provide medical treatment to individual patients should be alert to the possibility of applying their treatment methods to groups in need of health care. As an example, surgical procedures that are developed and administered to individuals can be generalized to provide relief to groups needing the same surgery.

As previously noted, public health practice is focused on preventing disease and disability in populations (i.e., groups of people with common characteristics) who are at presumed health risk. The presumption of risk may come from surveillance, epidemic investigation, and/or laboratory science. Examples of populations presumed at risk for adverse health outcomes include persons with high cholesterol levels, workers exposed to workplace hazards, and children who lack vaccinations. Even as behavioral scientists attempt to understand the lifestyle behaviors of individuals within populations at risk, the focus nonetheless remains on preventing disease and disability in populations.

Medical practice, in distinction to public health practice, focuses on curing individuals' disease, mitigating disabilities, and relieving suffering. It is part science and remains part art. The practice of medicine, whether human or animal, draws upon contemporary scientific knowledge from physiology, anatomy, psychology, chemistry, and physics, just

* This distinction, of course, is not absolute. In many instances research on laboratory methods must precede application of laboratory services.

to name a few areas of science critical to medical practice. How and when to apply medical practices (e.g., how much of a therapeutic drug to administer) requires both scientific knowledge as well as personal experience. The art of medical practice stems from a practitioner's experience, the so-called physician-to-patient relationship. For example, for reasons not well understood, patients can improve their recovery from disease or disability by adopting a positive attitude about their prognosis. Health care providers' reinforcement of positive attitudes can therefore contribute to the healing process.

1.6.2.1 Benefits and Risks

Both medical care providers and public health practitioners must assess benefits of a health action evaluated against potential health risks. Consider the surgeon who must decide if a patient is too ill or too elderly to merit undertaking a complicated surgical procedure, e.g., an organ transplant, which could place the patient's life at risk. Simply put, whether the patient will survive the surgery is a question faced by the surgeon. Similarly, physicians and hospital administrators must assess the benefits of patients' extended postoperative stay in hospital versus the financial costs to the hospital and the patient.

These kinds of benefit vs. risk decisions are also made by public health organizations. Will the health benefits to a population at putative health risk outweigh any risks to the target population? Consider the public health official that must decide if spraying a mosquito-infested area to reduce the numbers of mosquito-borne infections outweighs the small risk of some persons being sensitive to the toxicity of the pesticides being sprayed. Consideration of benefits would include estimating the numbers of persons benefiting, nature of benefits (e.g., fewer mosquito bites), social improvements (e.g., decreased incidence of mosquito-borne disease), and impacts of benefits on other public health interests (e.g., decreased health care costs).

The astute reader will have observed that "benefit vs. risk" was the term of choice in the foregoing narrative. Considerations of *costs* associated with putative benefits of a specific public health program or an individual medical procedure have not been discussed. This "lapse" stems in part from historical beliefs that human health was too important to be reduced to economic bases. In a sense, a naive belief prevailed that "the money will always be there" to fund public health programs. Until the early 1980s, budgets for federal public health and environmental protection programs were generally moderately increased each year, with increases occurring mostly in support of new program initiatives, e.g., the development in the 1960s of new federal public health programs to research the effects on human health of environmental hazards such as air pollution. However, in the 1990s the U.S. public became less supportive of what they perceived as ineffective government programs. Further, these concerns were interwoven with those of escalating government budget deficits and rising taxes. As a result, federal budgets, in particular, came under greater congressional scrutiny as to justification, especially beginning in 1994 when Republicans gained control of both houses of Congress. From these changes that began in the 1990s have come the concepts of cost containment and cost–benefit analysis.

Cost–benefit analysis is a systematic assessment of whether the cost of an intervention is worth the benefit by measuring both in the same units; monetary units are usually used [26]. Its utility as a tool for policy formulation will be discussed in a subsequent section of this chapter. Cost–benefit analysis forces health care providers and public health officials to estimate the economic consequences of proposed programs and actions. What, for instance, would be the economic impact on a local health department if mandated by county commissioners to screen all young children for exposure to lead in the environment? Would the benefits of a small increase in IQ in children due to a community-wide program of removal of lead in the environment be worth the cost? Assume that the analysis affirms the need for a children's lead surveillance program. What kind of program would be the most effective? And, moreover, how would "effective" be defined by the local health department?

These questions are addressed through what is called cost-effectiveness analysis. Cost-effectiveness analysis measures the net cost of providing a service as well as the outcomes obtained. "Outcomes are reported in a single unit of measurement, e.g., per life saved, per life year gained, and per pain or symptom-free day" [27]. Returning to our example of a local health department's decision on how to implement a children's lead prevention program, if resources were limited, would a more focused program on those children with greatest risk of exposure be more efficacious? This is the kind of question that now permeates public health and health care organizations.

1.6.2.2 Sociopolitical Factors

Some persons might think that preventing disease and disability in populations (public health practice) and caring for sick individuals (medical practice) are sufficiently altruistic and noble to be spared of sociopolitical influences. Moreover, shouldn't these practices be on a sufficiently high plane to also be spared the rough and tumble of political negotiations, deals, and compromises? The answer is no. Why? This is because both public health and medical practice are to a considerable extent supported by public funds. The appropriation of any public funds is always a political exercise. Elected officials must decide funding priorities, and the fundamental decision on who gets what. Vested interest groups attempt to influence public health appropriations, as also occurs with appropriations for medical care programs such as Medicare and Medicaid, hospital construction, and such. Sociopolitical considerations are therefore essential for facilitating decision-making processes in both practices of public health and medical care.

1.7 THE ROLE OF GOVERNMENT

A historic role of government is to promote the public good and to protect against threats to well-being. Government by its very nature, represents a society's quest for protection of

individuals in ways not always possible by individuals acting alone. Examples of government's protective role would include provisions for national defense and for assurance of public health. That is not to say that nongovernmental organizations do not have a role in meeting certain societal needs. However, when authorized, government can provide resources and authorities not available to nongovernmental organizations. This section will describe the roles of federal, state, and local governments in establishing environmental health policies and practices.

1.7.1 U.S. Federal Government

Of the three branches of government in the U.S. (federal, state/tribal, local), the federal government was the last to assume a significant role in protecting the natural environment and related consequences to public health. This will be discussed in Chapter 3. However, suffice it to say here that local and state governments predated federal involvement in establishing various environmental policies. For example, small villages took action to provide water supplies before either state or federal policies emerged. The village well was both a source of drinking water and a social gathering place. Similarly, some states, e.g., California, developed air pollution control programs prior to federal action.

Over time, the U.S. federal government achieved primacy in developing national environmental health policies. This occurred because of a slow awakening in the U.S. public and members of Congress that environmental hazards, e.g., air pollution, were no respecter of local and state boundaries. Moreover, until the early twentieth century, the role of federal government was largely confined to areas specifically stated in the U.S. Constitution, e.g., national defense and foreign affairs. In the early twentieth century, federal legislation and laws emerged that were intended to protect the public's health. As presented in Chapter 10, the Federal Meat Inspection Act (FMIAct) and the Food, Drug and Cosmetic Act (FDCAct), both legislated in 1906, brought the federal government into the environmental health arena. In the mid-twentieth century, Congress enacted legislation that provided federal primacy, working in cooperation with states, to control such environmental hazards as air pollution, water contaminants, hazardous substances, and improper disposal of solid and hazardous waste. These federal programs are increasingly being coordinated with international environmental organizations through the mechanism of national treaties, as described in Chapter 5.

1.7.2 State Government

U.S. state governments have a significant responsibility for controlling environmental hazards that can impair their residents' health. Some state environmental health programs fulfill federal statutory responsibilities, e.g., implementing CAAct regulations developed by the EPA, but enforced by states with EPA oversight and approval. Other state environmental programs derive their authorities and resources from state legislatures. Such legislation addresses environmental hazards that are specific to state jurisdictions. State-based statutes that define the legal limit for blood alcohol levels in motor vehicle drivers are such an example. How states develop and implement their environmental health programs varies between the states. In some states, environmental health programs are placed in departments of health; in other states, similar programs are located in departments of environmental quality or similar entity. Environmental health programs will differ between states, but many programs address common environmental hazards, such as hazardous substances, sanitation, and emerging problems like the spread of the West Nile virus.

As an example of one state's environmental health programs, Georgia's Department of Public Health administers a large public health effort that includes: epidemiological and outbreak investigations, maternal and child health programs, emergency medical services, vital records and health statistics, chronic disease prevention and health promotion, laboratory services, and infectious disease prevention, including sexually transmitted diseases. The department's mission statement is, "To prevent disease, injury and disability; promote health and well-being; and prepare for and respond to disasters" [28]. Within the department's Division of Primary Protection is the Environmental Health Program, whose mission is "Provide primary prevention through a combination of surveillance, education, enforcement, and assessment programs designed to identify, prevent and abate the environmental conditions that adversely impact human health" [28]. The program consists of activities and services in the following areas: chemical hazards, emergency preparedness, food service, healthy homes and lead, health impact assessment, hotels, motels, campgrounds, indoor air/mold, insects and diseases, pools, rabies, tanning facilities, wastewater (septic tanks, portable toilets), and well water [28]. Where appropriate these resources and services are coordinated with county and municipal health departments in Georgia.

1.7.3 Local Government

As previously noted, environmental protection and public health programs, following the establishment of the EPA, have been placed in separate organizations within federal and most state governments. However, this separation does not usually occur at local levels of government. County and city health departments ordinarily handle a suite of environmental problems, coordinating their programs with state health and environmental agencies. Local health agencies conduct myriad actions for their communities, including a range of environmental health responsibilities such as food and sanitation inspections, pest control, and audits of environmental hazards. There is no national catalogue of local health departments' environmental health programs, but one organization has provided helpful information that provides a useful perspective on such programs, as described in the following sections.

1.7.3.1 Environmental Health Responsibilities

The National Association of County and City Health Officials (NACCHO) provides technical assistance to county and city health departments. They develop and advocate policy and political positions for their membership. As noted above, city and county health departments conduct a host of public health programs, including those in environmental health [29].* The National Association of County Health Officials (NACHO) was interested in ascertaining a national picture of environmental health priorities, as expressed by their membership.

In 1990, NACHO conducted a national survey of local health departments to assess needs and resources for environmental health programs [29]. Their survey did not define environmental health. The purpose of their study was to identify: (1) various environmental health issues that challenge local health departments; (2) how these challenges are being met; and (3) the kinds of education, training, and other support local health departments need to adequately assess, communicate, and reduce environmental health risks. The NACHO survey of 1990 still represents the only national data on environmental health priorities specific to local health departments.

A questionnaire was used by NACHO to survey a stratified random sample of 670 of the 3169 local health departments operating in the U.S. at the time of the survey. The sample was stratified according to the size of the population served, which NACHO used as an indicator of resources required by the department. Representative percentages of the total sample within each population range were selected to reflect a national picture.

From the survey, the most frequent environmental health services reported by local health departments are shown in Table 1.4. From this table, one observes that these six services are intended primarily to protect the public from chemical and biological hazards in food, drinking water, swimming pools, sewage, and nuisances such as animal vectors of disease (e.g., rabid animals). Local health departments are also involved in directly providing, or coordinating with others, emergency response services. Given the terrorist threat to the U.S., the role of local health departments in responding to chemical and biological threats will continue to increase in importance. Although these NACCHO data are somewhat dated, they remain unique and likely still remain representative of most local health departments' environmental agendas.

TABLE 1.4
Environmental Services Most Often Provided by Local Health Departments and Percentage of Departments Providing Them

Food protection	91%
Nuisance control	88%
Sewage treatment	85%
Private well testing	83%
Swimming pool inspection	83%
Emergency response	80%

Source: NACHO (National Association of County Health Officials), Current roles and future challenges of local health departments in environmental health, National Association of County Health Officials, Washington, DC, 1992.

* NACHO changed its name to NACCHO subsequent to the 1992 report. The organization is based in Washington, DC.

1.7.3.2 Case Study: DeKalb County, Georgia

Because each local health department tailors its programs, including environmental, to the needs of its geographic area of coverage, some variation in activities occur between departments. An example of one local health department will illustrate the range of environmental health programs.

DeKalb County, Georgia, is an area northeast of the city of Atlanta, with a population of approximately 714,000 in 2013. It is one of the counties that constitute metropolitan Atlanta. The mission of the DeKalb County Board of Health is stated to be "The mission of DeKalb County Board of Health is 'to protect, promote, and improve the health of those who work, live, and play in DeKalb County'" [30]. In support of this mission, the Division of Environmental Health services the environmental health needs of the county. Its mission is stated as "Reducing the risk of illness and injury related to interactions between people and their environment." The division's programs are alphabetized into the following activities and services" [30].

- Body Crafting—(Tattoo and Piercing): Ensures safety of health issues through education and inspection of tattoo and body piercing establishments.
- Food Safety: Ensures food safety and prevents foodborne illness by working with food service facilities through inspections, education and risk assessments.
- Hotels and Motels: Inspects hotels, motels and campgrounds for sanitary conditions and compliance with regulations.
- Indoor Air Quality: Assesses homes, schools and commercial facilities for indoor air quality issues including carbon monoxide, carbon dioxide, mold, mildew and radon.
- Lead Poisoning Prevention: Eliminating childhood lead poisoning through elevated blood lead level investigations, lead based paint inspections, risk assessments and health education.
- Public Health Hazard Investigations: Provides assistance to homeowners concerning public health hazards such as raw sewage, garbage, scrap tire piles, pests and animal waste.
- Rabies Control: Enforces home quarantines for cats and dogs, locates persons exposed to rabid animals and alerts the public of rabies outbreaks.
- Radon: Identifies homes with radon concentrations which can pose a serious health threat increasing the risk of developing lung cancer.
- Rodent Control (Rats and Mice): Investigates rodent problems, identifies conditions that may attract

rodents, locates areas that may provide access into homes and assists with control.
- Septic Systems: Regulates and monitors residential and commercial on-site sewage management systems to minimize the risk of health problems related to untreated human sewage.
- Swimming Pool, Beach and Spa: Ensures safe and healthy public swimming facilities to prevent drowning, injuries and the spread of infectious diseases.
- Tools for Schools: Assists schools to develop and use indoor air quality management practices to reduce exposures to indoor environmental contaminants.
- West Nile Virus: Works with residents to reduce mosquito infestations and takes an aggressive role in preventing infections of West Nile virus or additional arboviruses [30].

As a matter of policy, the division's environmental health programs mirror those of the Georgia Department of Public Health environmental programs, an arrangement that is common between state and county/municipal health departments.

1.8 PUBLIC'S POLICY EXPECTATIONS

Having now defined various key words and terms, such as health, public health, environmental health, and policy; and having explained the key differences between the practices of public health and medicine, it is time to discuss some public policies that have current relevance to environmental health policies. Public policies are referred to here as actions taken in accord with current expectations of the U.S. public. Some public policies, as will be illustrated, are the consequence of legislation; others have evolved as matters of public education or products of advocacy groups.

1.8.1 Accountability

The notion of accountability is rooted in both ethics and law. For the former, human experience has evolved through religious teachings and secular wisdom to hold persons accountable for their actions. Whether based in religion or secularism, it can be argued that avoidance of chaos is a societal goal. Chaotic social structures are inherently unstable and don't have a good prospect of long-term survival. As a matter of law, an individual's accountability comes into question when societal expectations, expressed as a body of law, are not met. This is true whether the law is based on English Common Law, Native American Tribal Law, or national law based on religious theology (e.g., some Arab nations). For example, if murder of another human being is forbidden, the commitment of the act will bring some kind of specified societal response, e.g., incarceration.

Holding government and corporations accountable for their actions is a relatively recent public policy in the U.S. At the federal level, Congress enacted the Government Performance and Results Act (GPRA) in 1993, in part to "improve Federal program effectiveness and public accountability by promoting a new focus on results, service quality, and customer satisfaction" [31]. This act was meant to hold executive branches of government more accountable to the public. To the extent that the act is meeting its goal is currently unknown. On a corporate level, the financial irregularities associated with the Enron Corporation in 2002 contributed to public skepticism and demands for more controls on how corporations manage their financial accountability to employees, stockholders, and the public. The public's trust in regard to environmental protection is diminished by catastrophes such as the *Deepwater Horizon* Oil Spill in the Gulf of Mexico in 2010. In regard to environmental health policy, the public expects environmental and public health agencies to respond to their concerns and to be accountable for protecting environmental quality and human health.

1.8.2 Communication of Risk

The communication of risk to the public goes hand in hand with the use of risk assessment as public policy (Chapter 19). This is a corollary of the public's right to know. The emphasis here is on how to best communicate risk in order to enhance public understanding and achieve health actions. Indeed, risk communication has become a specialty discipline in some academic institutions, leading to research on how to more effectively communicate risk and evaluate the impact. As an example, how should information about potential threats by terrorists to public safety be communicated? Should every threat, bogus or creditable, be relayed to the public? If not, what are the criteria for selecting those threats that should not be communicated? These are difficult questions that have no easy answers. Experience and research are needed if these kinds of particularly challenging risk communications are to be effective in preventing acts of terrorism, and at the same time, not unduly raise the public's anxiety.

1.8.3 Cost–Benefit Analysis

Although the U.S. public looks skeptically at personal health decisions that are based on their financial cost—consider the negative reactions of many persons to health maintenance organizations, where costs allegedly drive decisions on health care—the emergence of cost–benefit analyses and hazard management decisions have become policy within government agencies and business operations. As noted by Greenblott, "The concept of benefit-cost analysis in analyzing societal decisions can be traced to the beginning of the 19th Century and has gradually become an integral part of federal policies and government legislation. President Thomas Jefferson's Secretary of the Treasury, Albert Gallatin, emphasized the need to compare the benefits and costs of proposed waterway improvements. […] The first specific legislative mandate for benefit-cost analysis in federal environmental legislation can be tracked to the Federal Reclamation Act of 1902, which required analysis of irrigation project repayment capacity. The Flood Control Act of 1936 required that the total benefits of water resource projects must exceed the total costs.

[…] The U.S. Bureau of the Budget formally adopted the central role of the efficiency function in benefit-cost analysis as public policy to determine Presidential program priorities in its 1952 Budget Circular" [31a].

In years since 1952, both the Congress and the White House constructed various attempts to integrate cost–benefit analysis into federal legislation or executive orders, respectively. This history is available in the cited reference [31a]. However, Greenblott notes that "The opportunity (or mandate) for EPA to consider benefits and costs in its regulatory decisions varies according to the specific statutory requirements and court interpretations, usually on the degree to which costs must (or cannot) be considered in implementing legislation. For example, EPA is specifically required to balance benefits and costs under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The Clean Air Act, on the other hand, significantly restricts consideration of cost when setting certain standards. In addition, the Regulatory Flexibility Act specifically requires federal agencies to determine if a regulation will have a significant economic impact on small business, and then identify alternative approaches to reduce the burden and still achieve the regulatory goals." More will be said about cost–benefit analysis for air pollution and water contamination in Chapters 9 and 10.

Perspective: Cost–benefit policy has occurred in government because of legislative directives and federal court decisions and within business operations that must have a sense of costs associated with their products, working conditions, and consumer affairs. On the surface, considerations of cost and benefits to the public are important and reasonable. But current cost–benefit analysis necessarily forces decisions about the worth of human life, forces estimates of technology costs by using projection models, and forces decisions when adequate information may be lacking on the costs and benefits to different races, cultures, and age groups. Cost–benefit will remain a public policy cloth, but with frayed edges until better data on benefits become available.

1.8.4 Environmental Justice

How environmental hazards are experienced by people of color became a matter of social justice in the U.S. in the 1970s, as described in Chapter 18. Minority communities and persons of low income expressed their belief that toxic chemicals, in particular, were being deliberately released into their communities from hazardous waste dumps, incinerators, and pollution from industry. The resulting expressions of concern led to the establishment of environmental justice, defined by the EPA as "[t]he fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies" [32]. Federal government policies emerged in the early 1990s that were intended to address a number of environmental justice concerns. For example, offices of environmental justice were established at the EPA, the U.S. Department of Energy (DOE), and elsewhere. State governments have emulated the federal example by creating offices that investigate environmental justice allegations and recommend corrective actions. While the effectiveness of federal, state, and some private sector actions to prevent environmental injustices continues to be debated, the public policy to prevent environmental injustices has become a cornerstone in the foundation of U.S. social justice.

1.8.5 Federalism

Federalism is a form of government that is structured around a strong central (i.e., federal) government, with specified authorities delegated to lower levels of government, such as states and local governments. How power is shared among the central and subordinate governments must be specified in a constitution that binds the parties. The U.S. Constitution is an example, having been developed by the country's founders after a looser confederation of states was found to be ineffective. In contrast, a confederacy is a loose relationship among a number of smaller political units. The vast majority of political power rests with the smaller governments; the central federal government has very little power in a confederation.

The U.S. Constitution specifies the powers of the federal government and delegates all other responsibilities to the states. State constitutions, in turn, specify the degree of power sharing with local governments. The sharing of power and authorities between the U.S. federal government and states and local governments is a public policy that crosscuts almost all social programs and discourse in the U.S., including environmental statutes. As an example pertaining to environmental health policy, as will be discussed in Chapter 8, states have the primary responsibility for enforcing air pollution regulations developed by the federal government (i.e., EPA), with overall responsibility for the development of air quality standards vested with the federal government.

1.8.6 Polluter Pays for Consequences of Pollution

In the 1970s, environmental groups adopted the strategy that those who cause pollution should pay for its effects on the environment and remediation. The first federal expression of this theme is found in the CERCLAct (Chapter 12). In particular, companies, government agencies, and others that created uncontrolled hazardous waste dumps were liable for the costs of their cleanup and associated effects on human health and natural resources. A similar legal philosophy spread to the European Union (EU)* and elsewhere. Polluters' paying for the consequences of their pollution is a kind of accountability policy, but is specific to environmental health. This policy has led to copious litigation between those who generate pollution and those, particularly governments, who have the

* As of 2016, the EU comprises an organization of 28 European countries that cooperate through formal mechanisms on matters that include trade, common currency, environmental directives, and legislation. See Chapter 5.

responsibility for enforcing remediation of polluted sites and attendant financial costs under cost recovery statutory authorities. This is discussed in Chapter 12, where the "polluter pays" policy is discussed as a component of the CERCLAct.

1.8.7 Prevention Is Preferred to Remediation

Common sense tells us that avoiding a problem is preferable to having to fix its consequences. Prevention of disease and disability is the cornerstone of public health. This cornerstone is policy at all levels of public health, from federal to state to local health departments and their programs. Disease and disability reduce a person's quality of life, can lead to costly health care, and lessen societal strength by eliminating or reducing ability to work and contribute to society. Although not always evident, environmental statutes in general are expressions of the prevention policy. All such statutes are predicated on protection of human health and environmental quality. This protection is addressed through control of pollution levels in the environment, as pursued through regulations and standards and their enforcement.

1.8.8 Product Safety

Over its relatively brief existence, the U.S. national economy has been based first on agriculture and trade, followed by industrialization, then manufacture of consumer goods, information services and finance, and chemical/pharmaceutical commerce. Each change in the country's economic engine has affected the public policies of the time. The current U.S. economy is heavily based on what is called consumerism, which is the production, sale, and use of personal products as diverse as personal computers, automobiles, clothes, and video games.

With consumerism has come public policy specific to product safety. Consumers do not want products that could harm them or their children. The result has been federal resources directed to the prevention of harmful consumer products' entry into commerce. The Consumer Product Safety Commission (CPSC), in particular, identifies commercial products (e.g., children's toys) that can be hazardous. For example, in 2003, a scooter manufacturer voluntarily recalled about 30,000 electric scooters and 55,000 electric mini bikes due to 80 reports of injuries caused to young children. The injuries were associated with a malfunction in the products' electrical control circuits, causing the bikes and scooters to continue to run after the power had been cut off [33]. Other notable examples of products perceived unsafe by the U.S. public include automobile tires, sport utility motor vehicles, and canned baby food—all from specific manufacturers. These flawed products quickly attract the attention of news media, social media, public advocacy, attorneys, and elected officials; all of whom decry the product, its producer, and the failure to protect the public. Eventually, these public outbursts and private negotiations can lead to specific products being recalled by the manufacturer and strengthened inspection systems by the producer, and where warranted, by the government.

1.8.9 Public's Right to Know

It has become public policy in the U.S. that individuals have the right to know of conditions that may be hazardous to their health and well-being. The public's right to know is not absolute. For example, matters of national security and confidential business secrets are excluded from public view, unless ordered by a court. While the importance of right to know may seem self-evident, it has not always been the case, especially in the realm of information available to workers and consumers of commercial products. Not until the passage of the U.S. OSHA in 1970 were there general requirements to inform U.S. workers of on-the-job hazards (e.g., hazardous chemicals). Similarly, producers of consumer products had no requirement to inform U.S. consumers that flaws in product design or manufacture could be hazardous to them until enactment of the federal Consumer Product Safety Act of 1972 (CPSAct). Other examples will be given later in Chapters 7 through 12, where specific federal environmental laws are discussed.

1.8.10 Risk Assessment

How do we determine what level of risk is caused by a particular hazard, e.g., ozone in ambient air? What scientific data should be examined and how should they be considered? And who should make these kinds of decisions about risk to human health and ecological systems? These questions are neither new nor confined to government. As individuals, we decide whether to use tobacco products, wear seatbelts while riding in motor vehicles, or reside in an area of dense automobile traffic, even in the face of information that advises different courses of action. Government agencies are directed to assess risk and take actions when risks are presumed in need of elimination or reduction. Businesses must pay attention to the risk posed to consumers by their products. So what's new about risk assessment and its adoption into policy by government? It is the public's gradual acceptance of a formal process, called risk assessment, which has become a policy for risk determination of hazards common in everyday life (Chapter 19).

Risk assessment and risk management have become particularly dominant in the area of environmental health. As will be discussed in Chapter 19, beginning circa 1980, federal regulatory agencies, primarily the EPA and the OSHA, adopted formal risk assessment procedures to estimate the degree of risk posed by individual environmental hazards. The impetus for this development came from federal court decisions which found that the EPA and OSHA regulators had failed to establish degree of risk in certain proposed regulatory actions. In effect, the courts ruled that risk must be consequential, not trifling or unsupported, in any regulatory action.

The framework for the regulatory agencies' risk assessment procedures came from the U.S. National Academy of Sciences, which articulated the key components of risk assessment (toxicity assessment, dose response assessment, exposure evacuation, risk characterization) and recommended that risk assessment be kept separate from considerations of risk management [34]. The academy's report and

recommendations have had a profound impact on how environmental hazards are regulated.

1.8.11 Social Support

Cultures have learned over eons of evolution that their survival depended on social support systems. These included hunting in groups for food, banding together to defend territory, and traveling in groups on trading expeditions. Living in close proximity, not as isolated individuals, gave protection to groups, eventually forming villages, cities, and nation states. Nations have developed social support structures that are intended to enhance the survival of both the state and the individual. Assistance to persons who need food, shelter, and education is generally commonplace worldwide. In the U.S., assistance programs include public education, subsidized housing, health services to the elderly and the indigent, and monetary subsidies to farmers and others. These are examples of public policy meant to provide social support to meet basic needs of members of a society. Unmet basic needs can lead to societal disruptions (e.g., political turmoil, chaos) that reduce a society's ability to protect itself, to foster economic gains, and enhance quality of life for individuals. How much of a society's resources should be devoted to social support systems has been, and will remain, a legitimate debate among policymakers and public advocacy groups.

1.9 CRITICAL THINKING

Establishing environmental health policy—indeed, any kind of policy—is a difficult undertaking. Much more is said in Chapter 2 about the mechanics of policymaking, but suffice it to say here that critical thinking is vital to the process of policy establishment. Critical thinking means different things to different people. However, for the purposes of this book, *critical thinking* means:

- Asking "why" and "what if?"
- Looking beyond the obvious
- Identifying interconnections
- Understanding the players involved in policymaking, their roles, and their motivations
- Recognizing that complexity is the norm, not the exception

As the five elements imply, critical thinking is an intellectual process that attempts to probe below the surface of contemplated actions in order to identify potential consequences.

Consider the following example. Assume that a community advocacy group has asked a member of a county's board of commissioners to support a proposed county ordinance that would require recycling of household waste. The proposed plan would require homeowners to separate their household waste into various categories of recyclable materials prior to pick up by trash crews. How should the commissioner proceed? The commissioner's critical thinking could proceed along these lines:

- What benefits of recycling household waste would accrue to homeowners? Moreover, how might the county's ordnance, if enacted, be perceived by individual homeowners? What would be the financial costs of the recycling program to the county? How would funds be found to operate the program? What if the program began operation and then became the target of citizens' discontent?
- If it is obvious that the community advocacy group has some citizens' support, just how extensive is their support? It is also obvious that the county's residents support environmental protection programs in general, but does this support extend to recycling of household waste?
- Interconnections between the state's environmental protection department and possibly the EPA would be required to effectuate any county-wide recycling program. What roles will these other layers of government assume in regard to recycling?
- Start-up and operation of a county-wide recycling program would be a difficult and complex operation. Does the community advocacy group understand the complexities? How will this be explained to the group and to the county residents should the board of commissioners approve the recycling proposal?

This kind of critical thinking should be applied during the course of any policy development, whether it be a personal policy or a federal environmental health policy.

1.10 SUMMARY

This chapter has summarized the evolution of environmental health, placing the evolution in a historical context. Humankind's search and aspirations for a less hazardous environment date from antiquity. Notable were ancient civilizations' attempts to acquire potable water and sanitary disposal of human wastes. The struggles of ancient peoples for healthful environmental conditions have continued into modern times. Only the means toward the end—control of environmental hazards—have changed.

One relatively modern development for controlling the effects of environmental hazards is described in this chapter. The emergence of government as the primary force in hazard control is, over the long course of history, relatively new. In the U.S., the triad of federal, state, and local governments all have roles to play in controlling environmental hazards. This traditional triad of government partners is essential for effective public health policies and programs, and without it, public health programs of disease and disability prevention, such as immunization and quarantine, would be far less effective. However, as will be discussed in the following chapter, this triad becomes strained when the subject becomes the control of environmental hazards, and in effect, the triad must multiply itself in order to accommodate their federal, state, and local environmental protection partners.

The purpose of this chapter was to set the stage for what follows in the subsequent chapters. In order to navigate through the often turbulent waters of environmental health policymaking, a clear sense of direction and firm grip on resources are required. Sense of direction is predicated on an awareness of the linkage between environmental health policies (as often expressed in environmental statutes) and the control of specific environmental hazards (e.g., contaminants in drinking water). Resources required for environmental health policy navigation begin with a working knowledge of key definitions, e.g., *environmental health* and *policy*. Without a common and mutually understood vocabulary, effective communication is impossible. This lack of mutual understanding of terms often ferments disagreements between community groups and government officials when addressing concerns about toxic substances.

Another resource described in this chapter includes an appreciation of contemporary public policies that the U.S. public expects of elected officials and others who have the power to affect their health and well-being. Described in the chapter were policies of accountability, communication of risk, cost–benefit analysis, environmental justice, federalism, polluters paying for the costs of their pollution, prevention being preferred to remediation, risk assessment, and social support. These public policies are important in their own right, but are all the more important when developing environmental health policies. Policymakers must be aware of these polices when developing new environmental policies or revising existing policies.

This chapter has set the course for an introduction to environmental health policy. The next chapter provides a discussion of the steps, processes, enforcement, and monitoring involved with policymaking.

1.11 POLICY QUESTIONS

1. Using the definition of *policy* provided in Chapter 1, discuss: (a) who are policymakers? Give examples of those who affect your daily life; (b) how do environmental policies, e.g., environmental protection, affect you? And (c) a personal policy and its benefits to you.
2. Using WHO's definition of *environmental health* given in Chapter 1, (a) give examples of *social and psychological factors* that could fit within the definition and (b) discuss their importance to you in comparison with *chemical and biological factors*.
3. If *politics* is "the complex of relations between people living in society," discuss what you consider to be the positive aspects of politics, and then discuss the negative aspects. Be specific and give examples based on your own life experiences.
4. Discuss the roles of the judicial branch in setting environmental health policy. (a) Give examples drawn from this text and other sources. (b) Under what circumstances can the courts change policies set by legislative bodies?
5. This chapter provides definition of "hazard" and "risk." In an essay of appropriate depth discuss the relationship between the two. Discuss hazards you personally face each day and discuss each hazard in the context of risk assumption.
6. Eleven elements of public policies in the U.S. of relevance to environmental health were presented in Chapter 1. Select any five and discuss each one's impact on your life. Give examples.
7. Do you think that the public's right to know is absolute, i.e., government should *never* withhold any public health information from the public? If not, discuss situations where, in your opinion, information should be withheld. Give specific examples and justify your reasons.
8. Assume that you are a newly hired environmental health specialist working for a county health department in the U.S. As the only environmental health specialist, the department's director asks you to provide a prioritized list of environmental health problems. (a) How would you proceed to develop the list? (b) What would be your key assumptions in developing the list? (c) Would you involve the public? If so, how?
9. Given this chapter's discussion of historical environmental hazards, discuss the significance of historical data on modern-day environmental problems, as you have personally experienced them. Be specific.
10. Rachel Carson's book *Silent Spring*, published in 1962, is given much credit for enhancing concern in the U.S. public about environmental hazards. Discuss, in your opinion, (a) why the book had such a significant effect, (b) opine whether such a book today would achieve the same sociopolitical prominence, and (c) speculate on what stance Carson would have taken on environmental policymaking in the year 2017.
11. The definition and concept of "ecology" were given in this chapter. Discuss the ecosystems that directly impact you each day. Prioritize them in terms of importance to your well-being.
12. The Gaia hypothesis was presented in this chapter. Do you accept the concept of Gaia? If so, why? If not, why? Demonstrate critical thinking when formulating your response to this question.
13. Ethical conduct was discussed in this chapter. Without discussing your personal ethics, analyze the ethical conduct that you expect of others and present your analysis in an essay of appropriate depth. Be specific.
14. Information sources were mentioned in this chapter. Discuss the Internet as a source of information for your personal use and societal use in general. Discuss the benefits as well as any disadvantages of gleaning information via Internet sources.
15. A good principle in public health is to imagine yourself in the place of others who are in alleged or real harm's way of adverse health effects. Put in different words, "How would you feel if you were there?" As an example, imagine yourself as a young parent residing

in fourteenth century Europe during the epidemic of Black Death. Prepare an essay of appropriate depth that describes your imagined life and emotions.

16. In your opinion, is government too involved in attempting to control the hazards in your life? Prepare an essay of appropriate depth that presents the details of your opinion.
17. For the purposes of this book, this chapter presented five essentials for human survival. Do you consider this list complete as they pertain to your life? What other items might you have added to the list of five? Be specific and give details.
18. In your opinion, what one change in environmental conditions has contributed the most to the well-being of humankind? Be specific and provide an analysis that supports your choice.
19. Project yourself 20 years hence. What environmental hazards will be the most threatening to human health? Be specific and provide an analysis that supports your choice.
20. Congratulations! You have completed your review of this chapter. Discuss in an essay of appropriate depth the most important information that you learned and why.

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2 Steps in Environmental Health Policymaking

2.1 INTRODUCTION

Whether enacting federal legislation that covers national environmental issues such as clean air or a local business that decides to sell only lumber that comes from new growth forests, setting environmental health policies is typically a complicated undertaking. In particular, establishing environmental health policies is crucial to protection of human health, ecosystems, and environmental quality. These policies can result from legislation of new laws, changes in existing regulations and ordinances, and voluntary actions adopted by community groups, businesses, and individuals. Different points of view are always expected during consideration of a new or revised environmental health policy. As a democratic process, informed debate is essential, but necessarily lengthens the time to enact a particular environmental health policy.

Understanding the process of making environmental health policy requires an understanding of how government functions, since government is the primary source of environmental policies (discussed in Chapter 3), and an appreciation of the influences that can influence policymaking. This chapter provides a summary of key steps in environmental policymaking, commencing with a description of factors that can influence the establishment of environmental health policies, followed by a simplified model of policymaking. A particular kind of policy for controlling environmental hazards, called command and control, is discussed along with nonregulatory alternatives to command and control. The chapter concludes with a brief discussion of environmental ethics, since a framework of ethical behavior should accompany any policy of environmental protection and public health practice.

2.2 INFLUENCES ON ENVIRONMENTAL HEALTH POLICYMAKING

Establishing environmental health policy is a complicated political undertaking. This is true whether the policy is to be developed by government or an entity in the private sector (e.g., a corporation). Government policies must involve the public because of the Administrative Procedures Act, which will be described in Chapter 3. Policies of commerce are also complicated in their establishment, but sometimes receive less input from the public. The nineteenth century German leader Otto von Bismarck is credited with saying, "There are two sights unfit for the human eye: making sausage and making legislation." Bismarck's observation surely applies to the messy and sometimes unpleasant making of environmental health policy. Why is this? Why should establishing environmental health policies that are intended to protect environmental quality and human health from hazards in the environment be a complicated, often passionate affair? This chapter presents some of the factors that challenge environmental health policymaking.

Setting government environmental health policy, be it to protect ecological or human health, normally forges lines of differing public opinion, organizes bases of support and opposition, and energizes legislative machinery. When contemplating federal legislation (e.g., to protect the quality of the nation's supplies of drinking water), major issues quickly arise—not the least being the potential economic costs. Legislators are confronted with sorting out the impact issues that may accompany any enacted legislation. They must consider: What is the extent of the hazard (e.g., contaminated drinking water)? What would be the benefits to the public's health? What will be the burden on various business and government entities? How will the public react in general to the legislation? And will the enacted legislation meet specific environmental purposes? Addressing these questions will energize vested interest groups and often stimulate considerable passion. For instance, business groups will often allege that the economic costs of proposed regulations will be too great for them to bear. Environmental groups may argue that proposed legislation or regulations don't go far enough in protecting the environment.

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There is no policy recipe or political cookbook that gives specific directions on how to successfully develop environmental health policy. Figure 2.1 shows seven factors that can influence the establishment of environmental health policy. Not all are of equal consequence, and specific elements may be inconsequential at local and state government levels. These seven factors are discussed in the following sections.

The state of a national economy is a major factor in effecting policymaking by elected officials, concerned private sector entities, and activist individuals. Economies that are in recession, or worse, depression, present concern to the public and policymakers alike. During such difficult economic times, jobless rates increase, money for capital investment is scarce, and the availability of food and other essential

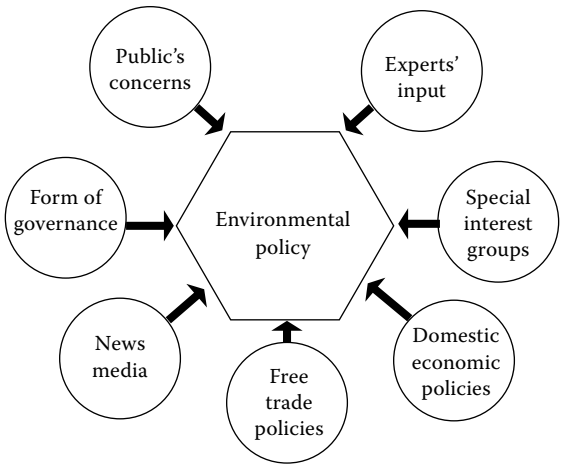

FIGURE 2.1 Factors that can influence environmental health policy.

elements of life become strained. In such times, policymakers' attention is directed to developing policies that might repair the economy and restore confidence in the public. This was the situation during what is called The Great Depression, an economic slump in North America, Europe, and other industrialized areas of the world. This collapse of national economics began in 1929 and persisted for about a decade. It was the longest and most severe economic depression ever experienced by the industrialized Western world. The U.S. federal government commenced various social programs, e.g., public works projects, instituted banking reforms, and established partial regulatory controls on stock markets and other financial institutions. During this period, World War II arose and was a factor in both North America and Europe in reestablishing national economies. Policymaking during the war years was strongly focused on polices to support the war effort. These policies created jobs, stimulated manufacturing of war supplies and services, and enhanced development of natural resources such as oil and coal supplies.

In contrast, starting in the 1960s and lasting through the end of the twentieth century, the industrialized nations were largely at peace with each other and policymakers began to give attention to what might loosely be termed "catchup agendas." Compared to the periods of war and economic slumps and stumbles, the second half of the twentieth century saw policymakers refocus their legislative attention to matters of labor law, environmental protection, civil rights, voting reform, medical coverage and care, social services, and international treaties. In particular, as described in subsequent chapters on air pollution, water quality, food safety, and waste management, industrialized countries enacted powerful polices in the form of laws and attendant regulations that were intended for protection of the public health and social welfare in general. Environmentalism had arrived as had stable economic bases.

Mitigating the effects of environmental hazards requires policies and attendant actions agreed to by national governments, commercial enterprises, and concerned individuals. Because of multiple ingredients and interests in the outcome, this becomes a complicated stew for policymaking. One of the main constraints to environmental health policymaking is the political risk to potential policymakers.

Concerning political risks, any policymaking endeavor is a matter of politics. Recall that in Chapter 1 politics was defined as "(a) the art or science of government, (b) political affairs or business, (c) the total complex of relations between people living in society." In Chapter 1, it was proposed that all three definitions were operative as pertains to this book's purposes and content. Considering the first definition, policies made by and for government derive from the action or inaction of elected officials or their designed representatives, e.g., a government minister or department secretary. In governments based on democratic processes, policymakers are representatives of those who elected them. They also usually represent their particular political party and its base of supporters. While political parties vary in their philosophies of government, generally speaking, two major forms exist: conservative and liberal (sometimes called progressive).

Students of government might disagree with such simple characterizations, but conservatives generally anchor on smaller and less government, adherence to social tradition, and preference for social and legal precedent, while liberals anchor on government action for social issues, provision of public services, and policy reforms. This difference in political philosophy provides a vital dialectic for democratic-based policymaking. To be more precise, when conservatives hold the reins of political power, it is generally more challenging to enact policies that would generate government regulations or similar action. And correspondingly, liberals have been accused of rushing to enact public policies without full consideration of future consequences of their enacted policies. Pertaining to climate change, conservative governments have been slower to accept and act on policies for mitigation of climate change. That is not to say that lack of policymaking on environmental issues won't occur in a conservative political environment; just that political processes need to be modified in order to affect the policymaking process. For example, policies that contain checks and balances, performance reviews, and "sunset" clauses are favored by some conservative policymakers.

2.3 THE PUBLIC'S INFLUENCE ON POLICYMAKING

To establish environmental health policy through new legislation or refinement of existing regulations or ordinances requires concern expressed by the public—not all of the public, of course, but groups or individuals with vested interests or specific concerns. These interests can take the form of an environmental organization, citizens group, business association, public health agency, or similar groups with a specific concern about an environmental hazard. Setting environmental health policy is seldom initiated by individual elected officials; few elected officials are willing to lead legislative efforts that they may perceive as politically risky.

On the other hand, elected officials are generally responsive to concerns from the public—if the pressure is great enough and the political risks are relatively low. Consider the example of uncontrolled hazardous waste releases into community environments. More specifically, take the example of Love Canal, New York, in the late 1970s (Chapter 12). A community of homes had been constructed atop an abandoned chemical dump. Over time, the chemical waste migrated into the overlying homes, leading to community concerns that birth defects, cancer, and other grievous health conditions were occurring. These health concerns became the material for national news reports, amplified by the discovery of other toxic waste dumps in Kentucky, Missouri, and other parts of the U.S. Pressure to act was eventually exerted on Congress by national environmental organizations, Love Canal community groups, and public health advocates. In 1980, the CERCLAct was enacted and signed into law by President Carter. In retrospect, community concerns, well articulated by Love Canal spokespersons, had provided the impetus for new federal policy on managing uncontrolled hazardous waste.

The public can affect environmental policymaking, particularly via use of social media, which has provided a new method of the public's involvement in policymaking. Such media can effectively be employed to rally a group of supporters to take action on an issue of mutual interest. Examples of social media's role in major policymaking include the "Arab Spring" of 2011, wherein large groups of the public rallied for purpose of overturning incumbent national governments, e.g., Tunisia. On a smaller scale, social media has aided in organizing groups who opposed specific instances of property development thought to lessen space for parks and other greenspace.

2.3.1 Vested Interest Groups

A necessary component of setting environmental health policy is the presence of vested interest groups. These are organizations that have specific points of view relative to a particular environmental hazard or proposed policy. To be more specific, examples of vested interest groups include national environmental organizations (e.g., World Wildlife Fund), business advocacy organizations (e.g., American Chamber of Commerce), and public health associations (e.g., American Public Health Association). As a particular environmental policy becomes of interest to a legislative body (e.g., Congress, state legislature, county commissioners), vested interest groups will emerge to present their point of view and attempt to persuade legislators to support their view. This interaction occurs through presentations made by vested interest groups in public meetings (e.g., Congressional hearings) and private meetings with members of a legislative body and their staffs. Vested interest groups are important for assuring a full range of debate and discussion on a proposed environmental health policy, but can be an impediment to democratic processes if they wield undue influence on policymakers.

Two decisions by the U.S. Supreme Court have had a substantive effect on how vested interests can attempt to influence elections in the U.S. In a 2010 decision, *Citizens United v. Federal Election Commission*, the court by a 5-4 vote said political spending is protected under the First Amendment to the U.S. Constitution, meaning corporations and unions could spend unlimited amounts of money on political activities, as long as it was done independently of a party or candidate. The result has been a surge of money poured into political action committees (PACs). Further, corporations that fund PACs are legally protected from disclosing their support [1]. This 2010 decision by the Supreme Court was further elaborated by a 5-4 decision in the 2014 case, *McCutcheon v. Federal Election Commission*. The Court struck down a decades-old cap on the total amount any individual can contribute to federal candidates in a 2-year election cycle [2]. A product of these two decisions is the legal ability of affluent donors to pour money into election campaigns of persons who presumably agree with policies of the donors.

2.3.2 Newsmedia, Internet Communications, and Social Media

Newsmedia includes newspapers, television, radio, cable, and other commercial and public outlets of news and information. Internet communications include websites, e-mails, and blogs. Both the newsmedia and the Internet serve as a vital role in informing the public and shaping opinion. Much of what the U.S. public knows about environmental hazards is based on information from the newsmedia, particularly from television sources. Readers and viewers are presented with words and images that depict the presence and consequences of specific environmental hazards. Over time, the newsmedia have developed greater sophistication about which environmental reports to present to the public and how to convey their stories. What some would call "The Carcinogen of the Week" approach to environmental reporting has been replaced with a more cautious, thoughtful approach. Moreover, the amount of newsprint and television time devoted to environmental reports decreased during the 1990s, perhaps indicating a more pragmatic approach to reporting.

Few communication resources have proliferated as quickly and widely as the Internet. It began in the early 1960s at the Massachusetts Institute of Technology. University staff prepared concept papers that laid out the ideas of networking digital computers for purpose of exchanging packets of information. The World Wide Web technology was built upon the Internet infrastructure, allowing users to communicate globally [3]. One now has the capability of sending general information and personal communiqués around the globe, almost instantaneously, with but a stroke on a keyboard. It is now expected that any group that seeks public interest in its products, services, and agenda must have a website on the Internet. This, of course, includes environmental and public health groups and organizations. From such websites can be obtained information on specific environmental hazards, copies of environmental

laws and regulations, government policy positions, and vested interest groups' stances. All of this information can inform the public and thereby be used to protect an individual's health or become material for personal and group advocacy, e.g., letters to elected officials. However, there is a caution that must accompany use of information from the Internet. The credibility of a website source can vary, particularly on matters of science, because there are relatively few constraints placed on websites. On matters of science, the normal expectations of independent peer review* of research reports and their interpretations are not always followed. The consequence can be unsupportable scientific assertions that are intended to advocate a particular point of policy or other course of action.

In a policy context, newsmedia and Internet resources can bring environmental problems to the attention of the public, leading to concerns in vested interest groups and potentially affected members of the public. These concerns are soon brought to the attention of elected officials and other policymakers, who in turn are expected by a concerned public to take action. Consider the spread of the West Nile virus within the U.S. This virus, which is carried by mosquitoes and can infect birds, has caused loss of life in some persons bitten by infected mosquitoes. The presence of West Nile virus was first observed in the U.S. in 1999 in New York and other northeastern states. With the migration of birds, the virus was spread southward, causing additional loss of life. The newsmedia reported the presence of West Nile virus in the U.S., its public health consequences, and the spread of the virus into human populations. Reports of how to prevent human contact with infected mosquitoes were often presented by the newsmedia and found on Internet sites operated by public health departments. The information from newsmedia and Internet reports raised public awareness and kept elected officials and other policymakers alert to their responsibilities with respect to mosquito control.

The introduction and global adoption of social media as a means for communication has been nothing short of phenomenal. Through the use of "smartphones" and similar devices, users of social media technology can send and receive messages by simply "texting" or by sending/receiving images, sound, or videos. By the mere touch of a button on a smartphone, a message can be sent to multiple recipients. Social media effectively can be used to rally a group of supporters to take action on an issue of mutual interest.

In a policy context, newsmedia and Internet resources can bring environmental problems to the attention of the public, leading to concerns in vested interest groups and potentially affected members of the public.

2.3.3 Experts' Input

Environmental health policy can be influenced by the findings and recommendations from individual experts or groups of experts. Experts can be representatives from government agencies, universities, corporations, science councils, and such. Legislators and policymakers are often challenged to personally understand or appreciate the seriousness of a particular environmental hazard. In response to this challenge, legislative bodies will often turn to expert groups for their analysis and recommendations about a particular environmental hazard or issue. As an example, the U.S. Congress often asks (and funds) the National Academy of Sciences (NAS) to conduct an evaluation of an environmental issue and then provide their findings to the Congress and the public. These recommendations can help shape federal legislation. An example is the NAS report *Pesticides in the Diets of Infants and Children*, which reported on the public health hazard posed to young children from exposure to pesticides in the environment [5]. The report's recommendations for a greater level of protection for children had a major influence on the development and enactment of the Federal Food Quality Protection Act of 1998. This act requires the EPA and other federal agencies to develop and implement regulatory actions that provide a higher level of protection for children exposed to pesticides (Chapter 11).

2.3.4 Domestic Economic Policies

Federal environmental health policy, and to a lesser extent, state and local policies, are influenced by domestic economic policies. For example, the U.S. economy is a free market, free enterprise economy; one that is very much undergirded by consumer spending. Consumer spending means the production of products and materials and the purchase of goods and services. This places money in general circulation, providing even more funds for development and investment. A part of this economic engine produces goods and services that are sold to international customers. This produces wealth for companies and can help economic development in other countries.

During times of weak national economies, it is difficult for elected officials and policymakers to impose laws and regulations that could result in further economic hardship. For instance, a particular proposed environmental policy that could harm international trade would be difficult to enact in times of economic austerity. Vested interest business groups would argue that the contemplated environmental policy would result in job reductions, lessened corporate profits, stock devaluation, and such. Few elected officials would be willing to favor an environmental policy that might exacerbate a period of economic fragility.

The economies of industrialized countries, joined by the economy of China, remained relatively healthy and stable through the late first decade of the twenty-first century. Policymaking on environmental issues occurred in the U.S. and the EU, with examples that include new or amended laws on use of tobacco products, food safety, and nascent efforts on climate control. This period ended when what became known as the Great Recession emerged. According to one source, "The Great Recession—which officially lasted from

* *Peer review*—Evaluation of the accuracy or validity of technical data, observations, and interpretation by qualified experts in an organized group process [4].

December 2007 to June 2009—began with the bursting of an $8 trillion housing bubble. The resulting loss of wealth led to sharp cutbacks in consumer spending. This loss of consumption, combined with the financial market chaos triggered by the bursting of the bubble, also led to a collapse in business investment. As consumer spending and business investment dried up, massive job loss followed. In 2008 and 2009, the U.S. labor market lost 8.4 million jobs, or 6.1% of all payroll employment. This was the most dramatic employment contraction (by far) of any recession since the Great Depression" [6]. During this period of economic downturn, any support for environmental policymaking, particularly any policy that might entail regulating business or commercial activities, was nonexistent. This remained the policymaking noncourse until the second term of the Obama administration, which commenced in 2012.

2.3.5 Free Trade Policies

The trading of goods and services between nations and peoples is an ancient, even prehistoric, means of meeting personal and societal needs. Trading means exchanging (i.e., barter) or selling goods between persons. Depending on the circumstances, each sale or barter has the potential to produce an income for the seller, generating revenue. With sufficient revenue, regional and national economies can benefit. One way of enhancing the revenue from trade has been to place a tariff (i.e., a tax) on imported goods. This predictably leads to other nations placing tariffs on their own imported goods. This can lead to tariff, trade, and policy disputes between countries. Some disputes have had historic impact on a nation's growth and development. Consider the Boston Tea Party [7]. In 1773, the British parliament allowed the East India Company to export a half million pounds of tea to the colonies, but without charging the company a tariff on the tea. This waiver of a tariff on tea placed colonial tea merchants at an economic disadvantage, since they were still subject to paying a tariff on the tea they imported. On December 17, 1773 a band of colonial merchants boarded the British ships that contained the tea and threw the cargo overboard into the Boston Harbor, an event called the Boston Tea Party. This action, based on a tariff dispute, furthered an already worsening relationship between the British colonies and Britain.

Free trade policies remove trade barriers between nations and eliminate tariffs on goods. The EU has no trade barriers between EU Member States. In another example, Canada, Mexico, and the U.S. entered into the North American Free Trade Agreement (NAFTA) on January 1, 1994, a treaty between the three countries that removed barriers to trade across their borders. Some persons and groups argue that free trade translates into lowered environmental and public health protections. They assert that transnational corporations will relocate polluting and injurious (to workers) industries from countries with stringent environmental control to countries without such controls. Other persons and organizations argue that free trade agreements benefit the commerce of trading countries and enhance global competitiveness.

2.3.6 Form of Governance

How a country, region, state/province, tribal nation, or locality chooses to govern itself can influence how environmental health policy is implemented. In the U.S., the three branches of federal government (legislative, executive, judicial), discussed in Chapter 3, are mirrored at the state and local government levels. Any federal or state environmental statute, regulation, or local government ordinance is subject to judicial processes if litigation is brought by a party that disagrees with some aspect of the statute, regulation, or ordinance. In the U.S., the method of governance is a democratic republic, which means representatives are democratically elected and authorized to act for other persons who reside in a specific geographic area (e.g., a congressional district). As a democratic republic, serviced by elected officials, considerable input from the public on matters of environmental policy is both possible and desirable.

Another form of governance is based on the election of a parliament as the national seat of legislation. Parliamentary governments are derived from the Parliament of Great Britain, which in turn began in the Middle Ages as an advisory body to the monarch [8]. Beginning in the thirteenth century, the single advisory body evolved into the House of Lords (major landholders, chief nobles, and clergy) and the House of Commons (knights, lower clergy, and burgesses). In 1688, the Parliament succeeded in obtaining primacy over the monarchy for purpose of national government. In time, the House of Commons assumed the responsibility for enacting national legislation, with the House of Lords' power being limited to deliberations on legislation and initiating amendments to bills. Parliamentary government vests its legislative authorities with a parliament and its executive authorities with ministries (e.g., Ministry of Health). Courts are independent of parliament, except for receiving public funds through parliamentary appropriations. Following national elections, members of the House of Commons elect a prime minister, who forms a cabinet of ministerial officers, and who becomes the country's administrative leader.

Environmental health policy established within parliamentary systems is largely set by the relevant ministries of environment and health, operating under broad authorities of parliament. The amount of public input varies from one country to another, but is generally less than in the U.S. system of government.

Perspective: Many factors will influence the development of environmental health policy, whether being made by public or private sources. The seven factors shown in Figure 2.1 are but one set of influences. There are others that come into play, depending on the specific policy and circumstances. More important than the specifics of individual influences (e.g., newsmedia) is the recognition that establishing environmental health policies is difficult and requires sustained support to achieve a particular policy. Knowing about this challenge gives even greater respect for those persons and organizations that have contributed to legislation and policies that have improved the quality of the air that we breathe, the water that

we drink, the food we consume, the sanitary management of wastes, and nascent attempts to mitigate climate changes, each of which can threaten the public's health.

2.4 ESTABLISHING ENVIRONMENTAL HEALTH POLICY

The process of establishing environmental policy is usually a difficult proposition. This is because environmental issues in general elicit divergence in opinion between vested interest groups, especially if proposed policies might produce regulatory actions. Seldom do regulated organizations support new or expanded regulations that could have economic impacts. Rather, their opposition to a proposed environmental health policy will become part of the dynamic process that constitutes policy-setting. Although policy-setting is a difficult process, it can nonetheless be viewed as a structured process. For example, Rosenbaum [9] divides the policy cycle, which he defines as "the process of interrelated phases through which policy ordinarily evolves," into six phases:

1. *Agenda setting*—It is quite difficult, but not impossible, for an individual to get a proposed policy issue made into an institutional policy. An exception can occur when an individual is a policymaker (e.g., county commissioner) and therefore has direct access to the policymaking machinery. However, a group effort is usually required, since policymakers are more easily persuaded when there are a large number of proponents for a proposed policy. The first step in achieving a group's policymaking aspirations is to get the desired policy onto the agenda of policymakers. This is because policymaking is a political event, requiring political skill in the processes of negotiation and compromise. Examples of government agenda setters include local elected officials, state legislators, and members of Congress. In the private sector, agenda setters include company officials, boards of directors, and policy committees. Getting a desired policy into the hands of policy-setters occurs by lobbying, a time-honored process of political pressure brought upon elected officials and other policymakers.
2. *Formulation and legitimation*—Getting a policy proposal onto the agenda of a policymaker is the essential first step in policymaking. Rosenbaum's next step is formulation, which he states, "[i]nvolves setting goals for policy, creating specific plans and proposals for these goals, and selecting the means to implement such plans" ([9], p. 53). "Policies once created must also be legitimated—invested with the authority to evoke public acceptance." This usually is done through constitutional, statutory, or administrative procedures, such as voting, public hearings, presidential order, or judicial decisions upholding the constitutionality of laws—rituals whose purposes are to signify that policies have now acquired the weight of public authority" ([9], p. 54). Consider the formulation and legitimation of a municipal ordinance to prohibit tobacco smoking in public facilities. Policymakers would hold public hearings, meet with advocacy groups supportive of or against the proposed antismoking policy, and consult with attorneys to ascertain the legality of various possible forms of the ordinance. Following the acquisition of such information, elected officials would vote in a public setting on whether to enact an antismoking ordinance.
3. *Implementation*—Policy implementation means acting upon a policy that has been formulated and legitimated by a policymaking body, e.g., a tribal council. Environmental health policy normally specifies the agencies that are responsible for implementing the enacted policy. For example, amendments to the federal CAAct, discussed in Chapter 8, specify the EPA as the federal agency responsible for implementing the policy changes inherent in the amendments.
4. *Assessment and reformulation*—Implemented policies always attract attention and oversight, particularly by those individuals and groups who advocated for the policies. For instance, groups that successfully lobbied for a municipal nonsmoking policy in public facilities are likely to monitor the degree to which the policy has been effective. Implemented policies seldom go unchanged over time. Changes can occur as the result of court decisions, administrative experience, public dissatisfaction, and vested interest intervention.
5. *Policy termination*—Once in place, it is difficult to terminate a public policy, given the political nature of the policymaking process. Policymakers are loathe to terminate a policy unless it has been convincingly shown to be detrimental to the public good. As described by Rosenbaum, "Terminating policies, environmental or otherwise, is such a formidable process that most public programs, in spite of intentions to the contrary, become virtually immortal. Policies usually change through repeated reformulation and reassessment" ([9], pp. 54–55).
6. *Policymaking is a combination of phases*—It is important for those who desire to set policy to know that policy is made and implemented through a combination of phases, commencing with agenda setting. Some phases can occur concurrently, or nearly so. For example, the phases of implementation and assessment and reformulation can occur at the same time, since implementation of a policy is one way to ascertain if it needs reformulation or termination.

The six phases of policymaking, as described by Rosenbaum, can be simplified into a model that focuses on pressure, action, change, and modeling (PACM) that occur during the policymaking process, as described subsequently.

2.5 PACM MODEL

As prior narrative has stated or inferred, setting environmental health policies is a difficult, complex undertaking. It is a process that is thoroughly political—and should be, because one definition of politics is the "the total complex of relations between people living in society" [10]. Politics forces issues into the arena of discussion and debate, whether in the U.S. Congress or in one's family. Inevitably, all successful politics must include discussion, negotiation, and, ultimately, compromise. Just consider how politics shaped what became the U.S. Constitution. Representatives from the 13 U.S. states had many serious political disagreements over the content of the Constitution. For instance, smaller states had concerns that more populous states would take advantage because of greater numbers of representatives in a House of Representatives. This concern was settled by negotiating the creation of a U.S. Senate, a body that gave small states parity in representation.

Establishing any policy is political and the accompanying policymaking and practice of politics are as intertwined as macaroni and cheese. Recognition of this reality leads to a simplified diagram of policymaking, shown in Figure 2.2, which consists of four components: pressure, action, change, and monitoring (PACM). Figure 2.2 is arranged as a flow diagram, indicating how the four components interact. Establishing policy begins with pressure.

2.5.1 Pressure

Because setting any policy is a political event, and recognizing that all political systems have a certain amount of inertia, putting pressure on the system is required. This is because elected officials are often slow to support a proposed policy initiative until they have calculated the political implications of their support. The need to bring pressure on elected officials and other senior policymakers is particularly important on matters of environmental health policy, where economic impacts of proposed policies (e.g., regulating the siting and operating of incinerators) often become controversial.

Bringing pressure on political systems to set federal environmental health policies occurs through lobbying by environmental organizations (e.g., Environmental Defense, Natural Resources Defense Council), business associations (e.g., chambers of commerce), trade associations (e.g., American Petroleum Institute), professional societies (e.g., American Public Health Association), state governments, and specialty experts (e.g., National Academy of Sciences). The pressure is exerted through meetings with policymakers and their staffs, testimonies given at public hearings, reports in the newsmedia, messaging via social media, and other outlets that can influence public opinion and motivate elected officials.

Pressure can be brought to bear on business enterprises to achieve environmental goals and changes in business practices. Like pressure directed to government policies and practices, meetings between environmental groups and senior policymakers in business can bring about debate, negotiation, and compromise. An example is the successful pressure applied to the McDonald's food chain to effect changes in how food was packaged. Specifically, environmental groups sought to replace styrofoam containers with those fabricated of paper and cardboard. Environmentalists were concerned about the relatively lack of biodegradability of styrofoam materials, resulting in their presence in municipal landfills much longer than their paper counterparts.

2.5.2 Action

When sufficient pressure is brought to bear on a political system, action can occur. Action simply means that something occurs, gets done, or moves. Actions can take the form of

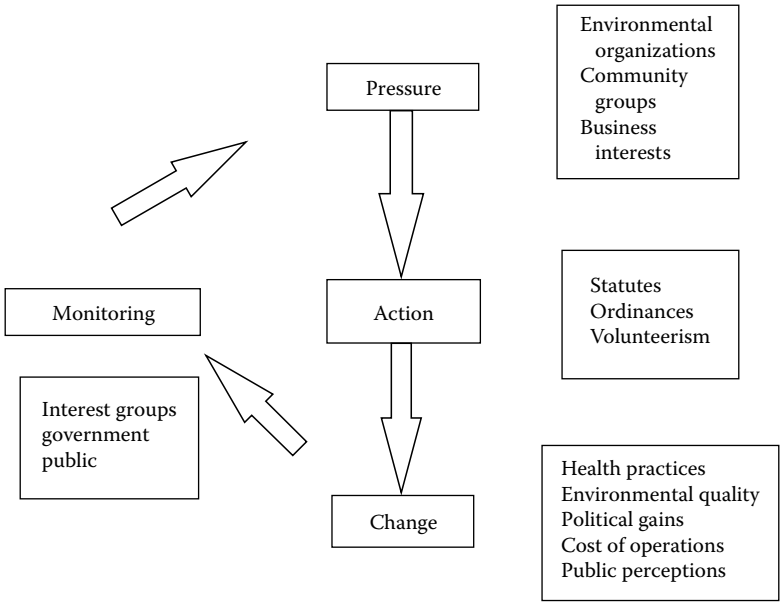

FIGURE 2.2 Simplified flowchart of environmental policymaking (PAM model).

enacted legislation by federal or state legislatures or ordinances promulgated by county and local governments. The enactment of the Food Quality Protection Act of 1996 represented action to improve how pesticides were regulated by the federal government. Action can also be new or revised federal or state environmental regulations or new policies. The EPA's reassessment of the risk of exposure to dioxins changed that agency's procedures for conducting risk assessments by including for the first time mechanisms of cellular toxicity in their considerations. This action adds further science to how risk assessments of environmental hazards will be regulated (Chapter 19).

2.5.3 Change

Change, simply put, means that a different course of action will occur from what was previously done. For example, whereas the Air Pollution Control Act of 1955 was limited primarily to research and technical and economic assistance to state and local governments, the CAAct Amendments of 1963 enlarged the EPA's responsibilities for controlling air pollution. At the same time, the act continued congressional intent that "[t]he prevention and control of air pollution at the source is the primary responsibility of state and local governments" [11]. As will be discussed in Chapter 8, amendments in later years further strengthened the federal government's primacy, working with state and local governments, in controlling air pollution.

Change can also occur when pressure is directed to Executive Branch agencies and departments. Such pressure is more narrowly focused and not always as visible to the public as pressure directed to legislative bodies. An example, as noted in Chapter 18, is environmental justice advocates pressured the Clinton administration to issue an Executive Order (i.e., an action) that mandates several actions of federal government agencies in order to prevent the unjust imposition of environmental hazards on minority populations (i.e., change). This order changed risk management policies by requiring federal agencies to give attention to how environmental risks to minorities were characterized and managed. As a specific outcome, the EPA created the National Environmental Justice Advisory Committee as a resource for advising the agency on communities' concerns about environmental injustice (Chapter 18). This committee has provided the EPA with advice on agency environmental justice policies and guidance on implementing the policies.

2.5.4 Monitoring

Just because a change in a policy has occurred does not always mean that those who initiated the change will be satisfied. The changes may be perceived as being ineffective, too costly, or misdirected. Monitoring (or surveillance) of the changes is a common means to assess the impact of a change in policy. Monitoring data can, in turn, be used to refine policies or even get them withdrawn.

As an example of monitoring, Title III of the Superfund Amendments and Reauthorization Act of 1986 created the Toxics Release Inventory (TRI), which requires business entities to annually provide the EPA with data on substances released into the environment and specifics on the quantities released. The EPA is required to make TRI data available to the public. Environmental groups, nationally and locally, have evaluated TRI data to assess trends in releases of toxicants and have used the data to bring public attention to those facilities that release large amounts of pollution into the environment. The response of businesses has often been to voluntarily decrease their emission levels. Some persons have referred to this action as "regulation by shaming" [12].

In summary, an understanding of the PACM model is fundamental for policy development, be it a national environmental policy or a family budget. Application of this simple model must be tempered with the wisdom that politics will be a consideration at each step. No policy gets established without the art of debate, negotiation, and compromise.

2.6 POLICIES TO CONTROL ENVIRONMENTAL HAZARDS*

As described throughout this book, environmental hazards not sufficiently controlled can cause adverse effects on the public's health and environmental degradation. In the U.S., over the course of many years, but particularly starting in the 1960s, policies have emerged that targeted the control of specific environmental hazards, e.g., chemical contaminants in drinking water supplies. The intent of the policies has been to prevent human exposure to those hazards that can cause human disease or disability. The most frequently used policy has been to legislate laws that required government agencies to develop and administer regulations to control the risk of exposure to select environmental hazards. However, alternative policies have emerged in support, or in lieu, of the regulatory approach.

This section will discuss some of the policy options that can be brought to bear on control of environmental hazards. At the core of these options is behavior—how individuals, public, and private entities act within a society toward attaining a common end. How behavior is expressed is the issue. For instance, society, acting through government, has controlled the behavior of polluters of the environment through the mechanisms of legislation, regulation, and enforcement. This is a kind of coerced behavior. But behavior can also be voluntary, as expressed by individuals, groups, and cultural entities such as corporations. Both coerced and voluntary behaviors are necessary for environmental policy purposes. The following sections will describe several policy choices for controlling environmental hazards.

2.6.1 Command and Control

To regulate is to control, because a regulation is defined as a rule or directive made and maintained by an authority. Some

* The authors express their gratitude to Prof. Melvin Myers, Rollins School of Public Health, Emory University, for his contributions to this section.

control is vital to a society's well-being. This is true in application for both individuals and groups comprising a society. Control can be self-imposed as well as group-imposed. Rules that control behavior are purposeful for survival. Even our most distant human ancestors learned that individuals forming groups or tribes had better chances of survival than if each individual acted alone. Rules evolved that protected tribes and small groups, e.g., recognition that murder of tribal members generally weakened the group—fewer hunters, warriors, child-bearers, for example. As government evolved as the primary instrument for protecting large societies, control was passed from individuals and small groups to government.

All governments impose control over their society. One method of control is by establishment of laws and regulations. This is the way that U.S. environmental health policy has occurred. While some might consider environmental policies to be a product of twentieth century U.S. government, in fact, environmental policies or practices have much deeper roots. Consider, for instance, the policy of indigenous people who took from the environment only what they could consume. An example is the reverence given to the bison by the indigenous people of what are now called the Great Plains of North America. The animal's body provided them with clothing, food, tools, and medicines. They took from the great bison herds only what they could consume. Contrast that environmental policy with the slaughter to near extinction of the bison herds by European settlers who emigrated westward from the eastern coast of North America. Herds were decimated for mere sport, pelts were made into "fashionable" clothing of the moment, and bisons' grazing lands were divided into farms and ranches. As another early example of a people's environmental policies, leaders of the Massachusetts Bay Colony had to forbid the use of lead-lined pots in which to prepare rum for sale [13]. So environmental health practices and rules are not simply of recent origin in North America.

In the early twentieth century, the U.S. Congress began enacting legislation that was intended to control environmental hazards of public health consequence. As will be discussed in Chapter 4, a considerable body of federal environmental legislation accrued during that century, peaking in the period between the mid-1950s through 1980. The enacted legislation, when signed into law by incumbent Presidents, brought to bear the weight of law to control environmental hazards, protect the environment and natural resources, and protect the public's health.

In general, this body of environmental law gave federal agencies (e.g., the EPA) the authority to *command and control* (also called *regulations and standards*) actions to control workplace and community sources of specific environmental hazards. Sources of pollution such as companies, businesses, and government agencies that are required to comply with specific regulations are called the *regulated community*. As an example, companies that generate electric power are a regulated industry under the provisions of the CAAct.

Rosenbaum [9] observes that command and control comprises five phases through which pollution policy evolves: goals, criteria, quality standards, emission standards, and enforcement. These five phases apply to both federal and state environmental health policies.

1. *Goals*: Legislative bodies must state goals for statutes intended to control the release of pollutants or other environmental hazards. The goals are normally stated in broad terms, e.g., a goal of protecting public health and safety. However, specificity in achieving some goals is added by Congress when there is impatience with ongoing regulatory processes. For example, slow progress by the EPA in regulating hazardous air pollutants (HAPs) led Congress to specify in the 1990 CAAct amendments more than 180 HAPs and timelines for which EPA was to develop regulations.
2. *Criteria*: "[t]he technical data, commonly provided by research scientists, indicating what pollutants are associated with environmental damage and how such pollutants, in varying combinations, affect the environment" [9]. Criteria serve many purposes. Legislative bodies need criteria when contemplating environmental and other legislation. For instance, do criteria indicate or suggest that pollutants may cause adverse health effects to humans or ecosystems? Similarly, regulatory agencies require criteria during the development of risk assessments and risk management plans for specific environmental hazards, e.g., contaminants in drinking water. Agencies often prepare criteria documents in support of risk management actions, such as recommendations on permitted exposure levels to hazardous substances found in workplaces or in the ambient outdoor air of urban settings.
3. *Quality standards*: How pure do we want the air that we breathe, the water we drink, or the food we consume? This question goes to the regulatory concept of quality—air quality, water quality, food quality. *Quality standards* express the levels of pollution that can be present in an environmental medium (air, water, food) without causing harm to human or ecological health. For example, the existing primary standards for outdoor ambient air levels of CO are 9 parts per million (ppm) measured over 8 h, and 35 ppm measured over 1 h (Chapter 8). Quality standards are legally enforceable. Quality standards are currently developed by U.S. regulatory agencies through risk assessment methodology, a structured process used to relate criteria to specific levels of pollutants in specific environmental media (Chapter 19).
4. *Emission standards*: To achieve quality standards requires knowledge about, and control of, sources of pollution. *Emission standards* regulate the amount of pollution that can be legally released into specific environmental media over a specified amount of time. To achieve emission standards requires emission controls, technologies that will reduce or prevent emission of pollutants. As an example, automobile

manufacturers must install emission controls (e.g., catalytic reactors) on motor vehicles sold in the U.S. in order to control vehicle emissions that contribute to air pollution.

5. *Enforcement*: Command and control regulatory policy, beginning with setting of goals, concludes with the enforcement phase. Simply establishing quality and emission standards is not sufficient to ensure that they will be implemented by the regulated community. Like other matters of law, regulatory standards must be supported by enforcement authority. Without enforcement authority, in effect, regulatory standards would become voluntary, i.e., sources of pollution could pick and choose those standards acceptable to them. Rosenbaum [9] observes, "[S]atisfactory enforcement schemes have several characteristics: they enable public officials to act with reasonable speed—very rapidly in the case of emergencies—to curb pollution; they carry sufficient penalties to encourage compliance and they do not enable officials to evade a responsibility to act against violations when action is essential."

Command and control is a controversial policy. The regulated community often objects to the alleged economic impact of quality and emission standards, usually arguing that the costs to them far outweigh the benefits to the public. This debate in recent years has led to the requirement by Congress that regulatory agencies conduct a cost/benefit analysis of proposed regulations. Moreover, even after cost/benefit analyses are conducted and regulatory actions made final, litigation often occurs when the regulated community disagrees with the final regulatory action.

The ergonomics* standard developed in the 1990s by the OSHA is an example of the politically thorny and difficult nature of current day attempts to develop and promulgate environmental regulations. As background, certain job activities, especially those that require repetitive body motion, can cause disorders in a person's musculoskeletal system. For example, persons who strenuously strike the keys of computer keyboards for data entry or typing can develop a painful wrist disorder called Carpal Tunnel Syndrome. Likewise, repetitive lifting of heavy objects, e.g., patients confined to hospital beds, can cause injuries to a hospital worker's back. These kinds of injuries are called musculoskeletal disorders (MSDs). They are almost always quite painful to afflicted individuals and can be debilitating, leading to job loss and workers' compensation demands. There is ample evidence to demonstrate that MSDs are prevalent, costly, and amenable to prevention strategies, such as better designed office equipment and mechanical aids for lifting and moving heavy objects.

OSHA spent the 8 years of the Clinton administration developing an ergonomics standard, i.e., a set of regulations that would "command and control" how repetitive motion jobs and other physical labor would be performed in industry and other business enterprises. OSHA's Ergonomics Program Standard went into effect on January 16, 2001, which was 4 days before the Clinton administration ended. By the time the standard had gone into effect, opposition to its implementation had formed across much of the U.S. business sector. It was characterized by business interests as too broad in its coverage of work activities, too vague in what would be an ergonomic hazard, too costly in its requirements to redesign job conditions, and too burdensome in its paperwork and reporting requirements. As the result of these concerns, business interests brought the PACM model to bear on the U.S. Congress.

On March 6–7, 2001, the Senate and the House of Representatives voted to repeal OSHA's Ergonomics Program Standard. Congress's authority derived from the Congressional Review Act of 1996,† which requires federal agencies to submit regulations to Congress before they go into effect. Congress must act within 60 days on a proposed regulation. A proposed regulation can be set aside by a Joint Resolution of Disapproval by a simple majority vote of both houses of Congress [14]. Repeal of the OSHA ergonomics rule was the first and to date only such action by Congress under the Act. OSHA is currently revising the repealed standard, but has made no firm commitment on when a revised ergonomics standard might be issued [15].

Congress's authority to repeal a federal agency's regulation is relatively recent, and in a policy context, contradictory. It is contradictory in the sense that Congress mandates federal regulatory agencies to develop regulations, using the most current and relevant scientific data and judgment, to control specific environmental hazards, but can then overturn an agency's proposed regulations, based on political pressure from vested interest organizations. This adds one more "hoop" for regulatory agencies to anticipate. On the more positive side, use of the Congressional Review Act can prevent the imposition of politically and, perhaps scientifically flawed, regulations before they are promulgated to a regulated community.

2.6.2 Alternatives to Command and Control

The previous section described the command and control approach for regulating environmental hazards. However, over time, alternatives have emerged to command and control as a regulatory policy. This has occurred in part because of dissatisfaction with the slowness of many federal regulatory actions and disagreement over whether regulatory policies should be risk based. In fact, the wheels of government do generally turn slowly, given the political processes inherent in government policymaking. Some voluntary actions, shown in Table 2.1, can proceed more quickly, as discussed in the following sections and the degree of personal control (e.g., litigation, market power) can be greater than if government is proceeding along a regulatory approach for the issue at hand.

* See Glossary.

† More accurately referred to as Subtitle E, Title II, of the Small Business Regulatory Enforcement Fairness Act of 1996.

TABLE 2.1
Alternatives to Command and Control

Litigation
Market Power
Performance Incentives
Precautionary Approach
Public Education
Sustainable Development
Voluntary Action by Industry

However, some of the alternatives to command and control can themselves be rather time consuming, with uncertain outcomes. Alternatives, therefore, must be carefully chosen and pursued.

2.6.2.1 Litigation

A substantial amount of environmental health policy has been established, or modified, through litigation. Courts have served as arbiters—and, by default, policy decision-makers—on many wide-ranging environmental issues. For example, national environmental organizations have litigated the EPA on whether the agency has complied with provisions of the CAAct, such as allegations that EPA regulations on controlling fine particulate matter have been too lax. Similarly, the EPA has litigated municipalities, e.g., Atlanta, Georgia, for failure to meet CWAct standards. In these examples of "proactive" litigation, courts have become final authorities on how well government agencies have met their legal environmental responsibilities.

Private industry has also turned to courts for relief from alleged burdensome regulations. In perhaps the most significant litigation against a federal regulatory agency, OSHA was litigated in 1980 over their proposed regulation to control benzene levels in occupational settings (Chapter 19). As related by Rodricks, "[O]SHA proposed simply to identify occupational carcinogens and to establish limits on worker exposure at the lowest technically feasible levels—in the absence of identifiable thresholds, technology should dictate the maximum allowable workplace exposures. When OSHA attempted to apply this regulatory philosophy to the leukemia-causing benzene, the affected industries mounted a legal challenge, based on the view that the law required OSHA to show explicitly the level of cancer risk the agency was attempting to control, and the level of risk reduction that would be achieved by the introduction of controls.

The legal challenge made its way to the Supreme Court, and its nine judges, by a margin of 7 to 2, agreed with the industry position (*Industrial Union Department, AFL-CIO v. American Petroleum Institute* 1980). They sent OSHA home with the assignment to engage in quantitative risk assessment when it attempted to regulate carcinogens [16]." The court's decision completely changed the way that federal regulatory agencies assessed the risk from environmental hazards. Quantitative risk assessment became the status quo whenever it could be applied to a regulatory action (Chapter 19).

Individuals can litigate private businesses when products are alleged to be unsafe or otherwise hazardous for personal use. Such litigation, called product liability suits, has often been used to address alleged harmful effects experienced by individuals. Examples of personal litigation include lawsuits against manufacturers of alleged defective automobile tires, toys, personal care products, tobacco products, and food products. Some lawsuits become "class action" litigation when many individuals join together as plaintiffs in a single lawsuit. The class action suits by asbestos-exposed workers against asbestos producers are an example.

Another example of a class action suit concerning an environmental issue pertains to the 1989 spill into the Prince William Sound in Alaska of crude oil from the ship *Exxon Valdez*. The ship had run aground, ruptured, and spilled 11 million gallons of crude oil, causing great damage to the local ecosystem and the region's economy. In the same year, a class action suit was filed against the ship's owner, the Exxon Corporation, by 32,000 fishermen and residents of the area [17]. The spill's cleanup costs amounted to approximately $2 billion. The spill led to considerable litigations, culminating in a settlement between the company and state and federal governments. The settlement was approved by the U.S. District Court on October 9, 1991. The settlement had three distinct parts:

1. Criminal Plea Agreement: Exxon was fined $150 million, at that time the largest fine ever imposed for an environmental crime. The court forgave $125 million of that fine in recognition of Exxon's cooperation in cleaning up the spill and paying certain private claims.
2. Criminal Restitution: As restitution for the injuries caused to the fish, wildlife, and lands of the spill region, Exxon agreed to pay $100 million. This money was divided evenly between the federal and state governments.
3. Civil Settlement: Exxon agreed to pay $900 million with annual payments stretched over a 10-year period.

The final payment was received in September 2001. The settlement contains a "reopener window" between September 1, 2002 and September 1, 2006, during which the governments could make a claim for up to an additional $100 million. The funds must be used to restore resources that suffered a substantial loss or decline as a result of the oil spill, the injuries to which could not have been known or anticipated by the six trustees from any information in their possession or reasonably available to any of them at the time of the settlement (September 25, 1991). On June 1, 2006, the U.S. Department of Justice and the State of Alaska Department of Law announced that they have taken the first step in asserting a claim under the Reopener provision by providing ExxonMobil Corporation with a detailed project plan for the cleanup of lingering oil at an estimated cost of $92 million, an outcome that awaits a final decision by Exxon and the federal and state governments [18].

2.6.2.2 Market Power

In a society that is based on a consumer economy, i.e., one in which products are created, distributed, and sold at a profit, consumers of products and services can influence environmental policies through their marketing policies and practices. With adequate consumer education, individuals and groups who purchase environmentally-sensitive products can help determine what products remain in commerce. As an example, the purchase by individuals of household detergents with low or zero phosphorus content helped reduce water pollution and algal growth in waterways. Similarly, companies, small businesses, and government agencies can voluntarily adopt policies on purchasing products that cause minimal harm to environmental quality.

Antismoking campaigns are an example of consumer power as environmental health policy in action. Antismoking activists have been quite successful in lobbying local governments and businesses to ban or restrict tobacco smoking in public buildings and in some private premises (Chapter 7). A contemporary example is the restriction of tobacco smoking in restaurants. Many local governments have required restaurants and other food service establishments to either ban tobacco smoking altogether, or in some localities, provide areas where smoking is prohibited. Where antismoking ordinances do not exist, consumers can exert pressure by selecting restaurants that have voluntarily adopted a no-smoking policy, thereby promoting an increase in the number of such restaurants. Similarly, pressure from airline customers and flight attendants eventually led to no-smoking policies on domestic and international air travel, illustrating how market power can have a global impact.

A strategy used in market power to reduce the impact of environmental hazards is called Green Commerce. This strategy can be implemented by consumers who preferentially purchase products that protect the environment. The strategy can also be implemented by industry and businesses that operate in the arena of green commerce, e.g., companies that develop and market "environmentally friendly" commercial products and services. It is a marketing strategy that intends to appeal to environmentally supportive groups in the general population. In effect, the Green Commerce policy strives to link commercial entrepreneurialism with environmental advocacy. There is no regulatory apparatus that comes into force that requires a policy of Green Commerce, assuming, of course, that the green products or services do not violate regulations on safety or environmental quality.

The introduction of Green Commerce products can be illustrated by changes occurring in the laundry, dry cleaning, and home cleaning businesses. In the dry cleaning business, less reliance on solvent-based cleansers means fewer hazardous pollutants released from dry cleaning establishments into the environment. Rather than dry cleaning, laundering garments by using phosphorous-free soap products is Green Commerce advancement. Similarly, Green Commerce has resulted in a host of home cleaning products that are derived from citrus and other natural materials. Use of these products results in less water contamination than through use of products containing synthetic chemicals. Consumers who purchase products or services from environmentally sensitive companies or from other business services can strongly influence positive environmental protections. Another Green Commerce example is the use of spent motor vehicle tires to make paving materials for roads. Spent tires are ground into small pieces, combined with a petroleum mixture, and used in lieu of asphalt for repairing roadways. Recycling old tires is a major benefit to the environment and public health, since old tires left in waste dumps can become a most fertile breeding ground for mosquitoes, which in turn, can carry viruses such as West Nile that can cause human illness.

Green Commerce strives to link commercial entrepreneurialism with environmental advocacy.

Sometimes changes in technology can bring about green marketing opportunities by giving customers more choices in purchasing green products. As an example, purchasing digital cameras rather than film cameras provides an environmental benefit, since the chemicals used in film processing are no longer necessary. In Sweden, water quality tests showed that silver levels have decreased by more than 50% in 5 years in the waters of the Stockholm archipelago. Swedish environmental officials attribute the dramatic decrease to the growing use of digital photography and the corresponding reduction in film processing laboratories [19].

An important market power initiative is called Green Communities, a 5-year, $555 million initiative to build more than 8500 environmentally healthy homes for low-income families. The initiative was created by the Enterprise Foundation, a national nonprofit organization based in Columbia, Maryland, that provides assistance to grassroots home ownership organizations in partnership with the Natural Resources Defense Council, a national environmental organization based in Washington, DC. The Green Communities initiative intends to transform the way the U.S. thinks about, designs, and builds affordable communities. The initiative provides grants, financing, tax credit equity, and technical assistance to developers who meet Green Communities criteria for affordable housing that promotes health, conserves energy and natural resources, and provides easy access to jobs, schools, and services. Projects are underway in the states of Massachusetts, Michigan, and Minnesota [20].

An advantage of Green Commerce policy is turning a free market loose to help eliminate specific environmental hazards. The creativity of free enterprise can be harnessed and applied to improving environmental quality and reducing public health impacts of hazards in the environment. Government involvement can be absent or minimal, a situation that appeals to many commercial interests.

Market power can also be used for environmental improvement through the use of government's use of *market-based instruments* (MBIs). The European Environmental Agency (EEA) (Chapter 5) observes that much environmental pollution and depletion of natural resources occur from incorrect

pricing of goods and services, because prices do not often reflect the true costs of production and consumption [21]. In particular, the impacts on the environmental are not always correctly factored into prices of goods and services. Examples of hidden costs include the costs that come from responding to damage from air and water pollution, disposal of waste, loss of soils and species, and effects of climate change, floods, heat waves, and storms. The EEA asserts that MBIs provide a stimulus to consumers and producers to change their behavior toward use of more ecologically efficient use of natural resources by reducing consumption, by stimulating technological innovation, and by encouraging greater transparency on how much consumers and producers actually pay for products and services. The EEA specifies five main kinds of MBIs:

1. *Tradable permits* that have been designed to achieve reductions in pollution (such as emissions of CO) or use of resources (such as fish quotas) in the most effective way through the provision of market incentives to trade.
2. *Environmental taxes* that have been designed to change prices and thus the behavior of producers and consumers, as well as raise revenues.
3. *Environmental charges* that have been designed to cover (in part or in full) the costs of environmental services and abatement measures such as waste water treatment and waste disposal.
4. *Environmental subsidies and incentives* that have been designed to stimulate development of new technologies, to help create new markets for environmental goods and services including technologies, to encourage changes in consumer behavior through green purchasing schemes, and to temporarily support achieving higher levels of environmental protection by companies.
5. *Liability and compensation schemes* that aim at ensuring adequate compensation for damage resulting from activities dangerous to the environment and provide for means of prevention and reinstatement [21].

According to the EEA, the use of MBIs in environmental policy has found increasing favor in Europe since the 1990s, particularly in the Scandinavian countries and The Netherlands [21]. MBIs that address taxes, charges, and tradable permits have been those most often used in setting environmental policy. The long-term effectiveness of MBIs awaits analysis, but in particular offers the promise of supporting policies of sustainable development.

2.6.2.3 Performance Incentives

Incentives are a powerful motivator of human behavior. In the sports world, some players' contracts contain performance goals that when achieved will result in extra remuneration. For example, a baseball pitcher who wins 20 games, has an earned run average less than 3.0, and is voted to the All-Star game would be paid more for achieving these goals if they were elements of his contract with his team. Similar in concept, salespersons who exceed sales goals are often paid extra. Incentives metaphorically are the "carrot and stick" approach to behavioral performance.

Pollution trading credits (PTCs), also called Cap and Trade credits, are an example of a performance incentives policy. The idea is relatively simple. A regulatory body (e.g., the EPA) grants individual polluting facilities (e.g., an electric power generating plant) an annual allocation of PTCs that equals the maximum amount of pollution that they can release into the environment. However, if a given facility releases less pollution than their emissions allocation, the difference in trading credits can become a commodity and sold to facilities that are not meeting their annual emissions limit. In other words, it makes good economic sense for a facility to overachieve in order to market their PTCs. This is the free enterprise system being used to drive gains in environmental quality. As discussed in Chapter 8, the 1990 amendments to the CAAct contain a provision that the EPA implement a marketplace program to sell PTCs to control acid rain.

2.6.2.4 Precautionary Approach

"In order to protect the environment, the precautionary approach should be widely applied by States according to their responsibilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation (Principle 15. Rio Declaration on Environment and Development)" [22].*

The preceding words constitute the core of what is called the Precautionary Principle. They are relatively simple words, but loaded with imprecision and chockablock with deliberate ambiguity. Let's take a step back and consider how these simple words of public health significance came to be.

The prevention of disease and disability is at the heart of all public health programs and practice. For environmental health hazards, elimination of a hazard (e.g., elimination of tetraethyl lead in gasoline) or reduced exposure (e.g., lower levels of toxicants released into the environment through remediation of hazardous waste sites) are effective primary prevention policies. These examples of environmental preventive policies also engage the subject of risk assessment, discussed in Chapter 19, and as such raise several essential questions. For example, what is the risk to human health posed by a specific hazard? And how is the risk determined?—and by whom? What is a reasonable time upon which to reduce an environmental hazard to acceptable levels? And is there a better policy to prevent the consequences of environmental hazards than what is currently used by U.S. regulatory agencies?

The preceding questions have been—and continue to be—the subject of serious debate among government agencies, legislative bodies, and vested interest groups (e.g., environmental organizations, business associations). From such debates, over many years, has emerged what is called the Precautionary Principle. According to Kriebel et al. [23], "The

precautionary principle has arisen because of the perception that the pace of efforts to combat problems such as climate change, ecosystem degradation, and resource depletion is too slow and that environmental and health problems continue to grow more rapidly than society's ability to identify and correct them." In other words, the command and control regulatory approach would be unnecessary in some circumstances if a precautionary approach were operative, since some environmental hazards would be interdicted prior to the need for regulatory action. Also, because it can be readily related to the public health core tenet of disease and disability prevention, the Precautionary Principle has found favor with public health and environmental groups. The following sections will review its history, elements, policy issues, and policy position of the U.S. Government.

2.6.2.4.1 History

The origin of what is called the Precautionary Principle is a matter of some disagreement. Many North Americans seem to link it as only a product of the Rio Conference on the Environment, convened by the UN Environment Programme in 1992 in Rio de Janeiro, Brazil, as elaborated in Chapter 5. However, the Precautionary Principle has earlier roots in Europe, the date of origin being a subject of some historical disagreement. Let's examine three somewhat different interpretations of the principle's origin.

The origin of the Precautionary Principle, according to Sand [24], was in Scandinavia circa 1970, in particular, the Swedish Environment Protection Act of 1969. According to him, this law was the first to translate the Precautionary Principle into a general legal rule. The act introduced the concept of "environmentally hazardous activities" and reversed the burden of proof required of Swedish regulatory authorities. More specifically, the mere, but not remote, risk presented by a hazard could trigger action by authorities; they did not have to demonstrate the certainty that an impact would occur. Precautionary action, not retrospective correction, was the gist of the Swedish Environmental Protection Act, an act still in effect in Sweden. Sand [24] also describes the spread of Precautionary Principle legislation into Denmark, Norway, and East European countries during the 1970s.

Another source states, "The precautionary principle emerged during the 1970s in the former West Germany at a time of social democratic planning" [25]. They observed that at the core of early concepts of precaution was the belief that the state should seek to avoid environmental damage through careful forward planning. The German government used the Precautionary Principle in the 1980s to justify policies that addressed acid rain, global warming, and pollution of the North Sea. However, in order not to put German industry at a disadvantage because of the government's adoption of the Precautionary Principle, Germany pressed the EU throughout the 1980s to adopt a similar principle. In 1993, precaution was adopted by the EU as a principle of the Union's environmental policy [25].

A third source, the EEA, located in Copenhagen, chose to date the Precautionary Principle's roots to 1896, when the first information emerged about the health hazard of radiation [26]. The agency based its date to the time when what is now called the Precautionary Principle could have been applied—in their belief, to prevention of exposure to radiation. The same agency produced an informative report *Late Lessons from Early Warning*, which is about "[t]he gathering of information on the hazards of human economic activities and its use in taking action to better protect both the environment and the health of the species and ecosystems that are dependent on it, and then living with the consequences" [26]. The report is based on 14 case studies that were selected by the EEA for their known environmental and human health impacts (Table 2.2). Each case study was conducted by scientists considered as experts in their respective subjects. Authors of each case study were asked "[t]o identify the dates of early warnings, to analyse how this information was used, and to describe the resulting costs, benefits and lessons for the future." The primary findings from the asbestos case study will suffice to illustrate how the case studies in the report were developed.

The case study of asbestos [27] can be summarized by the quotation made in 1931 by Thomas Legge and which begins their article, "[L]ooking back in the light of present knowledge, it is impossible not to feel that opportunities for discovery and prevention of asbestos disease were badly missed." Legge was the ex-chief of England's Medical Inspector of Factories. Asbestos is a naturally occurring mineral that was widely used for various industrial purposes, but primarily for its heat insulation properties. Inhalation of asbestos fibers is the main cause of asbestosis,* a lung disease caused by inhalation of asbestos fibers, and mesothelioma, an aggressive, almost always fatal, type of lung cancer. Workplace exposure to asbestos, in Europe alone, is expected to cause 400,000 cases of mesothelioma [27]. The authors of the case study found that the earliest reports of asbestos as a workplace hazard occurred in 1898, when reported by an inspector of factories in England, who was concerned about the crystalline properties of inhaled asbestos dust.

TABLE 2.2
Alphabetized List of Case Studies Evaluated by the EEA

Antimicrobials	Hormones
Asbestos	Mad Cow disease
Benzene	MTBE
DES	PCBs
Fisheries	Radiation
Great Lakes pollution	Sulfur Dioxide
Halocarbons	Tributyltin

Source: EEA (European Environmental Agency), Market-based instruments for environmental policy in Europe, technical report No. 8/2005. Publications of the European Communities, Luxembourg, 2005.

* "Breathing high levels of asbestos fibers for a long time may result in scar-like tissue in the lungs and its lining (pleural membrane) that surrounds the lung. This condition is called asbestosis" [28].

In 1897 came the first British report of lung disease (what would now be called asbestosis) attributed to inhaled asbestos dust in a worker. These lung disease findings were brought to the attention of the British government in 1906, but no action was taken. Additional articles published in the medical literature during the 1920s and 1930s described asbestosis in asbestos workers. In 1931, these findings led to the first asbestos dust control regulations in Great Britain, although they were widely ignored [27]. Both France and the EU banned the use of all forms of asbestos in 1998–1999. In the U.S., using authorities in the U.S. Toxic Substances Control Act (TSCAct) §5, the EPA banned all new uses of asbestos in 1989; uses before 1989 are still allowed. Subsequent EPA regulations required school systems to inspect for asbestos and to eliminate or reduce the exposure by removal or containment in place. Asbestos released into air and water are regulated under the CAAct and CWAct, respectively [28].

The EEA asbestos case study identified several reasons why prevention actions were not implemented, even in the presence of considerable medical data. Economic interests were a significant weight used against taking a precautionary approach toward asbestos. Asbestos was a valuable commercial product through the middle of the twentieth century in the industrialized countries. Asbestos companies paid local and other taxes and employed large number of workers, actions that helped boost local economies. However, costs did not include the eventual health costs associated with health care for asbestos victims. Another reason for not taking a precautionary approach in the early decades of the twentieth century included the unprofessional involvement of some company physicians, who presented data and reports to government agencies, denying any asbestos health problems in their companies' workers.

The 14 case studies in the EEA's report led to 12 general conclusions about implementing a precautionary approach to controlling environmental hazards (Table 2.3). Several of the recommendations address the need to have an adequate scientific basis upon which to predicate precautionary actions. Two lessons, numbers 10 and 12, merit further comment because of their policy implications.

Concerning Lesson 10, maintaining regulatory independence from economic and political vested interests is consistent with similar advice from the U.S. National Research Council in 1982 [29]. They strongly recommended that federal government agencies keep risk assessment separate from risk management; whereas the former should be based on scientific data and judgment, the latter necessarily involves economic and societal considerations. Keeping this separation intact within U.S. regulatory agencies has become a difficult policy, owing in part to involvement of vested interest groups during the preparation of specific risk assessments. This involvement occurs during public comment periods for a proposed risk assessment and from political lobbying of agency and legislative staffs.

Concerning EEA Lesson 12, preventing "paralysis by analysis" has become a sad reality for U.S. regulatory agencies, for which risk assessments may now require several years, particularly for high profile hazards. An example will suffice. The EPA, as of December 2015, has spent 24 years in its reassessment of the health risk of dioxin. One reason for the delay in completing EPA's update assessment was what weight to give to a body of basic science about cellular mechanisms of dioxin toxicity. Using this basic science as a means to predict dioxin's carcinogenicity, rather than relying on experimental evidence, was a precedent, which became the focus of controversy between vested interest groups—industry supporting, environmental groups opposing. This debate about the role of basic science in risk assessment helped contribute to a paralysis in the reassessment analysis of dioxin's risk.

TABLE 2.3
Lessons Learned from EEA Case Studies

1. Respond to ignorance as well as uncertainty.
2. Research and monitor for "early warnings."
3. Search out and address "blind spots" and gaps in scientific knowledge.
4. Identify and reduce interdisciplinary obstacles to learning.
5. Ensure that real world conditions are fully accounted for.
6. Systematically scrutinize and justify the claimed "pros" and "cons."
7. Evaluate alternatives and promote robust, diverse, and adaptable solutions.
8. Use "lay" and local knowledge as well as all relevant specialist experience.
9. Take account of wider social interests and values.
10. Maintain regulatory independence from economic and political special interests.
11. Identify and reduce institutional obstacles to learning and action.
12. Avoid paralysis by analysis.

Source: EEA (European Environmental Agency), Late lessons from early warnings: The precautionary principle 1896–2000, Office for Official Publications of the European Communities, Luxembourg, 2001.

2.6.2.4.2 International Charters

Regardless of how one interprets the history of the Precautionary Principle, it has been adopted as policy in several regional charters, although its definition varies between charters, and additional operational guidelines await. Applegate [30] notes the Precautionary Principle's presence in several international treaties and charters, including the 1993 charter of the EU, the 1991 Bamako Convention on Hazardous Waste in Africa, the 1992 Convention on Biological Diversity, the 1992 United Nations Framework Convention on Climate Change (UNFCC), the Treaty on European Union in 1992, the Cartagena Protocol on Biosafety in 2000, and the 2001 Stockholm Convention on Persistent Organic Pollutants (Chapter 5). Illustrative of the language found in these charters is wording in the Cartagena Protocol on Biosafety, "[I]n accordance with the precautionary approach contained in Principal 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms

resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements" [31]. This body of global charters is important because eventually the precautionary approach will be implemented through rules, regulations, and practices that flow from the treaties and charters.

Referring to the UNEP definition of the Precautionary Principle, placed at the beginning of this section, of note is the appearance of the words *cost-effective*. They are important words; they can be used to frustrate, or make more difficult, precautionary actions. For example, how is cost to be calculated? And who determines what is effective? The words *cost-effective* derive from actions attributable to the U.S. government. The words first appeared in Article 7 of the Second World Climate Conference in 1990 at the insistence of the U.S. and were later added to the Rio Declaration text (Chapter 6), but over the objections of the EU and Japan [24]. The U.S. government's position of cost-effectiveness is consistent with Congressional actions that have mandated cost–benefit analyses of federal regulatory proposals and other environmental health policies. Nevertheless, insistence on cost-effectiveness as a component of the Precautionary Principle seems to make it more difficult to operationalize the Principle.

Notwithstanding the introduction of the Precautionary Principle into regional and international charters and conventions, it was the 1992 Rio Declaration of the United Nations Conference on Environment and Development that elevated attention and created a greater awareness of the principle in North and South American countries. The Rio Conference is significant because it was the first international environmental conference attended by heads of state, rather than representatives of ministerial or equivalent levels of national governments. President George H.W. Bush led the U.S. delegation.

2.6.2.4.3 Elements of the Precautionary Principle

As Applegate [30] observes, "Despite its wide acceptance as a foundation of international environmental law, the precise meaning of the Precautionary Principle remains surprisingly elusive. It has been defined variously over the last two or three decades in international legal instruments and by commentators, and the overall concept admits of varying degrees of environmental protection." Consistent with the diverse interpretations of the Precautionary Principle is the absence of consensus agreement on its elements. One source [30] identified the four elements listed in Table 2.4, with actions associated with each element, but questions arise when trying to apply the elements to a specific environmental hazard. For example, when considering the trigger element, how does *serious damage* differ from *irreversible damage*, which is what the Precautionary Principle asserts? Moreover, what are the criteria for determining serious harm? As to timing, just how much of a scientific basis needs to exist before eliciting a prevention response? Again, are there criteria to determine the adequacy of key scientific findings? These are the kinds of questions that government agencies are debating when trying to make the Precautionary Principle operational, i.e., when trying to convert general policy into specific practices.

2.6.2.4.4 Environmentalists' Version of the Precautionary Principle

The precautionary approach has gained widespread, indeed, global favor with environmentalists, grassroots environmental organizations, and European governments. As previously noted, these and other organizations perceive that risk assessment-based, regulatory approaches are now bound up with delay and inaction. Acting upon these concerns, on January 23–25, 1998, 35 academic scientists, grassroots environmentalists, government researchers, and labor representatives from the U.S., Canada, and Europe met to discuss ways to formalize their version of the Precautionary Principle [32].

TABLE 2.4
Elements of the Precautionary Principle

Element	Action
Trigger	Potential serious or irreversible harm
Timing	Anticipatory action before causation can be scientifically identified
Response	Total avoidance
	Measures to minimize or mitigate harm
	Cost-effective regulatory measures
	Study alternatives, with an eye to prevention
Regulatory strategies	Bans and phase-outs
	Environmental effects assessment
	Pollution prevention
	Reversed burden of proof
	Polluter pays

Source: Jordan, A. and T. O'Riordan, The precautionary principle in contemporary environmental policy and politics, *Protecting Public Health and the Environment*, ed. C. Raffensperger and J. Tickner, 15, Island Press, Washington, DC, 1999.

The meeting was held at the Wingspread Conference Center, Racine, Wisconsin, and has become known as the Wingspread Precautionary Principle, stating, "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically" [23]. Although similar in theme to the Rio version of the Precautionary Principle, note that the words *cost-effective* are missing in the Wingspread version. One assumes that deletion of these words was deliberate and for the purpose of removing a perceived impediment in applications of the Wingspread version of the Precautionary Principle.

As an aid to operationalizing the Precautionary Principle, the Wingspread's participants defined four components: preventative action should be taken in advance of scientific proof of causality; the proponent of an activity, rather than the public, should bear the burden of proof of safety; a reasonable range of alternatives, including a no-action alternative, should be considered when there may be evidence of harm caused by an activity; and for decision-making to be precautionary, it must be open, informed, and democratic and must include potentially affected parties [32].

The Wingspread interpretation of the Precautionary Approach, as defined by its four components, has gained the interest of sustainable agriculture advocates, who have used it in the state of Washington to protest the use of hazardous waste in the manufacture of fertilizers and in the response to the federal government's organic agriculture rule [32].

2.6.2.4.5 Position of the U.S. Federal Government

There is strong support from environmentalists and public health groups for the U.S. government to adopt the Precautionary Principle as matter of environmental health policy. In the supporters' opinion, required use of the Precautionary Principle would lead to prevention of more environmental health hazards because regulatory agencies could act more expeditiously than what is currently the case. Counterbalancing that support is opposition from the U.S. business community, who fear possible adverse economic consequences from adoption of the Precautionary Principle. These consequences are asserted to include more stringent environmental standards, greater numbers of banned or otherwise regulated commercial products, and possible greater product litigation.

It is unlikely that the U.S. will anytime soon take a position in support of adopting the Precautionary Principle as government policy.

In response to those who support, or oppose, the U.S. government's adoption of the Precautionary Principle as policy, no official position has been taken. The EPA, which would be the U.S. agency most impacted by the Precautionary Principle as environmental policy, has never developed a position paper on it, stating that the time "[i]s not ripe for such a paper given the lack of a U.S. government position" [33].

It is unlikely that the U.S. will anytime soon take a position in support of adopting the Precautionary Principle as government policy. This assertion is based on practical considerations. First, a large body of U.S. law exists for the purpose of controlling environmental hazards. These laws have generally adopted the proposition that a substance is "safe" until proven otherwise. Contaminants are permitted, through emissions regulations, to be released into the environment, using risk assessment and risk management methods, to achieve safe environmental health conditions. As a matter of practicality, this body of environmental law, accompanying regulations, and court decisions is not likely to be significantly revised anytime soon. Second, the regulated community in the U.S. is generally opposed to adoption of the Precautionary Principle as government policy. There are too many uncertainties in how the Principle would be implemented in ways that could impact them.

2.6.2.4.6 Position of the European Union

The EU (Chapter 5) has adopted the Precautionary Principle as policy. This is not surprising, given its origins in Sweden and Germany. Moreover, the slow adoption in Europe of quantitative risk assessment, in contrast to the U.S., created something of a void in how to prevent adverse public health and environmental consequences of environmental hazards. In 2000, the European Commission, which is the administrative arm of the EU, published precautionary principle guidelines for the EU's Member States [34]. The guidelines include the following:

- The precautionary principle should be considered within a structured approach to the analysis of risk, which comprises three elements: risk assessment, risk management, and risk communication. The precautionary principle is particularly relevant to the management of risk.
- "Where action is deemed necessary, measures based on the precautionary principle should be, *inter alia*: proportional to the chosen level of protection, nondiscriminatory in their application, consistent with similar measures already taken, based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis), subject to review; in the light of new scientific data, and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment" [34].

These guidelines make clear that the EU has adopted the Precautionary Principle as policy and is working on ways to implement it. Similar guidelines and policy adoption do not exist in the U.S., since the federal government has taken no official position on the Precautionary Principle.

Adoption by the EU of the Precautionary Principle as policy has already had public health and economic consequences. An example of the former is found in an EU proposed program of chemical testing. In October 2003, the European Commission adopted legislation for a new EU regulatory framework for

chemicals [35]. Called the Registration, Evaluation and Authorisation of Chemicals (REACH) framework [36], the proposal would require the chemical industry to test tens of thousands of chemicals that are used—or proposed for use—in the EU and for which toxicity data are lacking. The Precautionary Principle was the driving force behind REACH, which has been vigorously opposed by the U.S. Government [37], asserting that the TSCAct (Chapter 11) is adequate for testing chemicals that reach the U.S. The global chemical industry also opposes REACH, primarily because of the high cost of conducting toxicity tests. As environmental health policy, better toxicological databases of substances already in commerce will help make better regulatory decisions and provide improved programs of public health.

In November 2005, the European Parliament approved a modified version of REACH. The amended REACH program reduced the overall number of chemicals that would be required for testing by chemical producers. Having entered into force in 2007, REACH provisions are being phased-in over a period of 11 years [38].

An example of the economic impact of the EU's Precautionary Principle comes from its use to protect European trade interests. As related by Goldstein and Carruth [39], the European Community used the Precautionary Principle to justify a more stringent EU aflatoxin standard, one lower than that recommended by the UN's Food and Agriculture Organization (FAO) and many other countries. The lower EU standard has been used to block the importation of aflatoxin-containing goods (e.g., peanuts) from African countries, thereby protecting farmers in EU Member States in southern Europe.

In summary, the Precautionary Principle, depending on how it is made operational, could serve as an alternative to the Command and Control policy by its use to forego a risk assessment-based policy that has become litigious and time consuming. A challenge in the adoption of a precautionary approach would be to avoid its becoming another form of command and control.

2.6.3 Public Education

As another alternative to the Command and Control policy, an informed public can make a significant difference in reducing the effects of exposure to environmental hazards. For example, informed individuals can choose to purchase green products and services, patronize companies and business enterprises that have evidenced environmental contributions, and advocate for the importance of nurturing environmental health policies. Acting on the basis of environmental information is activism in practice. But how does an individual acquire such information? And from whom?

National environmental organizations such as the Sierra Club, Natural Resources Defense Council, Environmental Defense, and Physicians for Social Responsibility have effectuated public education policies. These and similar organizations provide scientific documents, news alerts, and policy recommendations of relevance to environmental health policies and practices. Because environmental organizations have achieved considerable credibility with the U.S. public, their public education actions and products have great political and personal impacts. Much of these organizations' educational materials are now made accessible on the Internet and via social media.

An informed public can make a significant difference in reducing the effects of exposure to environmental hazards.

Many government agencies and academic institutions have also adopted public education policies. Environmental health information can be found on the Internet through the use of any Worldwide Web browser. For example, the Agency for Toxic Substances and Disease Registry, the EPA, and the National Institute of Environmental Health Sciences are federal government agencies that make environmental health information available to the public. Similarly, many schools of public health, e.g., the Harvard School of Public Health, publish environmental health information on their websites.

Environmental health information from creditable sources can form the foundation for community activist groups upon which to build specific agendas and action plans. As an example, cleanup of uncontrolled hazardous waste is a matter of concern to many community and neighborhood groups. A host of Internet resources can readily be accessed that contain information about the human and ecological effects of exposure to hazardous waste. Armed with such information, community groups can use the PACM model to bring pressure on government agencies, business enterprises, and individuals to adopt beneficial environmental health practices.

A well-known example of a successful public education campaign is the designated driver program promoted by Mothers Against Drunk Driving (MADD). The goal of the campaign is to reduce the number of alcohol intoxicated motor vehicle drivers, thereby reducing car crashes caused by drunk drivers. Designated drivers are persons chosen in advance by persons planning to attend social events where alcohol will be served. By foregoing alcohol consumption, a designated driver can function as a sober provider of transportation for the other members of the group. The designated driver and similar public education efforts are most successful when they include societal responsibilities in their messages. An example is the soundbite, "Friends don't let friends drive drunk," which is a clear, effective, societal admonition that has become social doctrine. Other examples where public education has led to public health benefits include awareness of the adverse health effects of tobacco products, defects in a manufacturer's vehicle tires, and the safety problems caused by some Sport Utility Vehicles that can tip over during vehicle operation.

2.6.4 Sustainable Development

The world's natural resources are not inexhaustible. Consider the loss of soil to erosion, oil lost to humans' on fossil fuels, forests lost to deforestation, fauna and wildlife disappearance

because of human clearing of forests, and fishing of some fish populations to near extinction, amongst other examples. While some natural resources are renewable or can be supplanted by other resources (e.g., use of renewable sources of energy), current and future generations of humankind must consider how natural resources can be preserved and economic and societal development sustained. One source observes that the main driving forces of human consumption of resources are population and economic development [40]. They note that the projected 50% growth in the global population over the next 50 years will put a significant strain on the environment. Further, the EEA observes that if the population of the developing countries achieves levels of material wealth like that in current-day industrialized countries, consumption of resources would increase by a factor ranging from two to five. Is there a policy solution to what appears to be a pending disaster of exhaustion of natural resources?

A policy that responds to the foregoing concerns and is gaining great international support is *sustainable development*. The concept is not new. Humankind has historically used principles of sustainable development upon which to exist. As examples, farmers long ago learned how to annually rotate crops in order to restore soil nutrients in farm fields, and nomadic peoples sustained themselves by domesticating animals, which then provided transportation, meat, milk, clothing, and commerce. A more current example is sustainable forestry, wherein lumber companies replace harvested trees with seedlings, achieving an overall balance of a constant or increased number of harvestable trees.

Sustainable development is "Development which meets the needs of the present without compromising the ability of future generations to meet their own needs" [42].

Humankind's ignorance (or unwillingness to practice) of sustainable development can be illustrated by a few examples. Overfishing of certain fish stocks in the North Atlantic Ocean (e.g., cod) has reduced them to near extinction numbers. Urban sprawl in large cities has led to destruction of local forests, contributing to loss of natural habitat for birds and other beneficial creatures. In industrialized countries, industrial waste was dumped directly into lakes, rivers, and other waterways, sometimes polluting them to the point of extinction of fish, shellfish, mammals, and other creatures. Currently, climate change is the most glaring example of failure to practice sustainable development. This is discussed further in Chapter 6.

Sustainable development as global policy is relatively recent, dating to the 1972 United Nations Conference on the Human Environment, held in Stockholm, Sweden (Chapter 6). The conference was convened for the purpose of developing a global environmental protection policy and for enunciating common principles to preserve and enhance the human environment [41]. While the Stockholm conference was significant for focusing global attention on the interconnections between human development and the environment, it was 15 years before a more precise focus was brought to bear on sustainable development.

In 1987, the World Commission on Environment and Development, chaired by the Prime Minister of Norway, Gro Harlem Bruntland, published the report *Our Common Future* [42], which imprinted sustainable development on the international environmental health agenda. The report is often referred to as the Bruntland Report. It contains the most often quoted definition of *sustainable development*, "Development which meets the needs of the present without compromising the ability of future generations to meet their own needs." This definition can be used equally by governments and private sector entities. Indeed, the latter group may hold the greater promise for making sustainable development a practical reality. Citing three principles will provide an overall sense of the Declaration's thrust:

- Principle 2—The natural resources of the earth, including the air, water, land, flora and fauna and especially representative samples of natural ecosystems, must be safeguarded for the benefit of present and future generations through careful planning or management, as appropriate.
- Principle 5—The nonrenewable resources of the earth must be employed in such a way as to guard against the danger of their future exhaustion and to ensure that benefits from such employment are shared by all mankind.
- Principle 13—In order to achieve a more rational management of resources and thus to improve the environment, States* should adopt an integrated and coordinated approach to their development planning so as to ensure that development is compatible with the need to protect and improve environment for the benefit of their population.

As a global environmental health policy, sustainable development came into full flower at the 1992 UN Conference on Environment and Development, also called the Earth Summit, held in Rio de Janeiro, Brazil, to discuss how to achieve sustainable development. Under the auspices of the UN, the Earth Summit brought together more than 180 countries, represented by heads of state or national leaders. The Rio Declaration on Environment and Development builds upon the sustainable development recommendations in the Bruntland Report. The Rio Summit created agreements and conventions on critical issues such as climate change, deforestation, and desertification. In addition, the parties to the Rio Declaration drafted a broad action plan, *Agenda 21*, as the strategy for dealing with future global environment and development issues. Moreover, *Agenda 21*, which is discussed in Chapter 5, includes commitments to reduce global poverty, promotes women's rights, bans racism, and fosters the welfare of children. These societal commitments are very much in the spirit of sustainable development. As a consequence of the Rio Declaration, regional and sectoral (e.g., business sectors) sustainability plans have been developed. Moreover, a host of

* States refers to Member States of the United Nations.

groups have adopted the concept of sustainable development. These groups include businesses, municipal governments, and international organizations such as the World Bank (Chapter 5). Indeed, the pervasiveness of sustainable development concepts portends a significant impact for better global environmental quality, resource management, and protection of human and ecological health.

As a follow-up to the 1992 Earth Summit, the World Summit on Sustainable Development (WSSD)* was held from August 26 to September 4, 2002 in Johannesburg, South Africa, to elaborate on *Agenda 21*. A primary objective of the summit was to develop concrete steps and identify quantifiable targets for better implementation of *Agenda 21*. Two areas of focus at the summit were alleviation of global poverty and protection of the natural environment and human health. However, as a matter of environmental health policy, having an agenda, stated goals, and targets for global improvement is an important resource for long-range national and international planning. According to the UN [43], areas of commitments from the WSSD Plan of Implementation pertinent to environmental health policy include water and sanitation, energy, health, agriculture, biodiversity, and ecosystem management.

The regular practice of the principles of sustainable development could obviate the need for regulatory control of some environmental hazards.

Given the importance of sustainable development, the United Nations Environment Progamme (UNEP) has actively monitored the world's sustainability of natural resources. In 2016 UNEP released the most comprehensive environmental study ever undertaken by the UN [44]. The study, which involved 1203 scientists, hundreds of scientific institutions, and more than 160 governments brought together by UNEP, concludes that without radical action the level of prosperity that millions of people in the developed world rely on will be impossible to maintain or extend to poorer countries. Degradation of the world's natural resources by humans is rapidly outpacing the planet's ability to absorb the damage, meaning the rate of deterioration is increasing globally, UNEP found the rate of damage to the natural environment was increasing globally, despite concerted efforts to persuade governments to take measures to improve the condition of vital natural resources, such as water, land and the seas.

The UNEP study notes that water scarcity is the scourge of some of the poorest regions on Earth, leaving developing countries increasingly unable to feed themselves, and causing hardship for millions of people. Water sources are under increasing threat from population growth, climate change, rapid urbanization, rising levels of consumption, and the degradation of lands that previously provided a natural replenishment of water resources. According to the UN, there appears little prospect of this dire situation being remedied without radical action being taken.

The UN has continued as a global institution to articulate concerns, policies, and actions pertaining to global sustainable development. Mindful of increased global human population, anthropogenic impacts on availability of natural resources, and portent of climate change, on September 25, 2015 the UN General Assembly adopted Resolution 70/1: Transforming Our World: The 2030 Agenda for Sustainable Development. Quoting from this resolution:

"*Preamble*: This Agenda is a plan of action for people, planet and prosperity. It also seeks to strengthen universal peace in larger freedom. We recognize that eradicating poverty in all its forms and dimensions, including extreme poverty, is the greatest global challenge and an indispensable requirement for sustainable development.

All countries and all stakeholders, acting in collaborative partnership, will implement this plan. We are resolved to free the human race from the tyranny of poverty and want and to heal and secure our planet. We are determined to take the bold and transformative steps which are urgently needed to shift the world on to a sustainable and resilient path. As we embark on this collective journey, we pledge that no one will be left behind.

The 17 Sustainable Development Goals and 169 targets […] demonstrate the scale and ambition of this new universal Agenda. They seek to build on the Millennium Development Goals and complete what they did not achieve. They seek to realize the human rights of all and to achieve gender equality and the empowerment of all women and girls. They are integrated and indivisible and balance the three dimensions of sustainable development: the economic, social and environmental.

The Goals and targets will stimulate action over the next 15 years in areas of critical importance for humanity and the planet.

People: We are determined to end poverty and hunger, in all their forms and dimensions, and to ensure that all human beings can fulfil their potential in dignity and equality and in a healthy environment.

Planet: We are determined to protect the planet from degradation, including through sustainable consumption and production, sustainably managing its natural resources and taking urgent action on climate change, so that it can support the needs of the present and future generations.

Prosperity: We are determined to ensure that all human beings can enjoy prosperous and fulfilling lives and that economic, social and technological progress occurs in harmony with nature.

Peace: We are determined to foster peaceful, just and inclusive societies which are free from fear and violence. There can be no sustainable development without peace and no peace without sustainable development.

Partnership: We are determined to mobilize the means required to implement this Agenda through a revitalized Global Partnership for Sustainable Development,

* See Chapter 5 for more details on the Rio and Johannesburg environment summits.

> based on a spirit of strengthened global solidarity, focused in particular on the needs of the poorest and most vulnerable and with the participation of all countries, all stakeholders and all people.

The interlinkages and integrated nature of the Sustainable Development Goals are of crucial importance in ensuring that the purpose of the new Agenda is realized. If we realize our ambitions across the full extent of the Agenda, the lives of all will be profoundly improved and our world will be transformed for the better" [45]. The cited reference provides specific goals and targets that comprise the Agenda.

In September 2015, the UN and its 193 member states embraced the organization's Sustainable Development Goals, which is a global agenda to fix climate change, stop hunger, end poverty, and extend health, and access to jobs, and more—all by 2030. The goals comprise 17 separate items and 169 detailed "targets" within them. The idea of measuring and aiming for economic, social, and environmental goals simultaneously constitutes a kind of triple bottom line. In 2016 a German foundation ranked the countries of the world based on where they stand at the outset of trying to achieve these goals over the next decade and a half.

Based on the data available, the report found that Scandinavian countries (Sweden, Denmark, Norway, and Finland) were the highest ranked. For example, Sweden was already 84.5% of the way to the best possible outcome across the 17 Sustainable Development Goals. The U.S., in contrast, ranked 25th, worse than Canada, which ranked 13th [46].

In summary, regular practice of the principles of sustainable development could obviate the need for regulatory control of some environmental hazards, e.g., over use of pesticides and herbicides in agricultural and other uses. Problems that do not occur do not require command and control response. Moreover, sustainable development focuses on improving the quality of life for all the Earth's peoples, without using natural resources beyond the capacity of the environment to supply them indefinitely. As policy, sustainable development can be practiced without resorting to legislation and regulations, although some governments, particularly in Europe, have incorporated sustainable development into legal frameworks. However, a UN study has reported that human reliance on natural resources is outstripping the planet's ability to replace them.

2.6.5 Voluntary Action by Private Sector Entities

Corporations and other businesses can adopt voluntary actions to eliminate environmental hazards in workplaces, communities, and homes. Voluntary actions are those not mandated by government agencies. A policy of Voluntary Action can reap benefits to business enterprises such as increased income, better community relations, and less litigation, depending, of course, on the nature of the voluntary action. As an example, in the fall of 2005 the Dannon Company announced that they would forego placing plastic overcaps on each container of yogurt, as had been their practice for many years, saving about 3.6 million pounds of plastic annually [47]. The result will lessen the amount of plastic that enters the waste stream, thereby lessening the volume of waste in sanitary landfills. As another example, producers of chemical stain repellants are redesigning their products to make them less hazardous to consumers and the environment. Stain repellants, used to ease the cleaning of carpets and clothing, are long-chain flurosurfactants, which can metabolize to a toxic compound. Replacement with shorter chain surfactants leads to a lesser hazard [48].

Other examples of Voluntary Action policies include a manufacturing plant's voluntarily decreasing the amounts of pollution released into the community environment beyond the levels permitted by environmental emission standards, e.g., clean water discharge standards. Sometimes, voluntary actions to reduce emissions are in response to public awareness of Toxics Release Inventory (TRI)* data required of a plant or facility. While reporting certain levels of emissions to the EPA under the TRI regulations is mandatory, reducing the amounts of emissions beyond air and water quality standards is voluntary. Some companies have exerted extra effort to decrease their TRI emissions in order to improve their community image, an outcome called by some as "regulation by shaming" [12]. In 2005, EPA reported that TRI data showed that the amount of toxic substances released into the U.S. environment had declined 42% between the years 1999 and 2003 [49]. If emissions released into the environment are thought of as waste, and as such, an indicator of inefficient production, decreased emissions can have a positive economic benefit to a company.

Voluntary action can result from litigation by an individual or group against a company or other business enterprise. In effect, a single episode of a litigated environmental hazard's impact can result in a much broader prevention effort. Take the example of scalding hot coffee formerly sold by a fast food company. In one instance, a customer who purchased a cup of coffee placed it between her knees while driving a car. The coffee spilled onto her skin, causing severe burns. Later, a jury awarded the customer $2.7 million (later reduced by an appellate court to $470,000) for her medical costs and damages. While the customer's wisdom in how the coffee cup was held could be questioned, the fact remains that the beverage's temperature was quite high, and as such, was an environmental hazard. Subsequent to the litigation's outcome, the fast food company voluntarily lowered the temperature of coffee served to millions of customers. This act of primary prevention (i.e., elimination of a hazard) extended worldwide, owing to the thousands of food service establishments operated by the company. In effect, one person's injury was multiplied into a public health benefit for millions of people.

2.6.6 Policy Cornucopia

The previous sections have described seven kinds of policies that have evolved in the U.S. and Europe for purpose

* As discussed in Chapter 12, under the provisions of the Emergency Planning and Community Right-to-Know Act of 1986, which is Title III of the Comprehensive Environmental Response, Compensation, and Liability Act (a.k.a. Superfund), releases of certain hazardous substances must be reported annually to EPA.

of controlling environmental hazards. Of the seven policies, only one, Command and Control, bears the force of law. The other six policies require voluntary action by interested individuals and groups. The voluntary polices have emerged over time as means to replace or supplement existing policies perceived to have failed or otherwise been ineffective in controlling specific environmental hazards. To be more specific, many environmentalists and public health officials have become frustrated with the often painfully slow process that now comes with establishing government regulations and standards. To wit, new standards (e.g., water quality) are routinely challenged by vested interest groups through protracted litigation and political pressure on legislative bodies. The rejected OSHA ergonomics standard is such an example, as previously discussed.

It is doubtful that Command and Control will, or should, be replaced as the anchor policy in controlling environmental hazards. Without the weight of law to control environmental hazards, it is highly improbable that sources of pollution would be abated voluntarily in amounts sufficient to make a real difference in environmental quality. Further, regulatory frameworks "level the playing field" by treating all sources of pollution the same. That is to say, water and air quality standards apply equally to contaminants released by big corporations or by small businesses. Without regulations and standards, based on statutes, industrialized countries would become no different from developing countries, where pollution controls are largely nonexistent.

However, as history has shown, promulgating workplace and community environmental regulations has become increasingly challenging to regulatory agencies. The regulated community generally has the economic and political wherewithal to block or alter proposed or adopted environmental regulations. Moreover, the regulatory apparatus has become thoroughly political, as illustrated by Congress's repeal of the OSHA ergonomics standard. Given the difficulty of establishing regulations and standards, reliance on voluntary policies, e.g., Sustainable Development, Green Commerce and Market Power, will increase in importance.

2.7 POLICY AS A MEANS TO EFFECT PUBLIC HEALTH

The prevention of disease and disability is the essence and focus of public health. Prevention modes of action are sometimes grouped into three categories: primary, secondary, and tertiary [50]. The boundaries between these modes are sometimes unclear, nor is it important that they always be distinct. Elimination or reduction of conditions that cause adverse health effects in humans is called *primary prevention*. For example, some local health departments use larvicides* to kill mosquitoes that carry West Nile virus, thereby preventing human contact with the virus. *Secondary prevention* refers to the use of education, protective equipment, relocation away from a hazard, or other means to avoid contact with a hazard.

* Larvicides are agents that prevent mosquito larvae from maturing [51].

TABLE 2.5
Examples of Policies Linked to Disease Prevention

Type of Prevention	Action
Primary	Environmental statutes
	Regulations and standards (R&S)
	Alternatives to R&S
Secondary	Right to know
	Public education
	Medical education

For example, educational materials presented and discussed with residents of older houses where lead-based paint could exist, constituting a health hazard to young children, would be an act of secondary prevention. Removal of the paint would be primary prevention. *Tertiary prevention* relates to health care and consists of the measures available to reduce impairments and disabilities and minimize suffering caused by existing departures from good health (adapted from [50]). For example, health care that reduces the suffering in children exposed to quite large amounts of lead could be considered as tertiary prevention.

Given the foregoing discussion, do environmental health policies relate to public health programs of disease and disability prevention? One can assert that such policies, in fact, do constitute elements of public health disease prevention. Some examples of environmental health policies linked to primary and secondary prevention measures are shown in Table 2.5. Consider the primary prevention examples. Many environmental statutes, e.g., the federal CAAct, contain provisions to control the levels of pollutants that can cause adverse health effects in humans. This statutory policy of pollution control comports with a strategy of primary prevention of disease, i.e., a reduction or elimination of a hazard. A similar line of reasoning would apply to the other primary prevention examples in Table 2.5.

Regarding the secondary prevention examples shown in Table 2.5, each example pertains to some facet of education. For instance, consider the right-to-know policy. Individuals in the U.S. can now usually obtain environmental information of relevance to their personal health. Persons can now access databases on the Internet such as EPA's Toxics Release Inventory and thereby obtain information about pollution sources within their community. This information can then be used to make personal decisions such as whether to relocate from the community or create advocacy groups to lower community pollution emissions.

2.8 ENVIRONMENTAL ETHICS

Is it ethical to pollute the environment? If so, under what conditions? And if it isn't, under what framework of ethical principles? What are the environmental ethics of national economies that are based on tenets of consumerism? What are the ethical dimensions of national and international policies about the environment? On an individual basis, is it immoral

to purchase consumer products that are not "environmentally benign" or, better, "environmentally friendly?" These are examples of serious and societally consequential questions that are being given increasing attention by ethicists who are turning their attention to environmental concerns under the rubric of environmental ethics, also called ecoethics. As an example, in Chapter 18 environmental justice is presented as a matter of environmental ethics and morality.

2.8.1 Ecoethics

Before turning to what constitutes environmental ethics, it is useful to clarify terms. Even though the words *ethics*, *values*, and *morals* are often used interchangeably (and sometimes appropriately so), there are important practical differences in the words' meanings. "*Ethics* traditionally refers to the systematic framework of thought and analysis that deals with questions of right and wrong and the nature of the good and proper life" [52]. An ethical act is an action that is consistent within an ethical framework. *Values* refers more to a quality considered inherently worthwhile or desirable. *Morals* generally refers to that natural working out of a personally affirmed ethical or value system. Morals become the conscious and visible basis for personal conduct and action. Morality therefore is concerned more with how a person acts than with the system that provides the framework for action [52]. How are these concepts of ethics, values, and morality integrated into what is called *environmental ethics*, or *ecoethics*?

According to Timmenman [53], "Many people date the rise of 'environmental ethics' as an academic discipline from a famous 1967 article in the journal *Science* by the U.S. historian of medieval science, Lynn White, Jr. In his article White accused some aspects of Christianity of fostering an attitude toward nature as an object for exploitation and manipulation. This debate illuminated a number of hidden assumptions in medieval and modern history about the images of the human and the natural." From this debate came agreement that *Environmental ethics* is concerned with the framework in which humankind relates to the natural environment. Although the intellectual underpinning of environmental ethics was provided by philosophers—ecoethics is now considered a subdiscipline in ethics—these concepts have had some influence on policymakers in developing the laws and policies that pertain to the environment.

Ecoethics forces us to confront why we do things and the consequences of our actions on the environment. If one accepts the proposition that industrial, agricultural, consumer, and personal practices have resulted in degradation of the environment and caused adverse effects on human and ecological health, then what accounts for the degraded state of environmental affairs in which we find ourselves? Lutzenberger [54] posits that an understanding of this question requires an examination of the basic philosophy of modern civilization. He asserts we do what we do because of the dogmas, premises, and postulates on which national and global economic activities are based. In particular, philosophical and religious thinking that has not integrated ecological concepts into their framework is seen by some as a major reason for current environmental problems that include deforestation, waste mismanagement, ozone depletion, and global warming.

Environmental ethics attempts to look at the world in a holistic view and through a different point of view, one that builds around a framework of the planet as an entity that must be shared by all human and natural occupants. In 1975, James Lovelock, a British atmospheric chemist, and Lynn Margulis, a U.S. microbiologist, proposed that Earth be viewed as one enormous, complex ecosystem, which they called Gaia, after the Greek goddess of the Earth, and that humans constitute cells in a tissue of this supraorganism [55, 52]. This has become known as the Gaia hypothesis—Earth as a single, self-regulating organism—and has developed a very large following, especially within the activist and "deep ecology" segments of the environmental movement. (The Norwegian philosopher Arne Naess in the 1970s separated ecology into two divisions: "shallow" and "deep." In his scheme, shallow ecology advocates a continuation of current environmental and political paths with only certain revisions to modem lifestyles and ways of life. Deep ecology advocates deep and fundamental changes in human relationships with nature) [52]. Regardless of this controversy, it seems important to retain the essence of the Gaia hypothesis: Earth is a complex ecosystem and we as humans are but members of this system. We must function within the ecosystem and understand our relationships within it in ways that will sustain it.

2.8.2 Ethics of Organizations

Organizations such as government agencies, corporations, and environmental groups, like individuals, are expected by society to act ethically, i.e., to do "the right thing." Laws and regulations are a formal, external means to express society's ethical expectations. For example, organizations that commit fraud are held accountable under applicable law. However, organizations' internal ethics are equally important as those imposed by external sources.

Internal ethics could include, for illustration of environmental issues, a commitment to protect the environment. From such an ethic could flow specific environmental policies, such as prohibition of environmental injustices, how waste is managed, support for employees' carpooling, purchasing of environmentally benign products, and support of actions to mitigate climate change. Internal ethics must have the support of an organization's leaders, ideally originating with them, and be facilitated by rank-and-file employees.

2.8.3 Ethics of Individuals

No person lives without impacting the ecosystem. In fact, the very act of life adds carbon dioxide and other bodily wastes to the environment. Ecoethics stresses the importance of a healthy and healthful environment that is capable of sustaining its quality. How we choose to protect the environment and minimize each person's ecological impact is a matter of individual choice. It is advisable to base one's personal ecoethics

on a principle drawn from a framework of ethical conduct. Principles adhered to can serve as a long-standing basis for personal ethical conduct. In the case of personal ecoethics, principles such as sustainable development and the precautionary principle can serve as platforms for an individual's ecoethical behavior.

Shown in Table 2.6 are examples of a personal ecoethical framework. The framework used to construct the table is based on the practice of sustainable development, i.e., using only those resources in amounts that can be renewed and thereby reducing an individual's ecological footprint. Consider the example of water conservation. It is an ethical act to help preserve water supplies, given contemporary global demands on water supplies because of such factors as increased human populations and climate change. Examples of ways to conserve water in everyday life could include reducing the amount of water used for showering and bathing, planting of plants that require less water for survival, and recycling of "gray water" (i.e., household water collected from showers, sinks, and laundries) that can be minimally treated by municipal water systems and used for specified purposes, e.g., irrigation of crops and lawns.

Individuals evolve their own set of ethics, based on circumstances that include family experiences, religiosity, education, peer pressure, and societal expectations. Like organizations, individuals who violate ethics expressed in law run the risk of facing legal retribution. But beyond the ethics imposed on individuals by society, there are the ethics that persons can choose for themselves, including those that pertain to the environment and human health. For instance, an individual can choose to live a life of environmentally nurturing ethics. Under such an ethical mode could follow personal policies such as purchasing green consumer products, conserving water usage, recycling household waste, lobbying local authorities for environmental protections, and becoming a member of groups that advocate environmental protection.

TABLE 2.6
Some Examples of Personal Ecoethics

Ethic	Illustrative action
Air quality support	Use public transportation; utilize vehicles with low emissions; do not use tobacco and other personal products of combustion
Biodiversity support	Support policies and actions that protect threatened or endangered species
Energy conservation	Drive energy-efficient vehicles; shut down energy use whenever possible; rely on renewable energy when available; avoid use of resources that emit greenhouse gases
Social support	Support conservation organizations; express environmental opinions to elected officials
Waste minimization	Recycle paper, paper products, and other recyclables; reuse household products; minimize food waste
Water conservation	Reduce volume of water used in bathing, showering, toilets, and lawn care

2.9 SUMMARY

An overview of the steps inherent in making environmental health policy was presented in this chapter. As described, many factors can influence the development and implementation of environmental policies, such as the public's concerns, vested interest advocacy, newsmedia reports, experts' inputs, and other influences. Policymakers need to know of, and respond to, these influences because they can have a powerful impact on the details of an environmental health policy. For example, vested interest groups have traditionally had a powerful effect on environmental legislation and subsequent regulations and standards. Such groups have exerted their influence through lobbying of members of legislative bodies. A simplified model, called the pressure-action-change-monitoring model, was presented as a way to understand the rudiments of environmental policymaking.

Controlling environmental hazards is the ultimate purpose of environmental legislation. The policy of command and control is characteristic of many environmental statutes. However, other policies have emerged that can supplement command and control. These alternatives include the Precautionary Principle, sustainable development, Green Commerce, and others discussed in the chapter. As presented, the Precautionary Principle has been viewed by some critics of the command and control policy as a preferable alternative. In particular, some public health groups and environmental advocates have contended that risk assessment, which undergirds many regulatory policies in the U.S., takes too long to complete and has too many uncertainties in its development. However, there is a long experience with the use of risk assessment in the U.S., which makes it uncertain if it will be replaced anytime soon, if at all.

Knowing the essence of making environmental health policy now opens the door to a description of the structure of the U.S. federal government, the major U.S. player in establishing environmental health policy, followed in later chapters by descriptions of the major federal environmental statutes and their public health implications.

2.10 POLICY QUESTIONS

1. Using the PACM model shown in Figure 2.2, discuss how an environmental activist group or an individual would organize a campaign in your county to recycle household trash. Be specific.
2. Apply the strategy of critical thinking discussed in Chapter 1 to a discussion of free trade policies as to the benefits and adverse effects on environmental health.
3. Discuss how the Precautionary Principle comports with the public health strategy of disease and disability prevention. Be specific.
4. Assume that federal, state, and local governments have no statutes or ordinances in place to control environmental noise sources. Further, assume that you are the leader of a grassroots environmental

group. Choose any four of the seven elements in Figure 2.1 and discuss them in terms of advocating for a community ordinance that your group proposes for noise control.

5. Discuss how you as an individual can promote the ideals of sustainable development. Include in your discussion those personal behaviors that would contribute to global sustainable development.
6. Describe how you can use Market Power to achieve environmental protection goals. How would your actions contribute to public health?
7. What are the differences between ethics and morals? Develop your own list of personal ecoethics, using Table 2.6 as a guide.
8. Using elimination of tobacco smoking in public places as environmental policy, discuss how primary, secondary, and tertiary prevention programs could be used in support of the policy.
9. Visit your local health department's website. Describe their environmental health programs and how they affect you. Be specific.
10. Select a "green" product or service that you use and describe how its use benefits you personally and your community in general.
11. By using Internet resources, review the current mission and role of the U.S. Surgeon General. What in your opinion are the two most significant responsibilities of the Surgeon General? In your opinion, should the Surgeon General have additional responsibilities for protecting the U.S. public's health? If so, name two additional responsibilities. If not, why not?
12. Peer review of technical literature was defined in this chapter. Should government regulatory programs rely only on peer-reviewed science to develop regulations? What about peer-reviewed science that was not published in science journals open to the public? Give examples.
13. Some alternatives to the command and control method of enforcement of government regulations were described in this chapter. Select the one alternative that you deem most effective for local policymaking purposes. Justify your selection.
14. Under provisions of the federal Clean Air Act, the EPA has authority to regulate outdoor ambient air levels of ozone. Describe the "regulated community" impacted by the EPA's ozone regulation.
15. What role should social media play in shaping local environmental health policymaking? Provide an example of a desirable local environmental policy for which you and others might attempt to influence via social media.
16. Of the influences on policymaking illustrated in Figure 2.1, select the one you consider the most important and in an essay of appropriate depth provide justification for your selection.
17. The precautionary principle was described in this chapter. In your opinion, should this principle be adopted by federal regulatory agencies? If so, why? If not, why? Present your argument in an essay of appropriate depth.
18. In your opinion, should all U.S. trade agreements with other countries require conditions of sustainable development? In an essay of appropriate depth, present the basis for your recommendation for or against such language in trade agreements.
19. In your opinion, should public health departments promote sustainable development policies? If so, why? If not, why? Be specific and provide support for your opinion.
20. Well done! You have completed your review of this chapter. Discuss in an essay of appropriate depth the most important information you learned. Be sure to describe why the information is important to you.

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3 U.S. Federal Government's Environmental Health Structure

3.1 INTRODUCTION

Chapters 1 and 2 described the fundamentals of public health and environmental policy, and presented the rudiments of environmental health policymaking. Both the chapters alluded to the U.S. federal government as a significant force in setting U.S. environmental health policy. In fact, since the 1960s, the U.S. federal government has been the big fish in the environmental health pool. The next chapter will describe the specific federal statutes that undergird much of U.S. environmental health policy. As preparation, this chapter lays out the federal government's environmental health structure, that is, a description of the federal agencies that have environmental health programs. In particular, attention is given to the establishment of the Environmental Protection Agency (EPA) and how its environmental health mandate evolved from the former responsibilities of the U.S. Public Health Service (PHS). Also described in this chapter is a summary of the structure of the U.S. government and the environmental health responsibilities of the PHS, EPA, and other federal departments and agencies. Because many federal laws require the development of regulations and standards for control of environmental hazards, the chapter concludes with a summary of the federal rulemaking process. To have an appreciation of the federal structure requires some understanding of the three branches of the U.S. government, which commences this chapter.

3.2 U.S. CIVICS 101

One way to set environmental health policy is to enact laws, which in turn contain operational policies and purposes. For example, the federal National Environmental Policy Act (NEPAct), as discussed in Chapter 4, contains the policy of individuals' responsibility to the environment, "[e]ach person should enjoy a healthful environment and that each person has a responsibility to contribute to the preservation and enhancement of the environment." Similarly, laws enacted by states and ordinances by counties and municipalities can contain, or be interpreted as containing, environmental health policies. States' environmental laws often emulate federal laws on corresponding environmental hazards, e.g., hazardous waste management. An example of a local environmental health policy is the application by county health departments of using larvacides to control mosquito infestation. Because of the importance of legislated environmental policies—since they bear the weight of law—it is important to have some understanding of the basic elements of government; particularly the U.S. federal government since federal environmental laws constitute much of the U.S. environmental framework.

One source defines government as "The set of legal and political institutions that regulate the relationships among members of a society and between the society and outsiders. These institutions have the authority to make decisions for the society on policies affecting the maintenance of order and the achievement of certain societal goals" [1]. There are several types of government worldwide, depending on such considerations as the nature of the ruling class, the kind of political institutions, the distribution of power, nature of national economy, and historical antecedents. Recognized types of government include monarchy, constitutional government, representative democracy, theocracies, and dictatorship. The two forms of representative democratic government are the parliamentary and the presidential. In the parliamentary form, political power is vested in an elected parliament (an elected legislative body similar to the U.S. House of Representatives), where the prime minister is the leader of government and must be a member of parliament, along with members of his or her cabinet. This type of government is found in Australia, Canada, Great Britain, India, and Israel. The presidential form of democratic government exists where voters elect a chief executive who is independent of the legislature, but whose responsibilities and actions are defined by constitutional authorities. Countries with presidential governments include France, Mexico, Russia, and the U.S.

How a society determines how their government distributes political power and authorities with other governments is another important classification. There are three generally accepted forms of government power sharing: federal systems, unitary states, and confederations [1]. Federal systems, or *federalism*, is structured around a strong central (i.e., federal) government, with specified authorities retained by lower levels of government, such as states and local governments. Government in the U.S. is an example of federalism. In *unitary states*, the national government performs all the governmental functions, but with subnational governmental units responsible for limited authorities within their jurisdictions. France is a country with unitary government, where strong central control is exercised over territorial administrative subdivisions of the country. *Confederations* are the weakest method of government power sharing. In such a system of government, a central government has rather limited authority over its confederate states. Member states within a confederation retain their sovereignty, delegating only limited authorities to the central government. In a sense, it is a kind of

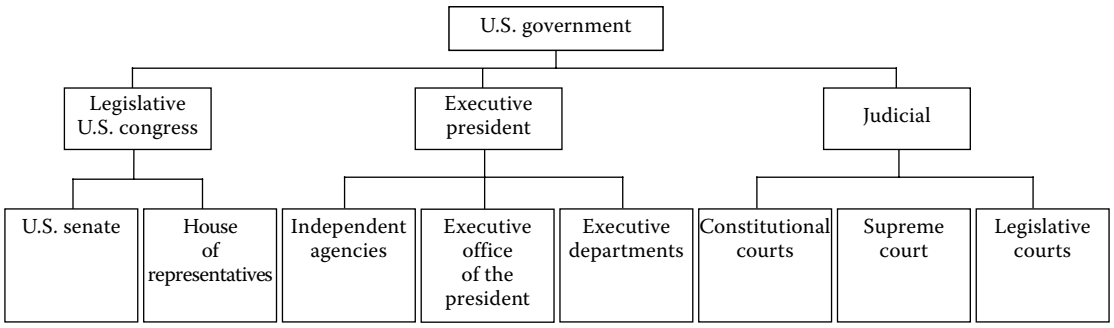

FIGURE 3.1 Core structure of U.S. federal government.

government by handshake. As an example, following the collapse of the Union of Soviet Socialist Republics (USSR), the Confederation of Independent States was formed, consisting of many of the member states of the former USSR.

The core structure of the U.S. federal government is shown in Figure 3.1. It derives from the U.S. Constitution. Of prime importance is the observation that the three primary branches are on the same organizational plane; that is, they are of equal rank and importance. This arrangement ensures a "check and balance" relationship among the three branches. In theory, there is supposed to be no "first among equals," but in reality, the legislative branch, which can enact legislation, appropriate monies to the executive and judicial branches, and override Presidential vetoes of legislation, holds sway over more policymaking power than the other two branches. Moreover, the legislative branch is the only branch authorized by the U.S. Constitution to: impose taxes on the public, raise funds, and provide monies to both the executive and judicial branches; and declare war. In addition, the Senate approves executive-level Presidential appointments (e.g., secretaries of executive-rank departments, federal judges, ambassadors).

The following comments about the structure of the U.S. government are based on the authorities specified in the U.S. Constitution and illustrated with regard to setting environmental health policy. Moreover, much of what follows also applies to the structure of U.S. state government—and to a lesser extent—county and city governments.

3.2.1 Constitutional Basis of the U.S. Federal Government

The U.S. government's environmental health statutes and the public health practices discussed in Chapters 6 through 12 rest upon a foundation of government. That is, legislative bodies must enact statutes for the purpose of controlling environmental hazards. Executive branches of government are tasked with implementing the statutes enacted by legislative bodies. And the judiciary (i.e., the courts) must decide specific points of law when statutory authorities are disputed by parties affected by those authorities. In the U.S., environmental health policy should be viewed not as a broth, but as a thick chowder. There are lots of policy ingredients in the chowder, with many cooks and seasoners.

Environmental policymaking in the U.S. is heavily reliant on governmental action at all levels: federal, state, and local. The federal government's regulation of environmental hazards and other matters is an activity that requires the efforts of all three branches of government. Moreover, because of the importance of regulatory approaches for protecting human health and environmental quality, some details of the U.S. regulatory process are in order. The federal government now serves the primacy role in environmental policymaking. It is important therefore to understand how the federal government is structured, based upon the U.S. Constitution, which defines the powers of each of the three branches of federal government. The following section provides a summary of the purpose and organization of the three branches of the U.S. federal government.

3.2.1.1 Legislative Branch

Article I, §1, of the U.S. Constitution states, "All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives." The framers of the U.S. Constitution were influenced by the two-body structure of the English Parliament: House of Commons and House of Lords. Moreover, in the U.S. Congress, to enact legislation requires that a particular bill (Senate) or resolution (House) be agreed to by both bodies. To be more specific, consider the legislative process that would be required to enact legislation to control an environmental hazard, e.g., outdoor ambient noise. First, pressure would be brought by public interest groups (e.g., environmental organizations such as the Sierra Club) on specific Members of Congress to take action, specifically, to support legislation that would reduce ambient noise levels.

If sufficient interest results from the pressure, public hearings would be held by congressional committees and various vested interest groups, expert groups, and government officials would present written and oral testimonies. Such hearings must be held within the rules of the House and the Senate. More specifically, standing committees and their subcommittees would convene the hearings. The usual sequence is to hold subcommittee hearings, which can lead to the subcommittee's preparation of a draft bill or resolution, which in turn, would be passed to the subcommittee's parent committee. Bills passed by committees are then taken

by the committee's chairperson to the floor of the House or Senate for vote. This assumes that House or Senate leaders are willing to schedule the committee's bill for floor action. Bills passed by both the House and Senate but differing in content are referred to a conference committee that comprises members from each responsible committee. Conference committees typically produce compromise bills that are then referred back to the appropriate committees. Both houses of Congress then vote on the compromise bill, either passing or defeating it. When enacted, the bill becomes an act and sent to the President for approval or rejection. The U.S. Constitution requires that the President must act within 10 days. If signed by the President, the act becomes public law. If rejected (i.e., vetoed by the President), Congress can override the veto if two-thirds of each body of Congress votes in the affirmative. If the President fails to sign the bill within the prescribed 10 days, it becomes law without his/her signature if Congress is in session. Public laws are "codified," i.e., combined into the numbering system for federal statutes known as the U.S. Code, which can be accessed on the Internet.

Legislation enacted by Congress contains language that mandates the Executive Branch to undertake specified actions. For example, the EPA and the Food and Drug Administration (FDA) are authorized in the Food Quality Protection Act of 1996 (FQPAct) to implement changes in how pesticides are registered in the U.S. and authorizes changes in risk assessment procedures in order to give greater protection to children exposed to pesticides (Chapter 11). *Authorizing legislation* such as the FQPAct must also contain language that authorizes the appropriation by Congress of public funds that can be used by a federal department or agency in support of its legislative mandates. *Appropriations legislation* authorizes specific amounts of public monies in the U.S. Treasury to be used by the executive branch in the conduct of authorized programs. Congressional appropriations committees are responsible for developing appropriations legislation, commencing with their consideration of the President's annual budget request to Congress.

3.2.1.2 Executive Branch

Article II, §1, of the U.S. Constitution states, "The executive Power shall be vested in a President of the United States of America." The executive branch, headed by the President of the United States, implements legislation enacted by Congress and signed into law by the President, or laws enacted by Congress through override of presidential vetoes. This agenda is accomplished by the various components of the executive branch (Figure 3.1). The primary components of the executive branch are the 15 executive departments (also called the cabinet-rank departments), which are listed in Table 3.1. One can glean from the table that the number and purpose of cabinet departments grew as the U.S. population and social policies increased. Also accountable to the President are independent agencies that are not part of any executive department. Such agencies include, among others, EPA, the National Aeronautics and Space Administration (NASA), Federal Communications Commission (FCC), National Science Foundation (NSF), and the Federal Emergency Management Agency (FEMA).

TABLE 3.1
Current Cabinet Rank Departments of the Executive Branch, U.S. Government, and Year of Establishment

Agriculture	1862
Commerce	1903
Defense (originally War Department)	1949
Education	1980
Energy	1977
Health and Human Services (née Health, Education and Welfare)	1953
Homeland Security	2002
Housing and Urban Development	1965
Interior	1849
Justice	1870
Labor	1913
State	1789
Transportation	1966
Treasury	1789
Veterans Affairs	1989

The third component of the executive branch is the Executive Office of the President, which has the responsibility for various offices, councils, and commissions that have been established by Congressional act or presidential appointment. These include, among others, the Office of Management and Budget (OMB), Council of Economic Advisers, National Security Council, and Office of Science and Technology Policy.

A means to establish federal policy on environmental health and other matters is afforded to the President through issuance of executive orders, which are directives to the executive branch for purpose of achieving a particular action and policy. Executive orders are important because they have direct impact on not only the federal executive branch, but indirectly, the public. Two examples of executive orders that have had influence on environmental health policy are illustrated by (1) an environmental justice directive and (2) energy policies for government facilities and operations. In the former, President Bill Clinton directed in 1994 that all federal agencies develop and implement plans to prevent the unjust imposition of environmental hazards (e.g., location of polluting industries) on minority populations. In the latter example, President George W. Bush issued an executive order in 2001 that directs all federal agencies to reduce energy consumption by specified amounts.

Concerning environmental health policy, the executive branch must implement Congressional legislation that has been signed into law by the President or passed into law through Congress's override of a Presidential veto. Using the example of the Food Quality Protection Act of 1996, the statute, upon its signature into law by President Clinton, directed EPA, the Department of Health and Human Services (DHHS), and the Department of Agriculture (USDA) to revise specific policies and procedures bearing on the review and approval of pesticides and their potential impact on children. Upon receipt of such directives, affected departments and agencies must interpret the language in the new statute. Some legislation is deliberately written in vague terms, a product of failure

by Congressional committees to negotiate more specific language. In such conditions, the executive branch must attempt its own interpretation of Congressional intent. Ultimately, the judicial branch is often required to interpret legislative intent and executive branch implementation. This occurs when concerned vested interests litigate a federal department or agency, forcing courts to bridge the language in statutes and agencies' interpretation and implementation of the same language.

3.2.1.3 Judicial Branch

Article III, §1, of the U.S. Constitution states, "The Judicial Power of the United States, shall be vested in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish. The Judges, both of the supreme and inferior Courts, shall hold their Offices during good Behaviour, and shall, at stated Times, receive for their Services, a Compensation, which shall not be diminished during their Continuance in Office." The courts established under the powers granted by the Constitution are known as *constitutional courts*. Judges of these courts, who are appointed by the President, with the advice and consent of the U.S. Senate, are appointed for life. The constitutional courts consist of the Supreme Court, federal district courts, and the federal courts of appeal. The federal courts' jurisdiction, which is defined in the Constitution, covers litigation in which the U.S. government is a party, to controversies between the states, to disputes between a state, or its citizens, and foreign governments or their subjects, and to controversies between the citizens of one state and citizens of another state.

The Supreme Court is the highest appellate constitutional court in the U.S. and, as such, is the final judicial arbiter of federal constitutional questions and of the scope of federal laws. The court consists of nine justices, one of whom serves as the chief justice, who has overall administrative responsibility for the court. Other federal courts, derived from powers held to be implied in articles of the U.S. Constitution, are called *legislative courts*. These are courts created in law by the U.S. Congress and serve within the judicial branch's authorities and power. Legislative courts comprise the Claims Courts, the Court of International Trade, the Tax Court, and the territorial courts established in federally administered territories of the U.S. (e.g., Guam).

Federal courts have had a profound effect on interpreting environmental health policies. Because particular environmental laws [e.g., the Clean Air Act (CAAct)] require the federal government to regulate specific environmental toxicants, controversies can arise that become the fodder for litigation. Disputes arise over how a government agency (e.g., EPA) interpreted its authorities in law, or over specific regulatory decisions (e.g., a national ambient air quality standard), or questions of fairness in a regulation (e.g., environmental justice issues). Federal courts have concurred with specific environmental policies, thrown out some policies or practices, or referred some litigation back to lower courts for further review and action. In some situations, the affected federal agency (e.g., FDA) will be required by a federal court to take some alternate path to regulating an environmental hazard.

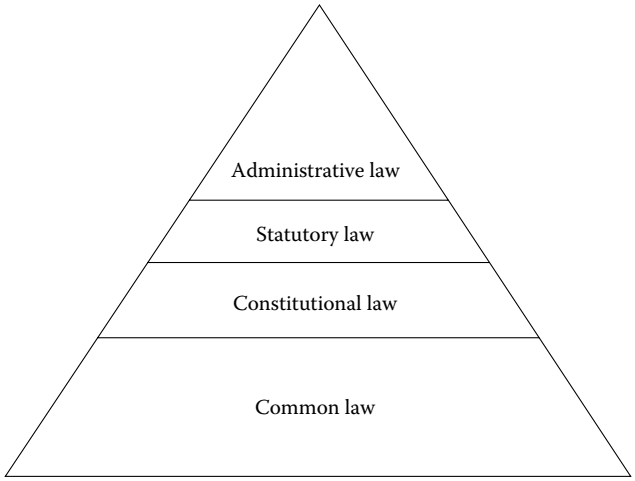

FIGURE 3.2 Levels of U.S. law. (Data from Wikipedia, History of the common law, http://en.wikipedia.org/wiki/Common_law, 2004; LII (Legal Information Institute), Constitutional law: An overview, http://www.secure.law.cornell.edu/topics/constitutional.html, 2004; Essortment, What is the statutory law? http://ar.essortment.com/whatisstatutor_rita.htm, 2004; LII (Legal Information Institute), Administrative agencies: An overview, http://www.secure.law.cornell.edu/topics/administrative.html, 2004.)

The U.S. judicial system has further evolved from just what is specified in the U.S. Constitution. Shown in Figure 3.2 are the four general layers of U.S. law [2–5]. As shown in the figure, each layer of law builds upon the layer below it. More specifically:

Common law—Common law developed under the adversarial system that emerged in eleventh and twelfth century England in order to meet the legal needs of the times [2]. Common law was adopted by the English monarchies as the means to make law common, or uniform, across the country. Common law was devised as a means of compensating persons for wrongful acts perpetrated against them. As a onetime colony of England, common law became a component of what became U.S. law. Common law applies in all U.S. states, except Louisiana, whose basis of law has French origin, not English.

Constitutional law—This kind of law deals with the interpretation and implementation of the U.S. Constitution [3]. As such, it is concerned with issues between the states, issues between the federal government and the states, issues between the three branches of the U.S. government, and the rights of individuals in regard to rights specified in the Constitution.

Statutory law—Statutes are defined as laws that are passed by the U.S. Congress, the various state legislatures and also includes enacted local ordinances [4]. Local ordinances are statutes passed by a county or city government to cover areas not covered by federal or state laws. Statutes form the basis for statutory law. Examples of statutes covered by statutory law include the federal CAAct and the Food, Drug and Cosmetic Act (FDCAct).

Administrative law—This area of law encompasses laws and legal principles governing the administration and regulation of federal and state government agencies. The affected agencies are delegated power by a legislative body to act as agents for the executive branch of government [5]. Generally,

administrative agencies are created to protect a public interest in distinction to protecting the rights of individuals. The Federal Administrative Procedures Act, which stipulates how federal government agencies must conduct their operations when effectuating the actions specified in federal statutes is an example of administrative law. Environmental health policies can be subject to each of the four layers of U.S. law. For instance, common law may apply to the civil litigation of a person claiming harm from exposure to substances released from a landfill. Corporations may be litigated under statutory law, specifically the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLAct), for failure to comply with that law's provisions for cleaning up uncontrolled hazardous waste sites. Constitutional law has been applied in some cases to question the constitutionality of some environmental statutes, e.g., provisions of the CAAct. Administrative law has often been applied when parties allege that federal environmental regulations were developed without compliance with the Administrative Procedures Act. It is important to understand the distinctions among the four levels of U.S. law and how each might apply to a specific environmental issue.

3.3 ORIGINS OF U.S. PHS AND EPA

Having discussed in Chapter 1 the fundamentals of environmental health policy, we turn our attention to the roles of the U.S. federal government in establishing and implementing environmental health policies and programs. It is a story commencing in the early years of the twentieth century about ascendancy of federal public health authorities on matters of environmental hazards, gradual loss of primacy by PHS, and succeeded in the late 1960s by federal and state environmental agencies established within the federal and state governments. As noted by one source, "The driving force behind United States environmental law and regulation is the clear and explicit intent of the government to protect human health and the environment. [M]ost environmental laws [e]stablish environmental standards at levels that protect human health. [T]hese regulatory requirements provide the health professional with an extensive database [f]rom which preventive or responsive health practices can be developed" [6]. However, in the opinion of some public health specialists, this approach has resulted in an organizational dichotomy that has handicapped both environmental agencies and their public health counterparts in the U.S., Canada, and some other countries.

The current environmental health dichotomy within the U.S. federal government will be discussed in this chapter. However, as prelude, the creation of EPA, postured by Congress to protect natural resources and human health through full regulatory authority, coexists with individual agencies of the DHHS that conduct research on environmental hazards but have limited regulatory authority. This arrangement has resulted in the creation of federal and state environmental protection agencies that possess public health responsibilities, but without sufficient depth in public health staff and practice. To complete the handicapped dichotomy, health agencies that conduct research on environmental hazards and offer services to states and the public often do so with too few staff with environmental experience, access to environmental databases, and insufficient practice in environmental science.

Beginning in the late nineteenth century, and continuing through the first half of the twentieth century, the U.S. federal government gradually became involved with protecting the public against environmental hazards, principally through congressional authorizations of authorities and resources. The existence of the PHS, created by Congress in 1796, provided a ready-made federal government structure to receive new Congressional environmental health mandates. However, many of the federal government's efforts in controlling environmental hazards did not begin until the 1960s and afterwards.

In an analysis done in 1991, the Congressional Research Service (CRS) identified 13 federal statutes that comprised the major portion of the legal basis for programs administered by EPA [7]. They are listed in italics in Table 3.2, with the date of initial enactment of the statute or its antecedent and a brief statement of each statute's purpose. For the purposes of this book, to the CRS list have been added other relevant environmental health statutes, each of which is discussed in subsequent sections of this book.

Several federal statutes have attendant regulations developed by EPA or other *regulatory agencies*, which are federal and state agencies that are authorized by specific statutes to develop, promulgate, and enforce regulations. Regulations are enforceable under the laws that mandate them. The reader is cautioned that the statutes cited in Table 3.2 are complex and their implementation by federal agencies is subject to change, because amendments to statutes occasionally occur and regulations change because of court decisions, agency updates, and legislative action. For instance, Congress enacted legislation in 1988 that gave itself the authority to review federal government regulations. Hence, caution should be exercised to ensure any contemplated action is consistent with current regulations and amendments to statutes. Consultation with the responsible federal, state, or local authority is advisable on any matter of regulatory compliance.

Of the various policy issues attending federal environmental statutes, none is more important to the public than the right-to-know requirements that are now found in several federal environmental laws. Right-to-know requires EPA and other federal agencies to make environmental hazards information available to the public. Environmental advocacy and community groups have used this information to pressure government and industry to take action to improve environmental quality. In other words, right-to-know policies have contributed to improved public awareness and better informed democratic processes. As examples, the Occupational Safety and Health Act of 1980 led the Occupational Safety and Health Administration (OSHA) to develop regulations that require private industry employers to make workplace safety and health information available to workers. The Emergency Planning and Community Right-to-Know Act, which was enacted as Title III of the CERCLAct, includes the Toxics Release Inventory (TRI) (Chapter 12). The TRI requires

TABLE 3.2
Titles and Summaries of Major U.S. Federal Environmental Health Statutes

Clean Air Act requires EPA to set mobile sources limits, ambient air quality standards, emission standards, standards for new sources, air quality deterioration requirements, and focus on areas that do not attain standards (1955)

Comprehensive Environmental Response, Compensation, and Liability Act (or Superfund), establishes a fee-maintained fund to remediate abandoned hazardous waste sites (1980)

Consumer Product Safety Act created the Consumer Product Safety Commission to protect against injuries from select consumer products (1972)

Emergency Planning and Community Right-to-Know Act. Title III of Superfund Act (1986)

Endangered Species Act gives strong protections to native species and established a federal listing system of officially "Threatened" and "Endangered" species (1973)

Energy Policy Act exempted hydraulic fracturing (fracking) in gas exploration from any underground injection control provisions related to the Safe Drinking Water Act (SDWA) (2005)

Environmental Research, Development, and Demonstration Authorization Act provides authority for EPA research programs (1976)

Family Smoking Prevention and Tobacco Control Act gave FDA sweeping new authorities to regulate the manufacture, marketing, and distribution of tobacco products (2009)

FDA Food Modernization Act is a comprehensive food safety statute, with prevention of illness as the operative policy (2011)

Federal Insecticide, Fungicide, and Rodenticide Act governs the sale and use of pesticide products (1947)

Federal Meat Inspection Act governs the production and use of meat and meat products (1906)

Federal Water Pollution Control Act (known as the Clean Water Act) established sewage treatment construction grant programs, and a regulatory and enforcement program for discharges into U.S. waters (1948)

Food Quality Protection Act amends the Food, Drug, and Cosmetic Act to provide a risk-based standard for pesticide residues in raw and processed foods and amends FIFRA (1996)

Food, Drug, and Cosmetic Act governs the production and use of food additives, prescription drugs, and cosmetics (1906)

Global Food Security Act requires the President to develop and implement a global food security strategy to promote global food security, resilience, and nutrition (2016)

Information Quality Act requires federal agencies to develop guidelines for determining the quality of scientific data used in decision-making (2001)

Lautenberg Chemical Safety for the 21st Century Act rewrites TSCA to require EPA to restrict the use of any chemical that the agency finds to present an unreasonable risk (2016)

Marine Mammal Protection Act is the first Congressional act to call specifically for an ecosystem approach to natural resource management and conservation, prohibiting the harassing, catching and killing of marine mammals by U.S. citizens or within the jurisdiction of the U.S. (1972)

National Environmental Policy Act established U.S. environmental policy and requires federal agencies to assess the environmental impact of major federal actions (1969)

National Noise Control Act gave EPA the primary role in controlling noise in the general environment (1972)

Occupational Safety and Health Act requires the Department of Labor to develop and enforce workplace standards (1970)

Ocean Dumping Act regulates the intentional disposing of materials into ocean waters and establishes research on effects of, and alternatives to, ocean disposal (1972)

Oil Pollution Act expands oil spill prevention, preparedness, and response capabilities of the federal government and industry (1990)

Pandemic and All Hazards Preparedness Act (2006)

Pollution Prevention Act (PPA) seeks to prevent pollution through reduced generation of pollutants at their point of origin (1990)

Public Health Cigarette Smoking Act of 1969 required package warning label, "Warning: The Surgeon General Has Determined that Cigarette Smoking Is Dangerous to Your Health;" prohibited cigarette advertising on television and radio (1969)

Public Health Security and Bioterrorism Preparedness and Response Act provides for planning, preparedness, and response to bioterrorism (2002)

Resource Conservation and Recovery Act provides cradle-to-grave regulation of solid and hazardous waste (1965)

Safe Drinking Water Act established primary drinking water standards, regulates underground injection practices, and establishes a groundwater control program (1974)

Solid Waste Disposal Act. Title II of Clean Air Act of 1965, now generally referred to as the Resource Conservation and Recovery Act (1965)

Toxic Substances Control Act regulates the testing of chemicals and their use in commerce (1976)

businesses to report to EPA their emissions of hazardous substances, which the agency must then make available to the public.* Amendments in 1996 to the Safe Drinking Water Act require water suppliers to state the nature and levels of contaminants in drinking water. The Food Quality Protection Act of 1996 required federal agencies to provide families with information about pesticide levels in raw and processed food. Other policies of significance to public health practice are discussed throughout this chapter.

3.3.1 Emergence of the U.S. Public Health Service

The role of the U.S. federal government in matters of public health dates from the late eighteenth century, the early days of the republic. As a young nation, the sea was a vital source of food, commerce, and security. Regarding commerce,

* As described in Chapter 12, the Pollution Prevention Act of 1990 requires companies and businesses to also report data on recycling of wastes and provide other information on pollution prevention plans and actions.

mariners were essential to the nation's increasing prosperity. Ships transported goods and cargo between ports in North America and Europe. In these post-revolutionary years, mariners traveled widely, often became sick while at sea, and infrequently could find health care in port cities. Since they all came from the new states or former colonies, and could become burdens to port cities, the health of mariners became a problem for the nascent federal government. In response, in 1798, Congress established a loose network of marine hospitals, mainly in port cities to care for sick and disabled mariners. The hospitals comprised what was called the *Marine Hospital Service* (MHS) [8]. Funds to pay physicians and build hospitals were appropriated by Congress by taxing mariners 20 cents a month, collected by seaport customs officers, then paid into the federal treasury. The tax was abolished in 1884, succeeded until 1906 by a tonnage tax on vessels entering U.S. ports. From 1906 to 1981, when they were closed, the hospitals were funded out of general federal revenues.

In 1870, Congress reorganized the MHS into a centrally controlled national agency with its own administrative staff, directed by a Supervising Surgeon, with headquarters in Washington, DC, and assigned to the Department of Treasury [8]. Dr. John Maynard Woodstock was the first Supervising Surgeon of the MHS and is therefore considered as the first Surgeon General of what became the Public Health Service (PHS). In 1876, the title was changed to Supervising Surgeon General of the MHS. The impetus for the reorganization of the MHS was the need for better accountability and improved medical services in what had been a loosely administered set of locally operated marine hospitals [9]. Later, in 1889, a Commissioned Corps of medical officers was created by Congress, an action that provided the MHS with a cadre of professional, mobile officers who could be quickly assigned to disparate geographic areas in times of medical emergencies.

A key event in the history of U.S. public health occurred in 1887 when the MHS created a small bacteriology laboratory, called the Hygienic Laboratory, at the marine hospital on Staten Island, New York. It was later relocated to Washington, DC. From this quite modest resource later sprang the National Institutes of Health, the world's premier biomedical research institution [9].

In 1902, Congress enacted legislation that expanded the scientific work of the Hygienic Laboratory and appropriated a budget specific to the work of the laboratory. The act also changed the name of the *Marine Health Service* to the *Public Health and Marine Hospital Service* (PHMHS), directed by a Surgeon General of the Service. The change in name presaged further changes in the nation's emerging federal public health resources, changes that focused less on marine hospital services and more on biomedical research and containment of disease epidemics.

The Public Health Service Act (PHSAct) changed the name of the PHMHS to the *Public Health Service* (PHS), directed by a Surgeon General, and again broadened its responsibilities by authorizing investigations into human diseases (e.g., tuberculosis, malaria, and leprosy), sanitation, water supplies, and sewage disposal [8]. This act provided the first policy framework for federal research and services in public health, moving the nation's health needs past just those needed by mariners. This state of affairs lasted for approximately 30 years.

Cincinnati, Ohio, has held a special place in the development of PHS environmental health programs. The prominence of this city can be linked to the Ohio River steamboat trade in the mid- to late-nineteenth century. Cincinnati was a busy port during this period, a place where merchandise, farm products, livestock, and industrial goods were shipped and received on steamboats and barges [10]. All this occurred during a period of major growth in the city's economy and population. About the latter, Cincinnati became the home of large numbers of German immigrants. The social and political impacts of the German migration was immediate and lasts even today. German social traditions of medical education, clinical services, public assistance, and support for cultural institutions were adopted by the city.

Cincinnati became the first port along the Ohio and Mississippi rivers to establish a medical service for steamboat crews. It seems that steamboats brought more than just goods and cargo to ports; their crews also brought sexually transmitted diseases, infectious agents, and vermin. The mariners' hospital quarantined disease-bearing crewmen, provided medical care, and generally tried to improve the health of both the city and that of individual crew members. The Cincinnati hospital was, in effect, an early occupational medicine facility of nineteenth century origin.

Beginning in the late 1950s, the PHS radiological health, water quality, air pollution, and occupational health research programs were conducted primarily in Cincinnati, Ohio. This location was attributable to several factors. One factor was the presence of the University of Cincinnati, which was home to an environmental health center and a radiological health program. Both university resources helped stimulate PHS programs in radiation protection, occupational health, and toxicology. Another factor was the construction of the Robert A. Taft Sanitary Engineering Center, which succeeded the Stream Investigation Station, which had been established under authorities in the PHSAct [9]. Although many of the former PHS programs and laboratories in Cincinnati were later moved to laboratories in North Carolina and Nevada, there remain major National Institute for Occupational Safety and Health (NIOSH) and EPA laboratories in Cincinnati.

3.3.2 Department of Health, Education, and Welfare and DHHS

In 1942, some members of Congress perceived the need to further develop the PHS. There were two primary motivations for the Congressional interest. First, the winds of war were beginning to stir in Europe, and the U.S. needed to have its public health capacity readied in case of war. Second, the Franklin D. Roosevelt administration desired a stronger, more active, PHS as part of the President's New Deal legacy [11]. The New Deal was the name for President Franklin D. Roosevelt's programs to combat the effects of the Great Depression, which devastated the global economy. The U.S. stock market collapsed in 1929, reverberating in loss of jobs for millions of U.S. workers.

At the depth of the depression, between 10 and 15 million people in the U.S. were unemployed, which was about 25% of the available workforce [12,13]. Roosevelt's New Deal programs of 1933 through 1935 created jobs through public works projects, home loans, and grants to individuals. Included in the New Deal were programs to stabilize and improve agriculture, business, and employment. New Deal policies and programs were unique in that the federal government assumed a primary social role in creating jobs and regulating private sector institutions in ways not previously experienced.

Real consolidation of the PHS began in June 1939, when it was transferred by President Roosevelt from the Department of Treasury to the newly formed Federal Security Agency (FSA), which combined a number of New Deal government agencies and services related to health, education, and welfare. All the laws affecting the functions of the services were also consolidated for the first time in the Public Health Services Act of 1944 [8].

The FSA was a noncabinet-level agency whose programs had grown to such size and scope that President Eisenhower as head of the executive branch submitted a reorganization plan in 1953 to Congress that called for the dissolution of the FSA and the transfer of its responsibilities to a newly created Department of Health, Education, and Welfare (DHEW). A major objective of this reorganization was to ensure that the important post-World War II programs of health, education, and social security be represented in the President's Cabinet. In 1979, DHEW's education tasks were transferred to the new Department of Education and the remaining divisions of DHEW, including the PHS, were reorganized as the Department of Health and Human Services (DHHS), which currently has administrative responsibility for several environmental health agencies and their programs, as will be described in subsequent sections of this chapter.

The DHHS currently comprises offices and operating divisions;* several of the latter have responsibilities for environmental health programs that represent a mix of research, services, and some narrow regulatory authorities. These programs are discussed in subsequent sections of this chapter.

3.3.3 Role of PHS Surgeons General

Two Surgeons General, Drs. Thomas Parran and Leroy Burney, were key leaders in shaping nascent federal environmental health programs.

The federal government's current environmental protection and environmental health programs have evolved over many years. Originally, the programs were the sole responsibility of the PHS. The Surgeon General of the PHS was the director of the early environmental health programs. These programs began in the early part of the twentieth century, undertaken by various Surgeons Generals.

The PHS is headed by the Surgeon General of the PHS, more commonly referred to as the Surgeon General, the title best known to the U.S. public. Actually, other components of the federal government, e.g., the U.S. Air Force, also have Surgeons General. Over time, the duties and authorities of the Surgeon General have changed. During the nineteenth century and up through the mid-twentieth century, the Surgeon General had strong, independent authorities and resources to bring to bear on preventing cholera, tuberculosis, polio, and other epidemics.

However, the Surgeon General's authorities over public health programs began to change in the mid-twentieth century. Less and less authority for programs of public health was vested in the Surgeon General, gradually transitioning to a position of "bully pulpit,†" that is, a position of advisor to the President on matters of public health and communicator to the public on health issues. During the twenty-first century the position of U.S. Surgeon General became largely a ceremonial position of limited visibility and influence. Sometimes, as during the Clinton administration, the Surgeon General concomitantly served as the Assistant Secretary for Health within DHHS. Currently, DHHS agencies and programs of environmental health, such as the National Institute of Environmental Health Sciences (NIEHS), report to parent *Operational Divisions*, e.g., the Director, National Institutes of Health, who in turn reports to the Secretary, DHHS. The Surgeon General now has no administrative authority over the DHHS operating divisions.

Through year 2016, there have been 19 Surgeons General. It is likely that all Surgeons General have had some involvement in what is now called environmental health. For example, issues of human waste management, water pollution, vector control, and food contamination have long been challenges to the public's health, rising to the attention of Surgeons General through the years. However, among the Surgeons General, two have had the greatest effect on modern environmental health programs and policies.

Dr. Thomas Parran, Surgeon General from 1936 to 1948, was a career PHS commissioned officer, a requirement at the time for serving as Surgeon General. In 1936, President Franklin Roosevelt appointed Parran as the nation's sixth Surgeon General. Fortuitously for the public's health, the Social Security Act of 1935, Title VI, provided the PHS with funds and authority to build a system of state and local health departments [9]. Surgeon General Parran was in today's parlance an "activist" who used the authorities, particularly those given by Title VI of the Social Security Act, to develop a system of federal grants to state and local health departments. These grants required health departments to match federal funds and ultimately established comprehensive public health programs within states and local health departments. The

* As of 2016, the DHHS operating divisions comprise the Administration for Children and Families, Administration for Community Living, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration [14].

† *Bully pulpit*: a prominent public position (as a political office) that provides an opportunity for expounding one's views [15].

grants forged essential links between federal, state, and local health departments that began in 1936 and continue to the present.

The PHS grants to states that started in 1936 added programs in industrial hygiene and plague control to ongoing PHS and state programs in malaria control, privy construction, and mine-sealing activities [9]. These efforts were therefore forerunners of later PHS and state health department efforts to reduce the human health toll of specific environmental hazards.

Later in his career, Surgeon General Parran became a key player in lobbying Congress to enact the Water Pollution Control Act of 1948. This legislation was a culmination of PHS's prior water quality investigations that dated from the PHSAct [9]. The Water Pollution Control Act provided PHS with authorities and resources that extended investigations of fecal contamination in water supplies and streams to include new water quality problems from chemical contaminants.

As the PHS's environmental health programs and budgets expanded in the late 1950s, expectations grew, especially within environmental organizations, that the PHS would become the federal government's leader in protecting the public against specific environmental hazards. However, as early as 1954, decreases in the PHS water pollution budget led to criticism by environmental organizations. Unfortunately, hope exceeded reality. Seeds of discontent with PHS's leadership of environmental health programs were being sowed.

The other Surgeon General who had a major responsibility for environmental health problems was Dr. Leroy E. Burney, the eighth Surgeon General, who served from 1956 to 1961. Burney had been appointed to his position in 1956 by President Dwight Eisenhower. Like Surgeon General Parran, Dr. Burney was a career PHS commissioned officer. He was at the PHS helm during a period of time, the mid-1950s, when evidence began to mount that chemicals in water supplies, poor outdoor ambient air quality, and increased radiation levels in the atmosphere from above ground nuclear weapons testing had become potential threats to the public's health. Surgeon General Burney, like Parran a decade earlier, took assertive steps to position the PHS to respond to these new environmental challenges.

Surgeon General Burney foresaw the need for research to elucidate the effects on the public's health of radiation sources, contaminated water supplies, and polluted air. Using his authorities in the PHSAct, Dr. Burney mobilized talented, multidisciplinary researchers in order to pursue answers to basic questions on the human health consequences of environmental hazards. These teams were composed of physicians, toxicologists, epidemiologists, engineers, chemists, physicists, radiation biologists, and statisticians, among others. Laboratory studies and measurement of environmental contamination levels were prominent activities whether in radiation, water quality, or air pollution research programs. The emphasis on conducting basic (e.g., hypothesis testing) and applied (i.e., collecting data on environmental quality) research fit within the traditional disease prevention model used by public health practitioners. Knowledge of your opponent (i.e., disease) before engaging it with regulations and forced responses was thought preferable to an attitude of predicting harm and later assessing impacts. In this public health approach, education and hazard control followed the establishment of sufficient scientific data to say that a public health problem could occur.

As related by PHS historian Mullan [9], Dr. Burney appointed a national advisory committee on radiation, resulting in the creation of the Division of Radiological Health, located in Cincinnati, Ohio, thereby consolidating all PHS radiation programs. In 1957, he convinced Congressman John Fogarty, a powerful member of Congress, to add language to the PHS appropriations bill in order to implement new PHS environmental programs and to expand existing programs. At the same time, a committee of experts was proposed for the purpose of advising the PHS and Congress on environmental health problems. As it turned out, this new Congressional interest and largesse to the PHS had set in motion events that would lead to an eclipse of PHS environmental health programs and leadership.

By 1960, Surgeon General Burney and PHS leadership were faced with a proposal in Congress to remove water pollution control from the PHS. This proposal was based on the argument that water pollution involved conservation and wildlife concerns in addition to sewage treatment, the area of PHS emphasis [9]. Of note, PHS engineers were apparently behind-the-scene proponents of the proposal being considered by Congress. Their advocacy was predicated on frustrations with the leadership of PHS, comprised largely of medical doctors.

By the early 1960s, PHS leadership of environmental health programs had begun to wane.

Dr. Burney, in a report to Congress, presaged the eventual PHS acquiescence of environmental health primacy. He wrote, "When we are dealing with the possible harmful effects of the byproducts of industry and the wastes of nuclear technology, our goal is not CONQUEST (emphasis added) but CONTAINMENT (emphasis added) [9]." In retrospect, this is a quite revealing comment from the leader of the PHS. Burney, who was one of the great Surgeons General, implies that primary prevention (i.e., hazard elimination) could not, or would not, be applied to environmental health problems. Would he have made such a statement about an infectious disease? Of course not. Surgeon General Burney's comment gives insight into the then disease-focused orientation of the PHS.

With President John F. Kennedy's election in 1960 came changes that quickly impacted the nascent PHS environmental health programs begun by Surgeons General Parran and Burney. Burney was not reappointed Surgeon General of the PHS, being succeeded by Dr. Luther Terry. In August 1961, Dr. Terry established the Committee on Environmental Health Problems and asked them to develop long-range objectives for the environmental health programs of the PHS. This

committee was the realization of Surgeon General Burney's efforts to convene an expert committee to advise the PHS and Congress on matters of environmental health.

The Committee on Environmental Health Problems [16] delivered its report to Surgeon General Terry on November 1, 1961. The committee's many conclusions included the following:

1. The Committee believes that immediate action should be taken to establish a center where the operational research, and training programs of the Service (i.e., Public Health Service) in environmental health can be brought together.
2. A major national effort, both government and non-government, must be started if the environmental health problems resulting from the rapid growth of our highly technological civilization are to be adequately understood and if measures for their control and ultimate prevention are to be developed.
3. The focus of this national effort should be centered in the U.S. Public Health Service.

These quotes portray the committee's strong support for PHS primacy in federal environmental health programs. But their aspirations were to be only partially realized. The PHS did not seize the opportunity and build momentum to establish its leadership role in environmental health policy and programs. Why did this lapse occur? The answers are complex and, in hindsight, predictable.

The PHS was established by Congress as a federal government resource to protect the public's health, primarily to prevent the spread of infectious disease, e.g., sexually transmitted diseases. Although engineers and sanitarians have always been key members of the PHS, physicians had dominated the leadership and programs of the PHS by reason of their numbers and influence. Regrettably, they were not, by virtue of their medical training and professional experience, well attuned to environmental health problems.

Other forces, in addition to the PHS leaders' discomfort with environmental health problems, contributed to Surgeon General Terry's failure to embrace recommendations from the Committee on Environmental Health Problems. The most significant force was an increasingly active environmental lobby, which saw environmental health in a larger dimension than just human health concerns. In particular, conservation groups and ecology organizations lobbied Congress for legislation that would add more emphasis to improving environmental quality and protecting natural resources. These lobbying efforts were not lost on the PHS leadership, which gradually relinquished any substantive efforts to provide the nation's leadership and serve as the primary resource in environmental health. Lack of environmental health vision within the PHS and leaders who lacked environmentally relevant backgrounds contributed to an eventual loss of PHS primacy in environmental health. The die had been cast for creation of EPA as the nation's principal environmental authority.

The role and authority of Surgeons General began to change in 1967 during President Lyndon Johnson's administration, when the position of Assistant Secretary of Health (ASH) was created, reporting directly to the Secretary of the DHEW. This position added another political appointee, along with the Surgeon General, to the department's leadership. In 1968, DHEW Secretary Wilbur Cohen redefined the PHS organizations structure and the Surgeon General's role by placing Dr. Philip Lee, Assistant Secretary for Health, in charge of the PHS, with the Surgeon General as his deputy. With the stroke of a pen, PHS leadership changed so that all PHS agencies (e.g., NIH, FDA, and Centers for Disease Control and Prevention [CDC]) reported to the ASH, not the Surgeon General. As a second consequence, the Surgeon General's authorities became largely advisory and somewhat ceremonial. The Surgeon General of the PHS remained as the nation's principal spokesperson on public health, preparing reports on major health problems (e.g., tobacco use), advocating for public health programs, and representing the U.S. government at international health meetings. The "bully pulpit" became the Surgeon General's primary source of authority and influence and remains so today.

Prior to EPA's establishment, an event occurred that created a lasting schism between public health programs and environmental protection organizations. In 1961, all authority for water pollution control was transferred from the Surgeon General to the PHS's parent leader, the Secretary of DHEW, later to become DHHS. In 1965, the Federal Water Pollution Control Administration was established by Congress; shortly thereafter this new administration was transferred from the DHEW to the Department of Interior (DOI). Upon this transfer, the DOI decreed that all PHS commissioned officers assigned to the water pollution program would have to resign their commissions and convert to civilian (i.e., Civil Service) appointments. This policy had an immediate and lasting chilling effect on a key PHS resource, its commissioned officers. The result was a hemorrhage of key personnel, particularly medical officers and some engineers who preferred to remain PHS officers, where retirement benefits and pay generally exceeded what were available to federal civil service employees. A personnel policy crafted by federal bureaucrats had led to a setback in public health protection.

Federal water pollution control efforts continued, but with a significantly different focus: pollution monitoring and application of engineering controls to reduce water pollution loads. Unwittingly, the DOI's personnel policy decision to discourage the presence of PHS officers was the genesis of a dichotomy in environmental health: environmental protection, standards, and regulations vs. public health, consensus recommendations, and voluntary action.

3.3.4 Establishment of EPA

The story of the environmental movement in the 1960s and 1970s has much to do with two men: Senator Edmund Muskie (D-ME) and President Richard M. Nixon (R-CA). Both were central to efforts to improve environmental quality

and protection of public health from specific environmental hazards. Both men exhibited tenacity and, ultimately, wisdom in how to deal with the U.S. public's growing concern in the 1960s about environmental hazards. Some context is required. In order to understand what led to the establishment of EPA as a component of the federal government requires some background. This context can best be understood in terms of the social, legislative, and governance climates of the 1960s and 1970s.

3.3.4.1 Societal Climate

The 1960s and 1970s were times of great, bitter societal turmoil in the U.S. It was a time of war in Vietnam and protesters of the war on U.S. streets. Looking back, these years saw the greatest change in U.S. social progress since the Civil War. These events included the awakening and national commitment to correcting civil rights abuses against African-Americans and other minority populations. Other notable, and lasting, changes in the U.S. social fabric included emergence of the environmental movement, feminism, peace activists, outer space exploration, and assassinations of national leaders, including a U.S. President. These events caused great strain on the nation's social fabric, which frayed at the edges, but did not rend.

Perhaps the pivotal event that precipitated a tidal wave of later social change was the assassination of President John F. Kennedy (D-MA)* on November 22, 1963, in Dallas, Texas. Kennedy's election in 1960 was seen by many persons to presage an era of progressive change, including improved civil rights for minorities, a shared vision for the nation's future, and a commitment to science and education. It was a brief period of national innocence and optimism. The President's death ended these feelings.

Upon Kennedy's death, Vice President Lyndon B. Johnson (D-TX) became President. Prior to his becoming Kennedy's vice president, Johnson had been the powerful leader of the U.S. Senate. He was justly renowned as a politician who got what he sought. He wielded absolute control over all Senate legislative matters. His intimate knowledge of the congressional legislative process would be needed as the nation focused its attention on correcting civil rights abuses that originated with the nation's founding by European settlers.

Led by the Rev. Dr. Martin Luther King, Jr., demands mounted on the U.S. Congress to correct civil rights injustices imposed on African-Americans in the southern states, such as voting restrictions, lack of unfettered access to public places, and denial to housing of choice. The major impediments in passage of civil rights legislation in Congress were Senators and Congressmen from southern states who chaired key congressional committees. Their opposition meant that civil rights legislation would founder in committee inaction. President Johnson was able to lead efforts that culminated in the landmark Civil Rights Act of 1964, which outlawed racial discrimination in public accommodations and by employers, unions, and voting registrars. This act was soon challenged in federal court, ultimately being decided by the U.S. Supreme Court, which held that the commerce clause of the U.S. Constitution applied, thereby overriding states' rights claims. In 1965, the Voting Rights Act suspended (banned in later legislation) the use of literacy or other tests of voter qualifications. In the aftermath of the assassination of Dr. King on April 4, 1968, Congress passed the Fair Housing Act of 1968, which banned racial discrimination in housing financed by federal funds. Overall, this body of civil rights legislation reinvigorated a proactive policy of making social change through federal law. One of these changes was a federal response to protect the natural environment.

Lyndon Johnson's leadership in getting U.S. civil rights legislation enacted into law would have been enough to make for a positive place in U.S. history. However, this place was denied to him because of his insistence on America's winning the war in Vietnam. This policy was widely unpopular, leading to widespread demonstrations against the war by thousands of street demonstrators and some acts of violence against people and property. Johnson chose not to seek reelection and was succeeded by Richard M. Nixon (R-CA), who was elected President in 1968. Ultimately, the war ended during Nixon's administration. The U.S., South Vietnam, and North Vietnam governments signed the Paris Peace Accord, which went into effect on January 17, 1973, and set into motion the end of U.S. military action in Vietnam [17]. In 1975, the last U.S. military personnel withdrew from South Vietnam. Shortly thereafter, North Vietnam overthrew the South Vietnam government, an action that unified the two Vietnams into one country. A lesson from the U.S. experience in the Vietnam War was the power of public protests on social policies (including protesting for pending federal environmental legislation), a lesson not lost by Congress and on pending federal environmental legislation.

3.3.4.2 Legislative Climate

The 1960s and 1970s saw the emergence of environmentalism as an engine of social change, although, as noted in Chapter 4, some laws and programs were already in existence. Prior to 1960, these laws primarily were focused on conservation of natural resources and, secondarily, on public health research and services pertinent to water quality, food safety, solid waste disposal, and radiation hazards. An opportunity to strengthen existing environmental laws, and develop new ones, began with the election in 1958 of Edmund S. Muskie (D-ME) (Figure 3.3) to the U.S. Senate. Senator Muskie, prior to his election to the Senate, was governor of Maine, a state heavily dependent on an economy based on timber, fishing, and recreation. As governor, he became concerned about protecting the state's natural resources. He carried these concerns to the Senate, along with his support for preserving the authorities of the states in environmental affairs.

As related by Landy et al. [18], Muskie's role in environmental legislation began inauspiciously. As a freshman Senator he had offended Senate Majority Leader Lyndon Johnson. As a result, Muskie was assigned to the Senate's Public Works Committee, a committee that was not held in high regard by

* It is common practice to denote elected officials by political party and state. Kennedy (D-MA) signifies Democrat from Massachusetts and Nixon (R-CA) denotes Republican from California.

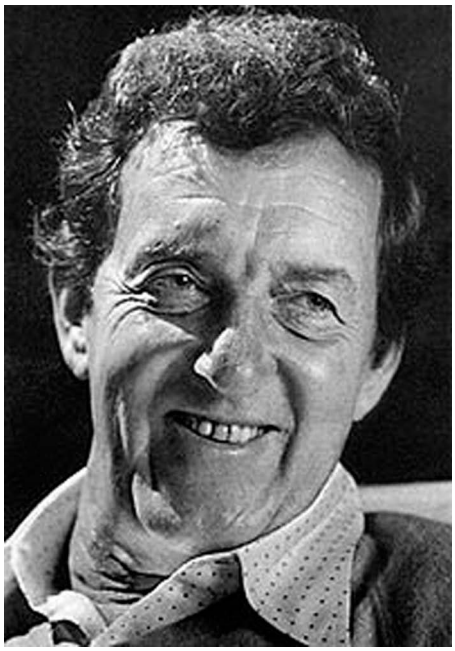

FIGURE 3.3 U.S. Senator Edmond S. Muskie (D-ME), circa 1955.

other Senators because it dealt with projects of special interest to members of the Senate, e.g., bridge repairs, highway construction, and canal dredging. In 1963, Muskie was appointed chairman of the Committee's newly created environment subcommittee, a position he kept for the next 17 years before he left the Senate to campaign for the Presidency.

Muskie sponsored a series of seminal water and air quality bills during the 1960s that had great impact on the nation's environmental policies. In 1963, he led the development of amendments to the Water Pollution Control Act, which transferred authority for water pollution from the PHS Surgeon General to the Secretary of DHEW. The Secretary was provided authority to establish water quality standards for interstate waterways if states' standards were deemed not protective of public health. The 1963 amendments became the Water Quality Act of 1965 [18]. In 1966, he sponsored the Clean Water Restoration Act, which provided states with federal funds for sewer construction.

Air quality legislation was also an interest and product of Muskie's subcommittee. In 1967, he sponsored an air quality bill that brought sweeping change. States were required to establish and enforce air quality standards that were to be based on scientific data from the federal government. Further, the act required the federal government to develop air quality standards for automobile emissions [18].

Although some critics of Muskie thought his body of air and water quality environmental legislation was too dependent on states' actions, his contributions to improving the U.S.'s environmental quality were both undeniable and vital.

3.3.4.3 Governance Climate

Another key player in the nation's emerging commitment to environmental protection was Richard M. Nixon (R-CA) (Figure 3.4). The election in 1968 of Nixon as President soon led to quite significant changes in the U.S.'s environmental policies and resources [18]. As President, Nixon perceived that the Republican Party needed to expand its voting base. He correctly understood the political implications of the migration, started in the 1950s, of persons moving from urban areas to the suburbs, areas where the outdoor ambient air was cleaner, green spaces were available, and housing was less expensive. Republican Party strategists thought suburbanites were more aware of good environmental quality and therefore ripe for Republican Party outreach to persons who supported improved environmental quality—and an expanded voting base of Republicans in the suburbs. Moreover, the inaugural Earth Day celebration of April 22, 1970, had drawn attention to environmental issues and raised public concern for the environment, situations ripe for political cultivation.

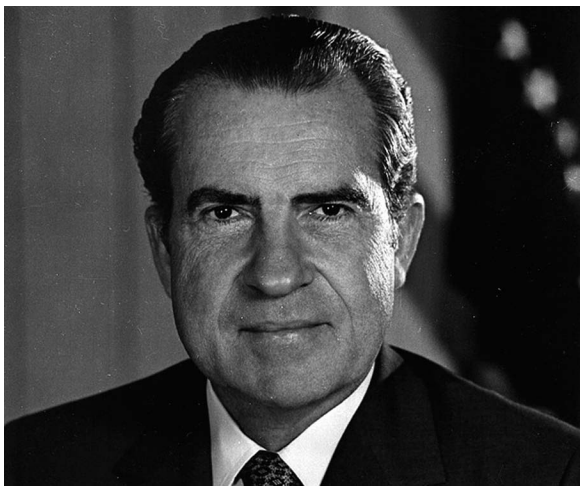

FIGURE 3.4 Richard M. Nixon (R-CA), 37th U.S. President, circa 1970.

For purpose of political gain, Nixon became a supporter of a stronger federal role in protecting the environment. He signed into law the National Environmental Protection Act of 1969, the CAAct Amendments of 1970, and the Occupational Safety and Health Act of 1970 (OSHAct). Further, in May 1969 he appointed the Environmental Quality Council, a cabinet-rank committee, and tasked it with preparing a strategy for addressing environmental issues. The committee failed to deliver its report, which led to the appointment of a task force to produce the report. In February 1970 a preliminary report was produced. It recommended the establishment of a new Department of Environment and Natural Resources (DENR) [18].

Nixon initially gave his approval to creating a DENR and asked an advisory committee on government reform, chaired by Roy Ash, formerly the head of Litton Industries, to consider the proposal. The committee became known as the Ash Council. Staff within the Council soon split over the merits of a DENR, in part because it would create problems within the existing congressional committee structure that had environmental responsibilities and in part because a DENR was seen as too large and unwieldy. The President withdrew his support for a DENR and settled, instead, on establishment of EPA, a

more focused and visible federal agency than what a DENR would have been. Notably, the Secretary of DHEW supported the plan for an EPA, aware that DHEW's public health environmental programs would be transferred into EPA.

On July 9, 1970, Nixon submitted to Congress his reorganization plan to establish EPA. According to an existing statute on executive branch reorganizations, Congress had 60 days to react to the proposal. Since neither the House nor Senate expressed opposition to the plan within 60 days, Nixon's plan went into effect on September 17, 1970 [18]. However, the White House disagreed with environmental groups and their congressional allies over the mission of the EPA and how the agency would relate to Congress. According to Landy et al. [18], the White House expected the EPA to pursue its mandate so as not to hinder industrial expansion and resource development. In contrast, the environmental community wanted the EPA to champion environmental values via statutes that bound the executive branch to enforcing strict limits on environmental hazards.

The debate about EPA's mission and how it would function within the executive branch was settled to a considerable extent by the agency's first administrator, William Ruckelshaus. He chose as policy to emphasize enforcement of air and water quality regulations [18]. This was a natural choice, given Ruckelshaus's background as Attorney General of Indiana, where he had aggressively litigated entities that had broken the state's environmental statutes. His decision cast the EPA's future as a regulatory and enforcement agency. Moreover, his orientation of the EPA as a regulatory agency met with support from environmental groups, which had become dissatisfied with the nonregulatory approach taken by the PHS. But with enforcement and the establishment of regulations and standards under specific environmental statutes came the inevitable opposition from companies and other entities that would be targets of environmental regulations and enforcement.

This new agency was constructed of several existing environmental programs transferred into the EPA from the DHEW and other federal departments, subsuming PHS programs in air pollution, solid waste, pesticides, drinking water, aspects of radiological health [9], and water pollution control from the DOI. The EPA did not repeat the personnel policy of the DOI by excluding PHS commissioned officers, although few medical officers chose to transfer to EPA. In fact, there remain today a substantial number of PHS officers on loan from the PHS to the EPA. Some would assert that the EPA's policy of retaining PHS officers has had a beneficial effect by infusing greater public health perspective into environmental protection; however, the relatively few numbers of medical doctors in the EPA remains a problem in regard to getting a medical and public health perspective infused into regulatory decisions.

Since its establishment, the EPA has had U.S. federal primacy in environmental protection and protection of human and ecological health against specific environmental hazards. Indeed, the current mission statement of the EPA is "[t]o protect human health and the environment" [19]. Protection of human health is pursued by controlling—using risk assessment policies and procedures—individual environmental hazards (e.g., contaminants in drinking water supplies) and managing the risks through "command and control" regulations. These endeavors are intended to reduce or prevent human contact with specified environmental hazards. Less exposure means a reduced potential for adverse human health effects and improved environmental quality. The EPA's environmental programs are effectuated through its program offices and 10 regional offices.*

In addition to creating the EPA, Nixon signed into law the OSHAct. This act established OSHA, a regulatory agency within the Department of Labor (DOL). As described in Chapter 4, OSHA has the responsibility for controlling workplace environmental hazards through control of workplace hazards, conduct of workplace inspections, and enforcement of workplace regulations and standards. The act also created the National Institute for Occupational Safety and Health (NIOSH), an agency now within the DHHS, for the purpose of conducting health and safety research on workplace hazards and other public health duties that are discussed later in this chapter.

3.4 DHHS AGENCIES WITH ENVIRONMENTAL PROGRAMS

The DHHS is home to several environmental health agencies and programs that date from the mid-twentieth century. The current programs are conducted through the use of the traditional public health approach of science, consensus, and services. As intended here, *science* comprises basic biomedical research, health surveillance systems, epidemiology, and applied research. Stakeholders include state and local health departments, expert advisory groups, and public health organizations. *Consensus* refers to the process of stakeholder dialog on the public health significance of scientific findings. *Services* flow from the consensus achieved. The services can include, depending on the nature of the identified hazard, such activities as public health education, resources for health care providers, immunization programs, and assistance to local health departments.

Even with the EPA's emergence as the federal government's principal regulatory authority on environmental health hazards, environmental health programs have remained, and grown, as components of DHHS, comprising agencies and offices. Agencies are organizational entities that administer programs authorized by law and specific to the purposes of each agency. Offices, in distinction to agencies, administer functions that support the administrative needs of the Secretary. Not all DHHS agencies and offices administer programs and activities of relevance to environmental health.

* EPA's program offices in 2016 were as follows: Office of Air and Radiation, Office of Chemical Safety and Pollution Prevention, Office of Enforcement and Compliance Assurance, Office of Land and Emergency Management, Office of Research and Development, and Office of Water. Regional offices are located in Boston, New York City, Philadelphia, Atlanta, Chicago, Dallas, Kansas City, Denver, San Francisco, and Seattle [20].

Following are précis descriptions of each DHHS agency and office that has environmental health responsibilities. They are presented in alphabetical order.

3.4.1 Agency for Toxic Substances and Disease Registry

In the late 1970s, the U.S. gradually became aware through intense and frequent news media reports of a new environmental health hazard: uncontrolled hazardous waste sites. Uncontrolled is used in the sense of abandoned or not under regulatory control. The most prominent case was a small suburban community, Love Canal, New York, located near Niagara Falls, New York, which had been built over a chemical waste dump [21]. As the buried drums of chemical waste gradually deteriorated, chemical fumes migrated through the soil and permeated the houses above. Residents became concerned that the vapors were associated with adverse health effects in their children. During the same time period, other news media reports of hazardous waste sites were often broadcast (Chapter 12).

As news media coverage of hazardous waste sites grew, the environmental lobby made waste site cleanups and protection of human health into a legislative priority. Two organizations, the Environmental Defense Fund (now called Environmental Defense) and the Natural Resources Defense Council, lobbied energetically for enactment of federal legislation, postulating that the public's health was at risk. Chemical companies and waste generators lobbied equally energetically to discourage hazardous waste legislation, arguing that the environmental and human health consequences had been exaggerated. The scene was set for a vigorous Congressional debate over hazardous waste site management.

Congressional debate divided generally along partisan political lines. Democrats generally favored federal action to identify and remediate (i.e., cleanup or fix) uncontrolled hazardous waste sites. Republicans generally favored state-based actions that might lead to state legislative action. In the House of Representatives, Congressmen James Florio (D-NJ) and John Dingell (D-MI) led the drafting of a bill that would become the CERCLAct. Similar efforts in the Senate were led by Senator Robert Stafford (R-VT). The CERCLAct is described in Chapter 12.

A key policy problem facing Congress was how to respond to pressure from community groups who represented people residing near waste sites and the environmental lobby, both of which demanded 'victims' compensation' for persons residing near uncontrolled hazardous waste sites. In concept, this proposal was similar to workers' compensation, arguing that one's residential location, through no fault of their own, had caused financial (lower property values) and health harm (cancer and other health problems). In a social justice context, residents asserted they had become victims, thereby deserving compensation. The Senate's CERCLA bill contained language to provide victims' compensation; the House version did not. In such instances of disagreement, a conference committee of House and Senate members is appointed and tasked with trying to find a consensus bill that then goes back to the House and Senate for vote. Resolving the differences over victims' compensation was among the conferees' challenges.

The ATSDR's primary mission is to conduct the public health agenda specified in the CERCLAct (Chapter 12).

House and Senate conferees eventually abandoned the issue of victims' compensation [22]. Conferees dropped the idea, fearing such a policy would be abused. Moreover, the policy was thought premature in light of considerable scientific uncertainty about actual health effects in persons residing on or near uncontrolled hazardous waste sites. Their solution was to create a new federal agency specifically tasked with assessing the health of persons potentially impacted by hazardous substances released from uncontrolled waste sites. This organization, Agency for Toxic Substances and Disease Registry (ATSDR), was therefore the Congressional prescription to avoid victims' compensation. The agency would, in theory, develop the health effects database that could be used by waste site area residents in private litigations against waste site owners. ATSDR's public health responsibilities under the CERCLAct are discussed in Chapter 12.

On December 10, 1980, President Jimmy Carter signed the CERCLAct into law. The ATSDR was made an agency of the DHHS. However, the incoming Reagan administration was philosophically opposed to any further growth in federal government programs and therefore chose not to provide resources to create ATSDR as a new federal organization. Rather, ATSDR's responsibilities to conduct health assessments of the CERCLAct waste sites were assigned to the CDC's Center for Environmental Health (CEH). In 1983, a lawsuit in federal court, litigated by unlikely bedfellows (Environmental Defense Fund, Chemical Manufacturers' Association, American Petroleum Institute), sued the EPA and the DHHS for failure to implement various sections of the CERCLAct. One of the points of litigation was failure of the federal government to fully establish ATSDR as a new federal agency. A settlement between the litigants led to agreement to organize ATSDR and provide it with resources. However, DHHS elected to tether the new agency to the CDC, designating the CDC's Director to also serve as the ATSDR Administrator. Both ATSDR and the CDC are headquartered in Atlanta, Georgia. Dr. James O. Mason served as ATSDR's first administrator. As a matter of environmental health policy, the arrangement between CDC and ATSDR was a marriage of necessity, given the antipathy of the Reagan administration to the creation of new government agencies, as well as an animus toward the CERCLAct itself. This is an example of a conflict over environmental health policy that occurred between the executive and legislative branches of the U.S. Government, requiring the third branch, the Judiciary, to settle the issue over how and when to structure the ATSDR.

Following its establishment, the Superfund Amendments and Reauthorization Act of 1986 gave additional responsibilities to ATSDR The agency's public health programs grew to include health assessments of communities impacted by

hazardous waste sites, the preparation of toxicological profiles on substances released from waste sites, health surveillance of persons exposed to hazardous substances, epidemiological investigations of populations exposed to hazardous substances, toxicological studies, and education programs for health care providers. These programs are conducted in collaboration with the EPA, CDC, and other federal agencies, and through grants awarded to state health departments.

3.4.2 Centers for Disease Control and Prevention

The CDC is based in Atlanta, Georgia. The agency's mission is stated to be "CDC works 24/7 to protect America from health, safety and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same. CDC increases the health security of our nation. As the nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish our mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise" [23].

CDC's roots were planted in World War II when control of malaria in U.S. troops was of great concern because of the large concentration of military bases in the southern U.S. A military hospital was established in Atlanta to provide medical care for troops who had contracted malaria. After the war, public health authorities continued with efforts to prevent malaria and typhus in civilian populations residing in the southern states and Caribbean countries. The authority for these efforts was the Malaria Control in War Areas program, which was developed in anticipation of troops returning to the U.S., having contracted various tropical diseases unfamiliar to U.S. clinicians [9].

A visionary PHS officer, Dr. Joseph Mountin, foresaw the nation's need for a public health agency that would monitor infectious disease outbreaks, provide education and services to state and local health departments, and conduct epidemiological investigations. His vision became reality when in 1946 the Communicable Disease Center was established as part of the PHS, later to become the Communicable Disease Centers, then the Centers for Disease Control, and now named the Centers for Disease Control and Prevention. The CDC's programs cover infectious disease, sexually transmitted disease, chronic disease, injuries, environmental health, occupational health and safety, bioterrorism prevention, and immunization. The core public health disciplines that serve as the spine of the CDC are surveillance, epidemiology, laboratory science and services, education, and health services. Within the CDC's structure are three organization components that have environmental health responsibilities, which are described in the following sections.

3.4.2.1 National Center for Environmental Health

The CEH was created in 1980 in response to a reorganization of the then Communicable Diseases Center, soon to become the Centers for Disease Control. Leaders of the CDC developed a long-term strategic plan that was based on mortality and morbidity statistics. They asked the question, "What are the leading causes of premature death and preventable disability in the American population?" From this exercise, environmental hazards, traumatic injuries, and chronic diseases (e.g., heart disease) were added to the list of existing CDC programs, principally focused at the time on the prevention of infectious diseases.

The National Center for Environmental Health (NCEH)'s programs include surveillance of environmental illnesses, prevention of lead exposure, epidemiological investigations of environmental hazards, and laboratory assessment of exposures to hazardous substances in the U.S. population.

The newly formed CEH assumed the responsibility for an existing federal vector control program, commenced the development of a laboratory to measure environmental toxicants in human tissues, initiated a program to reduce children's exposure to lead in the environment, and took responsibility for a nascent public health program created by the CERCLAct, even though the law had created the ATSDR for that purpose. In 1983, litigation brought against DHHS forced the Reagan administration to organize and fund ATSDR, which removed the hazardous waste program from CEH. In 1987, CEH was given responsibility for nonoccupational injury control programs and was renamed the Center for Environmental Health and Injury Control; the word *National* was added in 1991 [24]. At about the same time, the center assumed the responsibility for an existing vessel (i.e., cruise ships, primarily) sanitation program. Although no regulatory authority accompanies vessel sanitation, the cruise ship industry looks to NCEH to provide inspections of vessels and give advice on how to improve sanitary practices. As environmental policy, this is a good example of government and industry cooperation that improves public health.

NCEH's organizational structure and programs have changed over the years. In 1992, the injury control program was transferred from NCEH and became the CDC's National Center for Injury Prevention and Control, i.e., its own center. A similar change in NCEH's structure resulted from the Children's Health Act of 2000, which transferred NCEH's reproductive effects program into a new CDC center, the National Center for Birth Defects and Developmental Disorders. The current NCEH programs include public health surveillance, applied research, epidemiologic studies, laboratory analyses, statistical analyses, behavioral interventions, operations and systems research, communication and education, standards, guidelines, and recommendations, and training and technical assistance of officials of state, local, and tribal environmental health agencies in preventing and responding to environmental public health challenges. Details on these programs are available from the NCEH [25].

Of note is the CDC's Climate and Health Program, which is administered through NCEH. The program is the only

DHHS investment in climate change adaptation. According to NCEH, "We support state and city health department efforts to develop and pilot methods to adapt to the present and future health effects of climate change. Our program accomplishes this through funding provided to 16 states and two cities through the Climate Ready States and Cities Initiative (CSCRI). Funded states use the Building Resilience Against Climate Effects (BRACE) framework to identify likely climate impacts in their communities, potential health effects associated with these impacts, and their most at-risk populations and locations. BRACE helps states develop and implement health adaptation plans that impact health and address gaps in critical public health functions and services" [25].

3.4.2.2 National Institute for Occupational Safety and Health

In 1970, after a decade of effort, organized labor was successful in lobbying Congress to enact legislation to protect U.S. workers' health and safety. The OSHAct created a framework for regulatory control of workplace hazards and vested the responsibility with a new organization, OSHA, which was placed within the DOL. OSHA was given the responsibility to develop and enforce workplace standards, conduct workplace investigations, and conduct educational programs on workers' health and safety.

The OSHAct also created the National Institute for Occupational Safety and Health (NIOSH) and placed it within the DHEW. Placement of NIOSH and OSHA in different federal departments was necessary in order to gain the political support of Senator Jacob Javits, a politically liberal Republican from New York. His support was needed to ensure enough Republican votes to gain Senate passage of the OSHAct. He believed that NIOSH's public health and science responsibilities should be separate and independent from the influences of regulatory actions assigned to OSHA.

NIOSH is involved in a range of occupational safety and health activities including surveillance, research, and technology transfer.

Placing regulatory agencies administratively apart from health agencies is a significant environmental health policy, with both positive and negative consequences. On the positive side of separate organizations, if public policy issues such as regulating workplace levels of specific toxicants or community levels of air pollutants are to be based on firm scientific findings, one can argue that scientific research and its interpretation should be left to the purview of scientists unbiased by regulatory imperatives. Such imperatives would include taut timelines to publish a regulatory action to control toxicants and political pressures from business organizations and environmental groups to establish regulations that comport with their individual interests.

Further, independence of health agencies has traditionally been based to a great extent on investigator-initiated research, such as the biomedical research grants program at the NIH and NIOSH. Researchers are less bound to agency priorities than is the case with regulatory agencies, where priorities are more driven by regulatory interests. As such an example, the EPA has linked its research program to the needs of the agency for risk assessment data and prioritized its research support on the basis of comparative risk assessment of highest-ranked hazards to the environment and human health [26].

Arguments against a policy of separating regulatory agencies from public health agencies would include the same arguments in favor of separation, but with an opposite perspective. For example, some would argue that greater efficiency in resource expenditures would occur if public health research was more focused on priority environment and workplace hazards and the data needs of risk assessment. Moreover, risk assessors would have closer contact with agency scientists who might be more steeped in a specific issue of science that is relevant to a particular risk assessment. For example, in the first years of NIOSH, criteria documents were written to a considerable extent by institute scientists actively engaged in NIOSH research. As the number of criteria documents increases within an agency (e.g., NIOSH and ATSDR), the demands of preparing them outstrips the ability and willingness of intramural scientists to help prepare them. As a result, persons with scientific backgrounds and graduate degrees are hired expressly to write the documents, with some documents written by contract consultants.

NIOSH was given authority to conduct health evaluations of workplaces, develop substance-specific criteria documents, do surveillance and epidemiological investigations of workplace hazards, and offer training courses in workplace safety and health. NIOSH was created from the PHS Bureau of Occupational Safety and Health, based in Cincinnati, Ohio, thus building upon an administrative structure that had existed for many years. The first NIOSH director, Dr. Marcus Key, had served as the bureau's director. NIOSH is headquartered in Washington, DC, and is a component of the CDC, located in Atlanta, Georgia.

In an environmental health policy context, NIOSH has always been sensitive to the interests of organized labor, sometimes to the institute's detriment, because industrial and business groups perceived some NIOSH programs were not in their best interests. As an example, business interests became concerned about specific programs of research, e.g., ergonomics research and recommendations to OSHA for the development of workplace standards to control ergonomic hazards that cause musculoskeletal disorders. During the first Reagan term, NIOSH was targeted for elimination or major reduction in responsibilities, an agenda that was thwarted through the intercession of organized labor and professional societies such as the American Industrial Hygiene Association. On the other hand, organized labor's health and safety concerns helped develop a realistic agenda for NIOSH research and services, not to mention a stable political base of support for the institute. During the Clinton administration, NIOSH achieved more cooperative relationships with corporate and business interests, e.g., in developing a long-range strategic research plan in occupational health and safety.

3.4.2.3 Office of Smoking and Health

This office is the CDC's principal program on smoking and tobacco issues. The OSH states [27] "Our mission as the lead federal agency for comprehensive tobacco prevention and control is to develop, conduct, and support strategic efforts to protect the public's health from the harmful effects of tobacco use." The goals and primary actions of the OSH are as follows:

Goals:

- Prevent initiation of tobacco use among youth and young adults.
- Promote tobacco use cessation among adults and youth.
- Eliminate exposure to secondhand smoke.
- Identify and eliminate tobacco-related disparities.

Partnerships and actions:

The OSH works in partnership with local, state, national, and international leaders to

- Expand the science base of effective tobacco control.
- Build sustainable capacity and infrastructure for comprehensive tobacco control programs.
- Communicate timely, relevant information to constituents, policy makers, and the public.
- Coordinate policy, partnerships, and other strategic initiatives to support tobacco control priorities.
- Foster global tobacco control through surveillance, capacity building, and information exchange to address the worldwide epidemic of disease and death caused by tobacco, The OSH works with international partners to expand the global science base through surveillance and research; build capacity for data collection, analysis and reporting; and assist with linking surveillance data to tobacco control efforts.
- The OSH's National Tobacco Control Program funds health departments in all 50 U.S. states, the District of Columbia, and eight U.S. territories for comprehensive tobacco prevention and control programs.

As recapitulation, CDC's OSH is a primary federal program on prevention of tobacco-related adverse health effects. The OSH is a centerpiece of federal strategy and policy of the prevention of morbidity and mortality caused by use of tobacco products. This CDC office works with other federal agencies, states, territories, and tribal nations domestically as well as global partners with the common goal of preventing the health, economic, and social consequences of tobacco products.

3.4.3 Food and Drug Administration

The FDA, like the NIH, can trace its history to a small laboratory established in the nineteenth century. In 1862, the newly established USDA established a laboratory to analyze samples of food, soils, fertilizers, and other agricultural substances [28]. This was in response to public concerns that would today be called product safety. Some goods had been found to have been deliberately adulterated by merchants in order to increase their profits. An early question investigated by the laboratory was whether adding sugar to fermenting wine in order to increase alcohol content was food adulteration. (The laboratory concluded that adding sugar was legitimate.) In time, the laboratory grew into the Bureau of Chemistry. The public health problem of food adulteration was the responsibility of states until 1906, when the federal Food and Drugs Act was enacted. The Bureau of Chemistry enforced the 1906 law until 1931, when the Food, Drug, and Insecticide Administration was formed, to be renamed in 1931 as the Food and Drug Administration (FDA) [28]. In 1940, to prevent conflicts between food producers and consumers, the FDA was transferred from the USDA to the FSA, which, in 1953, became the DHEW [28], as previously noted.

As discussed in Chapter 10, the FDA has a significant responsibility for enforcement of the provisions of the FDCAct, along with provisions of various other laws pertaining to public health [29]. The FDA regulates many products that the U.S. public encounters daily. These include regulation of food (e.g., dietary supplements, product labeling), drugs, therapeutic devices, biologics (e.g., vaccines, blood products), animal feed and drugs, cosmetics, and radiation-emitting products (e.g., microwaves). Two FDA components are involved in impacts of environmental hazards, as described herein.

3.4.3.1 National Center for Toxicological Research

Research on the potentially toxic properties of substances of interest to FDA is conducted at the agency's National Center for Toxicological Research (NCTR), located near Jefferson, Arkansas.

As background to the establishment of NCTR,* during the Nixon administration the U. S. agreed to stop production of biological weapons. This policy was in reaction to international efforts to forego egregious weapons of human destruction. With great fanfare, President Nixon announced that all U.S. biological weapons facilities would be closed. As it turned out, how these newly surplused facilities were to be used was influenced by a report to the Secretary, DHEW, prepared by a consultant, Dr. Emil Mrak, who at the time was Chancellor, University of California, Davis campus.

In 1969, the DHEW established the Commission on Pesticides and Their Relationship to Environmental Health, which was tasked to conduct the first assessment of pesticide risks [30]. In December 1969, Dr. Mrak delivered the "Report of the DHEW Secretary's Commission on Pesticides and Their Relationship to Environmental Health" to the Secretary, DHEW [31]. The development of this report had been stimulated by Rachel Carson's 1962 book *Silent Spring* [32]. Mrak was well known for developing the food science department

* The authors are indebted to Dr. Morris Cranmer, first director of NCTR, for materials and insights on the establishment of NCTR.

at the University of California, Davis, and was also active in the work of the National Research Council.* In 1968, at the time that the commission was created, pesticides regulation was the responsibility of three different federal departments (Agriculture, Interior, and DHEW). The Commission operated during a period when the U.S. public had become increasingly concerned about the public health effects of pesticides in the environment.

The Mrak Commission's report recognized the need for increased research to develop better ways to assess the inherent risks associated with the use of hazardous chemicals. The Mrak Commission also recognized the need for an increased role of the federal government in developing methods to test chemicals for their potential to produce toxic effects in humans [30]. The Commission's report had a major effect on toxicology and the federal government's regulation of hazardous chemicals in the environment.

Given Nixon's decision to cease chemical weapons production, the need arose to redeploy surplused buildings and personnel that had previously been part of the U.S. chemical weapons program. There were two important ones, Ft. Detrick, Maryland, and the Pine Bluff Arsenal, Arkansas. The former was transferred to the National Cancer Institute (NCI). Concerning the latter, the Pine Bluff Arsenal had been built as a high security biological containment facility. Biological weapons were produced in buildings built of thick concrete walls and with state-of-art air handling equipment. Rather than demolishing the facility, President Nixon continued his environmental health epiphany by announcing that the Pine Bluff weapons facility was to be converted into an environmentally relevant research laboratory. Federal departments were encouraged to propose concepts for the facility's use. The U.S. Army had used the facility for its biological warfare materials production in the 1950s and 1960s. With closing of the Pine Bluff facility, the Arkansas congressional delegation, eager to protect 350 jobs at the Pine Bluff Arsenal, asked the U.S. Army to find another use for the facility. However, the Army declined. The Departments of Interior and Agriculture also declined because the facility was mainly a large, chemical production facility in disrepair, along with a few animal housing rooms and microbiology laboratories.

The FDA successfully proposed that the facility become a toxicology laboratory. The new laboratory was to conduct basic and applied research on the toxicity of drugs of interest to FDA, and through an arrangement with EPA, would conduct studies on environmental substances of interest.

The mission of NCTR is to conduct peer-reviewed scientific research that supports and anticipates the FDA's current and future regulatory needs.

The EPA was established on December 2, 1970, and given the responsibility to regulate pesticides and other chemicals in the environment. The FDA retained the responsibility to regulate chemicals in food. In January of 1971 the Office of Science and Technology, Executive Office of the President, issued a news release announcing the creation of the NCTR. The news release stated, "new major project aimed at investigating the health effects of a variety of chemical substances found in man's environment … [i]n the surplus facilities of the Pine Bluff Arsenal, Pine Bluff, Arkansas."

The NCTR began operations in early 1971 as a joint venture between the FDA and EPA. The NCTR program was provided oversight by a joint FDA-EPA Policy Board. NCTR was administratively organized as a bureau of the FDA. The director of NCTR reported to the Commissioner of the FDA. In 1971, Dr. Morris Cramer, an EPA scientist on detail to FDA, was appointed the first NCTR director. Over time, the EPA's interest in the NCTR's toxicology programs decreased as their own intramural toxicology laboratories increased in number, resources, and toxicological specialty.

NCTR states it mission to be "NCTR conducts scientific research to generate data for FDA decision making, and develops and supports innovative tools and approaches that FDA uses to protect and promote individual and public health" [33]. NCTR reports its four research focus areas: biomarker identification, bio-imaging, nanotechnology, personalized medicine, and regulatory science training.

It is interesting to reflect on the societal good achieved by converting a chemical weapons facility into a facility dedicated to preventing the harm done by substances found to be toxic to human health.

3.4.3.2 Center for Tobacco Products

The Family Smoking Prevention and Tobacco Control Act of 2009 (Chapter 7) gave FDA sweeping new authorities to regulate the manufacture, marketing, and distribution of tobacco products. The law gave the FDA the authority to establish the Center for Tobacco Products (CTP) as the agency's resource for implementing the provisions of the Act. Currently, FDA regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.

The CTP develops and disseminates educational materials to the public about the harms of tobacco products, working to reduce their appeal and keep them out of the hands of America's youth. The CTP focused on three top priorities: (1) reduce initiation rates and prevent youth from starting to use tobacco, (2) encourage tobacco users to quit, and (3) decrease the harms of tobacco product use.

Under the provisions and authorities of the Tobacco Control Act, the CTP

- Develops science-based regulations to safeguard the nation's health.
- Publishes guidance to help the tobacco industry comply with regulations for tobacco products.
- Conducts retailer inspections to ensure compliance with laws restricting sales of tobacco products to

* The National Research Council (NRC) is a nonprofit, nongovernmental organization. It is the research arm of the National Academies of Sciences, Engineering, and Medicine, which includes the National Academy of Sciences (NAS), the National Academy of Engineering, and the National Academy of Medicine. The National Academies is located in Washington, DC.

youth, and issuing warning letters and monetary penalties for violations.
- Require tobacco manufacturers to report the ingredients in their products so FDA can evaluate the harm caused by the ingredients.
- Review proposed modified risk tobacco products before they can be sold.
- Restricts the access and attractiveness of cigarettes and smokeless tobacco to young people.
- Enforces the ban on the manufacture and sale of fruit-or candy-flavored cigarettes.
- Prohibits the use of misleading claims such as "low," "light," and "mild" that falsely imply that some tobacco products are safer.
- Reviews new tobacco products to determine whether they can be legally marketed.
- Launches public information and education campaigns, particularly targeted to youth, about the dangers of regulated tobacco products [34].

3.4.4 Indian Health Service

The Indian Health Service (IHS) was established in 1955. Its headquarters are located in Bethesda, Maryland, with regional offices in western states and Alaska. The IHS is responsible for providing federal health services to Native Americans and Alaska Natives. The provision of health services to members of federally recognized tribes grew out of the special government-to-government relationship between the U.S. federal government and Native American tribes [35]. This relationship, established in 1787, is based on Article I, §8, of the U.S. Constitution. The IHS is the principal federal health care provider and health advocate for Native Americans and Alaska natives, including providing environmental health services.

The IHS is responsible for providing federal health services to Native Americans and Alaska Natives.

According to the IHS [35], the principal legislation authorizing federal funding of health services provided to recognized Native American tribes is the Snyder Act of 1921. It authorized funds "for the relief of distress and conservation of health … [and] … for the employment of … physicians … for Indians tribes throughout the United States."

In 1993, Congress enacted the Indian Self-Determination and Education Assistance Act, which provided tribes the option of either assuming from the IHS the administration and operation of health services and programs in their communities, or to remain within the IHS administered direct health systems. This is an interesting and significant policy option. In other words, Native American tribes and Alaska natives that are recognized as such by the U.S. Government have the option of operating their own health care system, with federal funding, or opting to have the IHS provide their health care. In 1994, Congress enacted the Indian Health Care Improvement Act, which is a health-specific law that supports the options in the 1993 Act. The goal of the 1994 Improvement Act was to provide the quantity and quality of health services necessary to elevate the health status of Native Americans and Alaska Natives [35].

In 2016 the IHS provided health services to approximately 2.2 million Native Americans and Alaska Natives who belong to more than 567 federally recognized tribes. IHS services are provided either directly or through tribally contracted and operated health programs. IHS services are administered through a system of 12 Area offices and 170 IHS and tribally managed service units. In addition, 34 urban Native American health projects provide a variety of health and referral services. Annual Patient Services (Tribal and IHS facilities) are inpatient admissions: 39,305 and outpatient visits: 13,742,078 [35].

Of relevance to environmental health policy, the IHS notes that since 1960, more than 230,000 Native American homes have benefited from IHS funding of water and sewerage facilities, solid waste disposal systems, and technical assistance for operation and maintenance organizations. The IHS also observes that the age-adjusted death rate from gastrointestinal disease for Native Americans and Alaska Natives has decreased by more than 91% since 1955, the year the IHS was established [35]. Approximately 93% of Native American and Alaska Native homes have been provided sanitation facilities since the inception of an IHS sanitation construction program. The IHS also funds construction of new and replacement hospitals and ambulatory care facilities and staff quarters. Moreover, the IHS provides technical assistance to Native American tribes on such environmental problems as hazardous waste removal, water purification, and food safety.

3.4.5 National Institutes of Health

The National Institutes of Health (NIH), headquartered in Bethesda, Maryland, is the nation's premier resource in biomedical research. The NIH can trace its history to 1887, when Surgeon General John B. Hamilton established the Hygienic Laboratory, a one-room facility in the Marine Hospital on Staten Island, New York [9]. The early work of the laboratory was in the areas of bacteriology and pathology. In 1891, the Hygienic Laboratory was moved to Washington, DC, near the U.S. Capitol [36]. In 1902, Congress enacted legislation that increased the Hygienic Laboratory's authorities and resources, authorizing the establishment of divisions of chemistry, zoology, and pharmacology. These changes established a firm and necessary link between scientific research and public health practice. In 1930, Congress formally created the NIH, renaming the Hygienic Laboratory, and in 1938 the construction began of buildings on 45 acres of land in Bethesda, Maryland, acreage donated to the federal government.

NIH's mission "is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability" [37]. NIH comprises 27 different components called Institutes and Centers [38]. The 21 institutes comprise the NCI; National Eye Institute; National Heart, Lung, and Blood Institute; National Human Genome Research

Institute; National Institute on Aging; National Institute on Alcohol Abuse and Alcoholism; National Institute of Allergy and Infectious Diseases; National Institute of Arthritis and Musculoskeletal and Skin Diseases; National Institute of Biomedical Imaging and Bioengineering; National Institute of Child Health and Human Development; National Institute on Deafness and Other Communication Disorders; National Institute of Dental and Craniofacial Research; National Institute of Diabetes and Digestive and Kidney Diseases; National Institute on Drug Abuse; NIEHS; National Institute of General Medical Services; National Institute of Mental Health; National Institute of Neurological Disorders and Stroke; National Institute of Nursing Research; National Institute of Medicine; and the National Library of Medicine. As indicated by their titles, institutes have a focus on specific diseases or disorders. NIH's six centers are Center for Information Technology, Center for Scientific Review, Fogarty International Center, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, and the NIH Clinical Center [38]. The programs at two of the NIH institutes are relevant to environmental health policies, as described herein.

3.4.5.1 National Cancer Institute

The NCI is the foremost cancer research and services organization in the U.S. It was established by the National Cancer Institute Act of 1937, which was signed into law by President Franklin D. Roosevelt on August 5, 1937. The Act's purpose was stated to be "To provide for, foster, and aid in coordinating research relating to cancer; to establish the National Cancer Institute; and for other purposes" [39]. An appropriation of $700,000 for each fiscal year was authorized by the 1937 Act, an amount which is now less than many NCI grants awarded to individual cancer researchers. The NCI is headquartered in Bethesda, Maryland.

Of historical note, the NCI was the centerpiece of a Presidential political platform. In 1971, President Richard Nixon declared his initiative called *War on Cancer* and made it a priority for his administration. Other presidents have made similar political declarations, e.g., President Franklin Roosevelt's *New Deal*, President Kennedy's *Great Society*, and President Johnson's *War on Poverty*; however, Nixon's *War on Cancer* was the first and only declaration that focused solely on a public health issue. As background, on December 23, 1971, Nixon signed into law the National Cancer Act of 1971 [40], which initiated the National Cancer Program; authorized the establishment of 15 new research, training, and demonstration cancer centers; established cancer control programs as necessary for cooperation with U.S. state and other health agencies in the diagnosis, prevention, and treatment of cancer; and provided for the collection, analysis, and dissemination of all data useful in the diagnosis, prevention, and treatment of cancer, including the establishment of an international cancer data research bank. This act gave a major boost to the nation's fight against all forms of cancer.

NCI supports a broad range of research to expand scientific discovery at the molecular and cellular level, within a cell's microenvironment, and in relation to human and environmental factors that influence cancer development and progression [41]. As to environmental health, NCI supports investigations that include cancer-causing substances in the environment, radon and cancer, environmental carcinogens and cancer, the genetics of cancer, and cancer disparities [42].

Of special note to environmental health policy, NCI's Human Genetics Program provides an expanded focus for interdisciplinary research into the genetic determinants of human cancer, including research to explore and identify heritable factors that predispose to cancer, including studies of gene–environment interactions. This kind of research will provide a better understanding of why some people contract cancer from an environmental hazard, e.g., a carcinogen, while other persons exposed to the same hazard do not express disease.

To the extent that scientific knowledge accrues about the causes of human cancer, environmental health policy will benefit through more focused legislation and health services.

3.4.5.2 National Institute of Environmental Health Sciences

NIEHS began in 1966 as the Division of Environmental Health Sciences, NIH, by action of the Surgeon General. The division was housed on the main NIH campus in Bethesda, Maryland. That location was changed the next year when the state of North Carolina donated 509 acres within the Research Triangle Park, located in an area between Durham, Raleigh, and Chapel Hill, North Carolina, as the home for the fledgling division. The park was created during the administration of Gov. Luther Hodges, who later became Secretary of Commerce in the President John F. Kennedy administration. Through political lobbying by North Carolina State officials, including Hodges, the Division of Environmental Health Sciences was proposed as a key occupant of the new park. Environmental health lobbyists were also active in promoting the establishment of a federal government entity that could help develop a scientific database that would be needed to reduce the effects of environmental hazards.

NIEHS awards research grants to investigate environmental hazards, and conducts intramural research focused mainly on mechanisms of toxicity and related matters of basic science.

In 1969, the Division of Environmental Health Sciences was raised to institute status within the NIH structure and became the NIEHS [43]. Dr. Paul Kotin, the division director, was appointed as the first director of NIEHS, serving through part of 1971. NIEHS was, and remains, the only institute of NIH that is located outside the Bethesda, Maryland, area. Its headquarters are still located in Research Triangle Park, North Carolina.

The NIEHS administers a broad-based program of research grants to universities and other eligible organizations. The grants are principally investigator-initiated and determined through the traditional NIH approach of ranking of grant applications by expert committees composed of nongovernment

scientists. The NIEHS also conducts intramural research focused mainly on mechanisms of toxicity and related matters of basic science, e.g., the environmental genome project that is investigating human genes possibly responsible for how individuals react to specific environmental toxicants.

In addition, the NIEHS provides the scientific and administrative leadership within the DHHS for the National Toxicology Program (NTP). As related in Chapter 11 (Hazardous Chemical Substances), the NTP had begun as a program conceived and administered by the NCI, which was reacting to environmental and Congressional pressures to investigate the carcinogenicity of chemicals found in the general environment. NCI's response was a program largely devoted to testing specific toxicants for carcinogenicity, using laboratory animals under controlled exposure conditions. The testing was conducted by commercial toxicology testing laboratories, using a study protocol designed by NCI. Unfortunately for the NCI, one of the major contractors was found inadequate and their alleged poor quality work became the subject of critical news media reports and articles in prestigious scientific journals such as *Science*. Weary of the negative publication, the Secretary of DHHS transferred the NTP to the NIEHS for administration.

3.4.6 Office of the Assistant Secretary for Health, DHHS

From the establishment of the PHS in 1798 through the middle of the twentieth century, Surgeons General were the Service's directors. Throughout this span of time, Presidents appointed career PHS commissioned officers to the post of Surgeon General. Although career officers, strictly speaking, Surgeons General were political appointees appointed by the President with the advice and consent of the U.S. Senate. In a policy sense, political appointees are persons whose authorities are enhanced by such appointments. They are expected to do their designated duties, and at the same time, have access to political advice, support, and resources within the political structure of the administration in which they serve. At the same time, political appointees must not use political allegiance to override the duties and responsibilities of their office. As an example of the latter, during the first term of President Reagan's administration, political appointees were selected for purpose of *not* implementing the newly enacted CERCLAct. Congressional hearings led to perjury charges brought against one political appointee, who subsequently was incarcerated.

The ASH has had responsibility for PHS environmental health programs in both the context of organizational line authority as well as program advice. Concerning the former, PHS agencies' budgets, program progress, and policy issues were subject to review and approval by the ASH. The ASH's line authority was in effect from 1967 through 1995, when a Clinton administration reorganization of DHHS resulted in all PHS agencies reporting directly to the Secretary, DHHS. The ASH became the primary health advisor to the Secretary, along with the Surgeon General. Sometimes the position of Surgeon General was not filled; rather, the duties and responsibilities were assumed by the ASH.

Concerning environmental health policy, in 1973, ASH Charles Edwards created the *DHEW Committee to Coordinate Toxicology and Related Programs* (CCTRP).* It was established as a multi-agency group to provide a forum to assure exchange of information on toxicology and related programs, to coordinate these programs, to enhance sharing of resources, and to provide advice to the Department. Membership of the Committee was composed of the ASH; Director, Office of Program Operations, Office of the ASH; Director of NIH as well as Directors of several NIH components (NCI, National Institute of Environmental Health Sciences (NIEHS), National Institute of Mental Health, National Library of Medicine); Director of CDC, Commissioner of FDA and the Director of FDA'S NCTR. In 1978, ASH Julius B. Richmond expanded the membership of CCTRP to include liaison representatives from the CPSC, EPA, NSF, OSHA, Council for Environmental Quality, Library of Congress, Department of Energy (DOE), National Oceanographic and Atmospheric Administration, and the following components of the Department of Defense (DoD): Department of Army, Edgewood Arsenal, Navy Department, U.S. Army Environmental Hygiene Agency, and Wright-Patterson Air Force Base.

In 1979, ASH Richmond changed the committee's name to *DHEW Committee to Coordinate Environmental and Related Programs*. With the new name came an expansion in purpose that included "[i]nformation on environmental health, toxicology and related programs, to coordinate these programs […]. The Coordinating Committee shall interface these activities with other components of the federal government in areas of mutual interest and concern." In 1985, DHHS Secretary Margaret Heckler changed the name to the *DHHS Committee to Coordinate Environmental Health and Related Programs* (CCEHRP). Once again the role of CCEHRP was expanded, "[t]o coordinate and promote the exchange of information; to provide advice, review and, where needed, carry out processes and efforts which encourage a balanced, objective consensus on all environmental health-related research efforts, exposure assessments, risk assessments, and risk management procedures, and to serve as the primary focal point within the DHHS for information coordination within and outside the Department for all environmentally related issues."

In 1989, Assistant Secretary for Health, James O. Mason established CCEHRP as a standing committee of the PHS, to be chaired by the ASH, with a Vice Chair. In 1992, the committee was renamed the *Environmental Health Policy Committee*, but with the same membership, purposes, and advisory function.

Over the years, the Environmental Health Policy Committee and its predecessors provided a useful structure and forum for the debate of DHHS environmental policies and for consideration of emerging environmental issues.

* The authors are indebted to Ronald Coene, retired executive secretary of the CCEHRP, for supplying much of the information about the CCEHRP and its antecedent committees.

Although the Committee has been inactive since the year 2000, several of its reports remain of significance to environmental health policies remain available. These reports include *Environmental Diseases from A to Z* (released in 1999), *Review of Fluoride: Benefits and Risks* (1999), *A Primer on Health Risk Communication* (1998), *Drinking Water and Human Health* (1997), and *Multiple Chemical Sensitivity* (1998), all of which can be obtained from DHHS [44].

Perspective: The foregoing material about the historical role of the PHS (and the role of Surgeons General), the creation of the EPA, and the current environmental health programs of the agencies of DHHS was meant to provide perspective on how environmental health programs evolved at the federal level of U.S. government. As was described, the emergence of concerns for protection of natural resources and improved environmental quality moved legislators and policymakers to create new policies that ultimately reduced the environmental health role of the PHS, but preserving a role of biomedical research and public health services for federal public health agencies.

Whether or not the bifurcation of environmental health programs into those of environmental protection and public health research and services is the best arrangement for serving the U.S. public is a topic that remains current and somewhat contentious. Some environmental organizations have argued for a greater public health perspective at the EPA, particularly in regard to the adoption of risk assessment as the agency's policy to determine priorities and management strategies for environmental hazards. Other groups have questioned the role of PHS agencies in not being more involved in environmental risk management actions. This kind of debate is useful, if for nothing more than trying to best arrange federal resources meant to protect both the environment and human health.

3.5 OTHER U.S. FEDERAL ENVIRONMENTAL HEALTH PROGRAMS

In addition to DHHS, other federal departments also have environmental activities of relevance to public health. These programs are derived from federal laws specific to individual federal departments. As will be described, some environmental health programs, under a particular federal law, are shared between federal departments.

3.5.1 Department of Agriculture

The USDA was established in 1862, thereby being one of the federal government's oldest departments [45]. The current USDA administers programs and services that include concerns for the economic well-being of farmers and the health of consumers of farm products. These activities include farm price supports, food stamps for low-income citizens, loans to farmers, soil conservation, biological research, the grading and inspection of meat and other products, crop forecasting, crop insurance, and negotiations with foreign governments for trade in agricultural products [46].

The USDA is responsible for some programs pertinent to environmental quality and, thereby, the public's health. For example, USDA's Pesticide Data Program provides data on pesticide dietary exposure, food consumption, and pesticide usage. This program is of great public health importance, because it provides essential background exposure data that epidemiologists and others can use in health research on U.S. populations of interest. Food products such as fruit and vegetables, fruit juices, whole milk, grain, and corn syrup have been tested for the presence of approximately 40 pesticides [46].

Two other USDA programs, the Center for Animal Health Monitoring and the Food Safety Research program [46], are also pertinent to public health practice. The center collects national data and conducts studies on interactions among animal health, welfare, production, product wholesomeness, and the environment. Poor health of domestic and feral animals can be an important sign of potential human health problems. An example is the finding that fish and waterfowl in the Great Lakes region displayed abnormal sexual development, attributed to chemical contaminants in lake water, which led to investigations of human populations for signs of adverse health effects [47]. As to the Food Safety Research program [48], the USDA provides funds to universities to conduct research on laboratory and epidemiological methods that can be used in assuring food safety. The USDA also offers services to farmers on managing wastes from farms, use of pesticides and other farm chemicals, and conducts market basket surveys of food contaminants.

3.5.2 Department of Commerce

Created in 1903 as the Department of Commerce and Labor, the department was reorganized into the DoC in 1913. The Department promotes economic growth, advancements in technology, negotiates trade agreements with other countries, and provides the public with information on weather conditions and business conditions. The DoC contains the Bureau of Census, which is responsible for conducting the census of the U.S. population every 10 years, as required by the U.S. Constitution [49] and the Patent and Trademark Office, which performs the services implied by the office's title. The Department's International Trade Administration monitors, investigates, and evaluates foreign compliance with trade agreements, and provides advice and services to U.S. companies that have, or desire, international sales of goods and services.

Of particular note for environmental purposes, is the work of the National Oceanic and Atmospheric Administration (NOAA), which was established in 1970. NOAA has numerous statutory responsibilities that pertain to oceanic and atmospheric science and services. The responsibilities include coastal zone management, the management and conservation of resources within 200 miles of the U.S. coast, issuance of weather forecasts and warnings, the preparation of nautical aeronautical charts and other navigational aids; and the management of NOAA laboratories [50].

The work of NOAA has significant import for public health. For example, warnings of severe weather help prepare public health and emergency responders for their delivery of public services and for preparing hospital and other health care providers.

Of note for ecological health, NOAA Fisheries, also known as the National Marine Fisheries Service is responsible for the stewardship of the nation's ocean resources and their habitat. The agency provides services for the nation: productive and sustainable fisheries, safe sources of seafood, the recovery and conservation of protected resources, and healthy ecosystems. As described in Chapter 16, under the Marine Mammal Protection Act and the Endangered Species Act (ESAct), NOAA Fisheries works to recover protected marine species while allowing economic and recreational opportunities. The agency is responsible for programs that include: sustainable fisheries, protection of resources, habitat conservation, science and technology, international affairs, law enforcement, aquaculture, and seafood inspection [51].

3.5.3 Department of Defense

In 1945, following the end of World War II, the Department of Defense (DoD) was organized in 1949 as a result of the National Security Act of 1947. It replaced the Departments of War and Navy. The DoD has environmental responsibilities and programs that involve managing the natural resources under DoD's stewardship, remediating DoD contaminated waste sites, developing pollution prevention programs, and implementing occupational safety and health programs for the Department's civilian and uniformed personnel [52]. Individual military services have specialized environmental programs that meet specific needs in toxicology, industrial hygiene, radiation biology, and environmental health. For example, the U.S. Army's Ft. Detrick laboratory performs toxicological testing of substances of military interest. Other DoD programs deal with environmental hazards at military bases such as housing, repair shops, and weapons testing facilities. Also, the DoD gets involved with the environmental consequences of military actions. For example, the effects of chemical defoliants (e.g., Agent Orange) on Vietnam War veterans remain a subject of debate and final resolution as a matter of public health. Similarly, research on the adverse health effects experienced by some Gulf War veterans and health services for them is an active program in the Department.

3.5.4 Department of Energy

In 1973 the U.S. suffered through a national oil crisis due to withholding of crude oil supplies from international sources. This crisis led to Congressional action for consolidation of existing energy programs and policies. On August 4, 1977, President Jimmy Carter signed into law The Department of Energy Organization Act of 1977 (Pub.L. 95-91, 91 Stat. 565), which created the U.S. DOE. It consolidated the activities of the Energy Research and Development Administration (ERDA), the Federal Power Commission, the Federal Energy Administration (FEA), and elements of other agencies. The DOE has wide-ranging powers to set energy prices, enforce conservation measures, and allocate fuel. It is also empowered to engage in research on new sources of energy and direct nuclear-weapons research and development. The DOE conducts and sponsors research on alternative sources of energy (e.g., solar power) and is responsible for assessing and remediating DOE hazardous waste sites [53].

DOE's National Institute for Global Environmental Change supports work on human-induced influences on the environment. The institute was created by the Energy and Water Development Act of 1990. This effort is pursued by dividing the U.S. into six regions in order to study environmental change on different geographical and geological systems. Each region has a regional center, usually a university, which develops and administers research programs conducted by individual investigators through competition for grants. For example, carbon levels in Great Plains grasslands and coastal margin research in the west are two kinds of regional research studies [54].

The Center for Excellence for Sustainable Development provides educational materials to communities facing problems of congestion, urban sprawl, pollution prevention, and resource overconsumption. The materials describe how sustainable development can provide a framework under which community resources and infrastructure are used more efficiently, and economic development is enhanced.

The U.S. Human Genome Project, composed of the DOE and NIH Human Genome Programs, is the national effort to characterize all human genetic material by determining the complete sequence of the DNA in the human genome. As stated by the DOE, "[t]he ultimate goal is to discover all the more than 30,000 human genes and render them accessible for further study" [55]. The DOE Human Genome Program supports research projects at universities, DOE national laboratories, and other research organizations. Information from the Project will dramatically change almost all biological and medical research.

In another environmentally important program, DOE's Carbon Sequestration Program is addressing environmental problems caused by CO_2 emissions from widespread use of fossil fuels. To stabilize and then reduce this particular greenhouse gas's (GHGs) emissions and atmospheric levels will require the sequestration of carbon. This includes carbon capture, separation, storage, and reuse. This DOE program studies processes to capture CO_2 and carbon separation, possible storage of sequestered CO_2 in geological formations, injection of CO_2 into oceans, and other sequestration concepts. As discussed in Chapter 6, CO_2 is the most important GHG and therefore is strongly associated with concerns for global warming. Methods to reduce CO_2 emissions will have great significance for global environmental health and human health consequences. Lessened emissions will equate with improved environmental quality (e.g., lesser arid areas) and protection of human health (e.g., fewer heat-related illnesses).

3.5.5 Department of Homeland Security

The various cabinet level federal departments, with one exception, have evolved as products of normal growth in the U.S. sociopolitical structure. Some departments, such as the State Department, date from the early beginnings of the U.S. government. Others, e.g., the DOE, came into existence when the U.S. became more heavily involved in the development of energy policies and the need arose to control the production of nuclear weapons. In one instance, in a crucible of fear, a department was created relatively quickly, based on reaction to a catastrophic event.

In 2002, the Department of Homeland Security (DHS) was created in reaction to terrorists' attack on the U.S. On September 11, 2001, 19 terrorists hijacked four airliners; two planes carried out suicide attacks against the twin towers of the World Trade Center in New York City, a third plane struck the Pentagon in Arlington, Virginia, and the fourth plane crashed in a field in Pennsylvania. More than 3000 people were killed during the attacks, including in excess of 400 police officers and firefighters. This horrific event changed overnight the U.S. policy on protection against terrorists; changing from a policy of reaction to terrorist events to a policy of preemptive strikes against individual terrorists and groups and countries that support them, and domestic preparations to prevent terrorist attacks.

The Homeland Security Act of 2002 created the DHS. It consists of agencies, resources, and programs formerly in other federal departments, including the U.S. Coast Guard, Secret Service, Customs Service, Border Patrol, Transportation Security Administration, and parts of the Immigration and Naturalization Services. The stated mission of the department is, "Prevent terrorist attacks within the United States; reduce America's vulnerability to terrorism; and minimize the damage and recover from attacks that do occur" [56]. The emphasis of the department is clearly the prevention of terrorist acts against the U.S. public.

As to environmental health, the U.S. Coast Guard* has responsibility under the CERCLAct, as amended, for coordinating cleanups of emergency releases of hazardous substances into internal and external waterways of the U.S. They also are a member of the National Response Team and provide personnel to operate the National Response Center. The Coast Guard also provides education to mariners and recreational boaters on environmental hazards and management.

DHS has key shared responsibilities for implementing Presidential Policy Directive 21 (PPD-21), issued February 12, 2013 by President Obama, entitled "Critical Infrastructure Security and Resilience" [57]. This policy advances a national policy to strengthen and maintain secure, functioning, and resilient critical infrastructure. PPD-21 identifies 16 critical infrastructure sectors and their lead responsible federal agencies [58]. Of the 16, the following sectors are particularly relevant for environmental health:

- Chemical Sector: DHS is designated as the Sector-Specific Agency
- Dams Sector: DHS is designated as the Sector-Specific Agency
- Emergency Services Sector: DHS is designated as the Sector-Specific Agency
- Energy Sector: DOE is the Sector-Specific Agency
- Food and Agriculture Sector: USDA and DHHS are designated as the co-Sector-Specific Agencies
- Healthcare and Public Health Sector: DHHS is designated as the Sector-Specific Agency
- Nuclear Reactors, Materials, and Waste Sector: DHS is designated as the Sector-Specific Agency
- Water and Wastewater Systems Sector: EPA is designated as the Sector-Specific Agency

As an example of this sector, the 2015 Water and Wastewater Sector-Specific Plan developed jointly by DHS and EPA addresses risk-based critical infrastructure protection strategies for drinking water and wastewater utilities, regulatory primacy agencies, and an array of technical assistance partners. The Sector-Specific Plan describes processes and activities to enhance the security and resilience of the Sector's infrastructure [59].

3.5.6 Department of Housing and Urban Development

The Department of Housing and Urban Development (HUD) is the agency principally responsible for federal programs relating to housing and urban improvement. It was created by Congress in 1965. HUD's programs include mortgage insurance for home-buyers, low-income rental assistance, and programs for urban revitalization that are developed in conjunction with state and municipal authorities. HUD also administers the Lead Hazard Control program, which awards grants to states in order to eliminate lead hazards in low-income housing, promote educational programs, and conduct research [60]. This program includes funds for blood lead testing of children living in low-income housing, removal of lead-based paint from low-income housing, inspection of low-income housing for detection of lead hazards, community education and outreach, and job training for lead hazard control workers. HUD also administers a Healthy Homes Program, which funds local projects that address a multitude of health hazards in houses. According to HUD, the grants help develop cost effective methods for assessing and controlling hazards in low-income housing.

On December 2, 2016 HUD announced a ban on smoking in all U.S. public housing. The new rule, which will take effect in fall 2018, follows the department's 2009 move to encourage public housing agencies to adopt smoke-free policies. According to HUD, up to 228,000 public housing units already have smoke-free policies, and the new rule will expand the coverage to 940,000 public housing units [61].

* The Homeland Security Act of 2002 transferred the U.S. Coast Guard from the Department of Transportation to the Department of Homeland Security.

3.5.7 Department of Interior

Created in 1849, the DOI administers conservation programs, manages fish and wildlife resources, operates national parks and historic sites, assesses mineral resources and directs their management on federal lands. The DOI also administers programs for the interests of Indian and Alaskan Native Americans and the inhabitants of Pacific island territories that are under U.S. administration. Of particular relevance to the purposes of environmental health policymaking are three components of DOI.

3.5.7.1 U.S. Fish and Wildlife Service

The U.S. Fish and Wildlife Service (FWS) has responsibilities for conserving, protecting, and enhancing fish and wildlife and their habitats for the continuing benefit of the American public through federal programs relating to migratory birds, endangered species, interjurisdictional fish and marine mammals, and inland sport fisheries. As history, the Bureau of Sport Fisheries and Wildlife was created as a part of the FWS in DOI on November 6, 1956 by the Fish and Wildlife Act of 1956. That act was amended on July 1, 1974 by Public Law 93-271 to, among other purposes, abolish the position of Commissioner of Fish and Wildlife and designate the Bureau as the FWS.

According to the FWS, "The U.S. Fish and Wildlife Service has three basic objectives: (1) to assist in the development and application of an environmental stewardship ethic for our society, based on ecological principles, scientific knowledge of fish and wildlife, and a sense of moral responsibility; (2) to guide the conservation, development, and management of the nation's fish and wildlife resources; and (3) to administer a national program to provide the public opportunities to understand, appreciate, and wisely use fish and wildlife resources. These objectives support the Service mission of conserving, protecting, and enhancing fish and wildlife and their habitats for the continuing benefit of the American people" [62]. The agency has an important role in administering the Endangered Species Act (ESAct) of 1973, as discussed in Chapter 16.

3.5.7.2 Bureau of Land Management

The Bureau of Land Management's (BLM's) roots go back to the Land Ordinance of 1785 and the Northwest Ordinance of 1787. These laws provided for the survey and settlement of the lands that the original 13 colonies ceded to the federal government after the War of Independence. As additional lands were acquired by the U.S. from Spain, France, and Russia, Congress directed that they be explored, surveyed, and made available for settlement. In 1812, Congress established the General Land Office in the Department of the Treasury to oversee the disposition of these federal lands.

As the nineteenth century progressed and the nation's land base expanded further west, Congress encouraged the settlement of the land by enacting a wide variety of laws, including the Homesteading Laws and the Mining Law of 1872. These statutes served one of the major policy goals of the young country: settlement of the Western territories. The late nineteenth century marked a shift in federal land management priorities with the creation of the first national parks, forests, and wildlife refuges. By withdrawing these lands from settlement, Congress signaled a shift in the policy goals served by the public lands. Instead of using them to promote settlement, Congress recognized that they should be held in public ownership because of their other resource values.

In the early twentieth century, Congress took additional steps toward recognizing the value of the assets on public lands and directed the executive branch to manage activities on the remaining public lands. In 1946, the BLM was formed within the Department of the Interior. The BLM had no unified legislative mandate until Congress enacted the Federal Land Policy and Management Act of 1976.

The BLM's mission is stated as "To sustain the health, diversity, and productivity of America's public lands for the use and enjoyment of present and future generations." The agency administers more public land—more than 245 million surface acres—than any other federal agency in the U.S. Most of this land is located in the 12 western states, including Alaska and Hawaii. The BLM also manages 700 million acres of sub-surface mineral estate throughout the nation [63]. As presented in subsequent chapters, the BLM plays a role in administering police that affect U.S. energy development and a role in protecting endangered species.

3.5.7.3 U.S. Geological Survey

Prompted by a report from the National Academy of Sciences, the U.S. Geological Survey (USGS) was created, by a last-minute amendment, to an act of Congress on March 3, 1879. This occurred just a few hours before the mandatory close of the final session of the 45th Congress, when President Rutherford B. Hayes signed a bill appropriating money for sundry civil expenses of the Federal Government. The agency was charged with the "classification of the public lands and examination of the geological structure, mineral resources, and products of the national domain." This task was driven by the need to inventory the vast lands added to the U.S. by the Louisiana Purchase in 1803 and the Mexican–American War in 1848. The scientists of the USGS study the landscape of the U.S., its natural resources, and the natural hazards that threaten it. The organization has four major science disciplines, concerning biology, geography, geology, and hydrology. The USGS is a fact-finding research organization with no regulatory responsibility [64].

The USGS conducts several programs of direct relevance to the public's health [65]. For example, they have conducted surveys on the environmental occurrence and distribution of organic chemicals known to adversely affect human health. One USGS survey pertains to drinking water quality, collecting data on potential contamination sources and strategies to protect sources of drinking water. An example is the USGS survey of arsenic levels in groundwater supplies in southeastern Michigan.

3.5.8 Department of Justice

The Department of Justice (DOJ), established in 1870, is headed by the Attorney General. The Department is the federal government's legal office. It is responsible for the enforcement

of federal laws, represents the federal government in litigations, and gives legal advice to other federal departments and agencies. The DOJ represents the federal government in litigations that involve environmental health and protection law suits, e.g., representing EPA when that agency seeks to recover costs for remediating uncontrolled hazardous waste sites or for prosecuting violators of clean air regulations.

3.5.9 Department of Labor

The DOL was established in 1913 to foster, promote, and develop the welfare of the wage earners of the U.S., to improve their working conditions, and to advance their opportunities for profitable employment. Two components of DOL directly relate to environmental health policies in workplaces.

Congress created OSHA in 1970 under provisions of the OSHAct. OSHA was established to develop and enforce safety and health standards in workplaces [66]. The agency has statutory responsibilities under provisions of the OSHAct to develop, promulgate, and enforce (e.g., workplace inspections) regulations and standards to control hazards in U.S. workplaces. The hazards include chemicals, physical agents, biological agents, and workplace procedures such as construction work. OSHA has regulatory authority over workplaces covered under the act, generally excluding small businesses, self-employed individuals, and various government agencies.

Another DOL component, the Mine Safety and Health Administration (MSHA), derives its authorities from the Federal Mine Safety and Health Act of 1977 (more commonly called the Mine Act) [67]. MSHA develops mandatory safety and health standards applicable to both surface mines and underground mines. They are required to inspect mines two (surface) to four (underground) times annually, unless regulations direct otherwise; investigate mine accidents; review for approval mine operators' mining plans; and provide technical assistance and training to mine operators.

3.5.10 Department of State

The Department of State (DOS) is the oldest federal department, created by Congress in 1789 [68]. The department's current responsibilities include negotiating treaties between the U.S. and other countries, representing the U.S. in foreign countries, and developing and implementing policies on global affairs. Of note to environmental issues, the U.S. Agency for International Development (USAID) assists other countries in developing their national economies and improving quality of life [69]. Of importance to environmental policy, USAID encourages nations to take "[a]n integrated approach to natural resources management. Land and water must be managed skillfully so that they are able to maintain our basic ability to produce food for the nine billion people that the world is expected to have by 2050." Without calling it such, this is a statement of the policy of sustainable development.

3.5.11 Department of Transportation

The Department of Transportation (DOT) was established in 1966. DOT states its mission to be, "Serve the United States by ensuring a fast, safe, efficient, accessible and convenient transportation system that meets our vital national interests and enhances the quality of life of the American people, today and into the future" [70]. The major divisions of the DOT are the Federal Aviation Administration, the Federal Highway Administration, the Federal Railroad Administration, the Federal Transit Administration, the Federal Motor Carrier Safety Administration, and the National Highway Traffic Safety Administration. The DOT has responsibilities for interstate shipment of hazardous cargo, emergency response programs, and remediation of DOT hazardous waste sites.

The DOT administers several environmental programs of note. These programs reside in DOT's Federal Aeronautics Administration (FAA), the Office of Hazard Materials Safety, and the National Response Center. The Office of Hazardous Materials (HMS) develops and recommends regulatory changes in the transportation of hazardous materials (hazmat) and implements guidance for approved polices on hazmat transportation. The HMS Office also provides technical support about hazmat classes and their containment and packaging. It also supports hazmat research and development programs and develops hazmat safety training policies and programs [71].

The National Response Center serves as the sole national point of contact for reporting of all oil, chemical, radiological, biological, and ethological discharges into the environment anywhere in the U.S. and its territories. Among several duties, the Center (1) receives and relays reports of incidents reportable under the Hazardous Materials Transportation Act; (2) receives incident reports under the Federal Response System, which is supported under the CAAct, CWAct, Title III of the CERCLAct, as amended; and the Oil Pollution Act of 1990, relaying incident reports to the EPA for response; (3), for the Federal Emergency Management Agency, the NRC serves as a 24-h contact point to receive earthquake, flood, hurricane, and evacuation reports; and (4) releases of etiological and biological agents are received and referred to the Centers for Disease Control and Prevention for response.

The FAA's primary mandate is aircraft and flight safety, including domestic airport security. The FAA's Office of Environment and Energy develops models to assess airport air quality from aircraft engines. Another environmental problem, noise from aircraft landing or departing from airports, is not an FAA responsibility per se because aircraft schedules are the responsibility of the airlines. However, the FAA does have responsibility for certifying engine noise performance.

3.5.12 National Aeronautics and Space Administration

NASA is the federal agency responsible for the development of advanced aviation, space technology, and space exploration, which is NASA's program best known to the public. The

agency's origins can be traced to 1915, with the establishment of the National Advisory Committee for Aeronautics (NACA). Through the 1940s, this Committee established centers for aeronautical research and development. In order to better coordinate federal civilian aeronautics programs, the National Aeronautics and Space Act of 1958 transformed NACA into NASA and provided administrative structure for space research and exploration [72].

NASA's environmental programs of relevance to public health include agency activities to reduce environmental pollution from NASA activities; pursuing new technologies using environmentally benign substances and processes; and expanding the use of environmental monitoring systems in NASA programs. The agency conducts efforts to remediate hazardous waste sites that are their responsibility. NASA conducts intramural programs of research and supports extramural grant programs of relevance for improving environmental conditions. For example, the Ultra-Efficient Aircraft Engine Technology program has the goals to: increase performance of a wide range of revolutionary aircraft; address local air quality concerns by developing technology for reducing NO_x emissions from aircraft engines; and increasing engine performance to enable reductions in CO_2. Reductions in NO_x and CO_2 emissions from aircraft engines will contribute to lower ozone levels and reduced global warming, respectively. Both kinds of reduction will contribute to improved public health; the former to reduced respiratory disease and the latter to fewer heat-related illnesses.

3.5.13 National Science Foundation

The NSF is an independent federal agency, established in 1950, which reports to the U.S. President [73]. The agency supports basic and applied research through grants and contracts to universities and other research organizations. NSF activities related to environmental research and education involve support of basic disciplinary research, except biomedical research, which is funded by NIH; focused interdisciplinary research; and other environmentally relevant programs. The NSF supports a broad range of educational, international, and outreach functions that span a wide spectrum of environment and natural resources scientific interests.

One of the NSF's priority areas is biocomplexity in the environment (BE), a program that promotes new approaches to investigating the interactivity between biota and the environment. As stated by the NSF, "The key connector of BE activities is complexity—the idea that research on the individual components of environmental systems provides only limited information about the behavior of the systems themselves" [74]. Grants are awarded to research institutions in response to NSF applications for grant proposals. Another NSF program of relevance to human health is the U.S. Global Change Research Program. This program supports activities that range from international collaborative field programs for collection of data critical to the development, testing, and application of improved models encompassing various geographic and temporal scales, and research on human contributions and responses to global change.

Having discussed the environmental health programs within departments and agencies of the executive branch of government, it is time to consider how federal agencies develop rules and regulations that are mandated by individual environmental statutes.

3.6 ADMINISTRATIVE PROCEDURES ACT OF 1946

Before discussing the federal government's process for developing environmental health regulations, it will be important to understand how the public is involved in the process. When developing regulations and standards, regulatory agencies such as EPA and OSHA must follow the terms and conditions specified under the Administrative Procedures Act of 1946, as amended. This little known federal law, which is more than a half century old, establishes specific citizen rights to access government information of relevance, to participate in government decisions affecting them, and to legal accountability for the agencies' decisions [75]. This access provides citizens with the ability to obtain copies of federal government documents, using the Freedom of Information provisions of the Administrative Procedures Act, except for documents that are exempted from distribution, such as military or security documents. Even in those circumstances, a citizen can challenge the government through litigation in a federal court.

Prior to proceeding, two definitions are in order [76]. *Rule* means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy, and *rulemaking* means agency process for formulating, amending, or repealing a rule. More specific to the subject of regulations and standards, the Administrative Procedures Act requires that all federal agencies must comply with rulemaking procedures specified in the Act, which include the following:

1. Make documents available to the public.
2. Conduct meetings open to the public, having publish in advance of the meeting the date and location of such meetings.
3. Accept data from the public on matters relevant to rulemaking.
4. Publish proposed, revised, and final documents in the Federal Register.*

The Administrative Procedures Act of 1946, as amended, provides citizens and other interested parties a powerful access to government rulemaking procedures and the documents and public meetings that accompany rulemaking. Moreover, rulemaking that is not in compliance with the act can be litigated in federal courts.

* The *Federal Register* is the executive branch's newsletter. It contains announcements of federal agencies activities, such as public meetings. It is available on the Internet.

3.7 U.S. FEDERAL GOVERNMENT'S REGULATORY PROGRAMS

Federal agencies such as EPA, OSHA, and FDA and at least 50 others are called *regulatory agencies* because they are authorized by specific federal laws enacted by Congress to develop, promulgate, and enforce rules (i.e., regulations) that carry the full force of a law. Moreover, regulations can be the subject of judicial review and decision. In other words, Congress provides the regulatory tool chest from which executive branch agencies choose the tools to use; judicial review can decide if the tool chest and the ways the tools are used are lawful. Most federal government regulations fall into one or more of the five categories shown in Table 3.3 and discussed below [77].

Process requirements—These are regulations that control emissions from sources of pollution and usually require the use of performance standards for pollution control technologies. For example, the CWAct specifies that those who generate water contaminants must use the "best available technology" that is economically feasible before releasing the contaminants into U.S. bodies of water.

Product controls—These regulations control certain commercial products, including a product's design and potential uses. For example, the FDCAct authorizes the FDA to control prescription drugs and medical devices.

Notification requirements—These regulations require notification of government regulatory agencies and/or the public about a company's actions. For example, under Title III of the CERCLAct, companies that release pollutants into environmental media in excess of specified limits must report the nature and quality of contaminants to EPA and the public.

Response requirements—These regulations require that a federal regulatory agency be notified when emergency conditions occur. For example, the CWAct requires that emergency releases of chemical contaminants into bodies of water be reported to EPA or the U.S. Coast Guard, depending on whether the spill occurred on land or a body of water.

Compensation requirements—These are regulations that require an individual or business entity to reimburse the federal government for actions detrimental to the public's welfare. For example, as discussed in Chapter 12, the CERCLAct authorizes EPA to recover costs of remediating uncontrolled hazardous waste sites from those parties responsible for creating the waste site.

TABLE 3.3
Basic Forms of U.S. Federal Regulations

Process requirements
Product controls
Notification requirements
Response requirements
Compensation requirements

Source: Chemalliance, Environmental regulations, 2001, http://www.chemalliance.org/Handbook/background/back-detail.asp.

According to the OMB [78], an office of the White House, the history of federal regulation in the U.S. of certain areas of commerce and other social endeavors can be viewed as having occurred in four periods. In the first period, which preceded the mid-nineteenth century, the federal government had little to no involvement in what would be called today *regulatory authority*, other than the establishment of tariffs on goods brought into the U.S. and the imposing of taxes on various commercial activities. The prevailing philosophy was that commerce, in particular, should not be impeded by government control, and that states should have the primacy in determining where control (i.e., regulation) should be exerted on business, transportation, and other commercial enterprises.

In the second period of regulatory development in the U.S., which could be called the *commerce and banking* period and extending through the first three decades of the twentieth century, the U.S. federal government began regulating specific commercial activities, in particular, in the areas of banking and securities exchange. The third period occurred during the late 1960s and lasted for approximately a decade. This period might be referred as the *quality of life* period of government regulation. During this period, regulations emerged that provided consumer protections, improved environmental quality and better workplace protections.

The fourth period could be called *regulatory relief*, or deregulation. It is difficult to pinpoint when this period began, but perhaps the deregulation of the airlines during the Carter administration could be cited as the nascent beginnings of deregulation, i.e., the repeal or substantial rollback of an existing regulation. In this example, airlines in the U.S., which had had their ticket costs and air routes regulated by the Federal Aviation Administration, were permitted to set their own ticket costs and participate in commercial activities that had previously required federal government review and approval. The regulatory relief period perhaps began in earnest with the election in 1980 of President Ronald Reagan, whose campaign had stressed the need to lessen the "burden of government rules and regulations." A brief history follows of how federal government rules and regulations have evolved in the U.S. [78].

The Quality-of-Life regulatory period began in the late 1960s with the enactment of comprehensive, detailed legislation intended to protect the consumer, improve environmental quality, enhance workplace safety, and assure adequate energy supplies.

According to OMB, the oldest federal regulatory agency still in existence is the Office of the Comptroller of the Currency, established in 1863 to charter and regulate national banks [78]. However, federal regulation is usually dated from the creation in the late nineteenth century of the Interstate Commerce Commission (ICC), which was charged with protecting the public against excessive and discriminatory railroad rates. The regulation was economic in nature, setting rates and regulating the provision of railroad services. The

Commerce and Banking period of U.S. regulatory development began in the early twentieth century, with the creation of the Federal Trade Commission in 1914, the Water Power Commission in 1920 (later the Federal Power Commission), the Federal Radio Commission in 1927 (later the FCC), the Federal Reserve Board in 1913, the Tariff Commission in 1916, the Packers and Stockyards Administration in 1916, the Commodities Exchange Authority in 1922 and the FDA in 1931.

The Franklin D. Roosevelt administration was actively engaged in creating a variety of new regulatory programs [78]. Some of Roosevelt's New Deal economic regulatory programs were implemented by the Federal Home Loan Bank Board created in 1932, the Federal Deposit Insurance Corporation created in 1933, the Commodity Credit Corporation created in 1933, the Farm Credit Administration created in 1933, the Securities and Exchange Commission created in 1934, and the National Labor Relations Board created in 1935. In addition, the jurisdiction of both the FCC and the ICC were expanded to regulate other forms of communications (e.g., telephone and telegraph) and other forms of transport (e.g., trucking). In 1938, the role of the FDA was expanded to include prevention of harm to consumers in addition to corrective action. The New Deal also called for the establishment of an agency to enforce the Fair Labor Standards Act of 1938 by the DOL, which is now called the Employment Standards Administration.

The Quality-of-Life regulatory period began in the late 1960s with the enactment of comprehensive, detailed legislation intended to protect the consumer, improve environmental quality, enhance workplace safety, and assure adequate energy supplies. In contrast to the pattern of economic regulation adopted before and during the New Deal, new social regulatory programs tended to cross many sectors of the economy (rather than individual industries) and affect industrial processes, product designs, and by-products (rather than entry, investment, and pricing decisions). The consumer protection movement of that era led to creation of several agencies designed to improve transportation safety. They included the Federal Highway Administration (created in 1966), which sets highway and heavy truck safety standards; the Federal Railroad Administration (1966), which sets rail safety standards; and the National Highway Traffic Safety Administration (1970), which sets safety standards for automobiles and light trucks. Regulations were also authorized pursuant to the Truth in Lending Act, the Equal Credit Opportunity Act, the Consumer Leasing Act, and the Fair Debt Collection Practices Act. The National Credit Union Administration (1970) and the Consumer Product Safety Commission (1972) were also created to protect consumer interests [78].

In 1970, the EPA was created as part of an executive branch reorganization plan by President Richard M. Nixon in order to consolidate and expand environmental programs. This effort to improve environmental protection led also to the creation of the Materials Transportation Board (created in 1975) (now part of the Research and Special Programs Administration in the DOT and the Office of Surface Mining Reclamation and Enforcement (1977) in the Department of the Interior.

OSHA (created in 1970) was established in the DOL to enhance workplace safety. Major mine safety and health legislation had been passed in 1969, following prior statutes reaching back to 1910. The Pension Benefit Guaranty Corporation and the Pension and Welfare Administration were established in 1974 to administer and regulate pension plan insurance systems [78].

Also in the 1970s, the federal government attempted to address the problems of the dwindling supply and the rising costs of energy. In 1973, the FEA was directed to manage short-term fuel shortage. Less than a year later, the Atomic Energy Commission was divided into the ERDA and an independent Nuclear Regulatory Commission (NRC). In 1977, the FEA, ERDA, the Federal Power Commission, and a number of other energy program responsibilities were merged into the DOE and the independent Federal Energy Regulatory Commission.

Another significant regulatory agency, the USDA, has grown over time so that it now regulates the price, production, import, and export of agricultural crops; the safety of meat, poultry, and certain other food products; now including the regulatory work of the U.S. Forest Service (created in 1905), the Natural Resources Conservation Service (1935), the Farm Service Agency (1961), the Food and Consumer Service (1969), the Agricultural Marketing Service (1972), the Federal Grain Inspection Service (1976), the Animal and Plant Health Inspection Service (1977), the Foreign Agricultural Service (1974), the Food Safety and Inspection Service (1981), and the Rural Development Administration (1990) [78].

As stated by OMB, "The consequence of the long history of regulatory activities is that federal regulations now affect virtually all individuals, businesses, state, local, and tribal governments, and other organizations in virtually every aspect of their lives or operations. It bears emphasis that regulations themselves are authorized by and derived from law. No regulation is valid unless the Department or agency is authorized by Congress to take the action in question. In virtually all instances, regulations either interpret or implement statutes enacted by Congress. Some regulations are based on old statutes; others on relatively new ones. Some regulations are critically important (such as the safety criteria for airlines or nuclear power plants); some are relatively trivial (such as setting the times that a draw bridge may be raised or lowered). But each has the force and effect of law and each must be taken seriously" [78].

The federal government's process of making regulations, called rulemaking, proceeds along the following course.

1. Congress must enact legislation, signed into law by the President (or by way of overturning a Presidential veto), that requires a federal agency to develop and promulgate rules (i.e., regulations) specific to a particular Congressional concern. Such legislation is called *authorizing legislation* or *enabling legislation*. For example, the CAAct requires the EPA to

issue regulations for controlling levels of outdoor, ambient air pollutants. Congressional legislation often results from pressure that individuals or vested interest groups place upon members of Congress. The formal proceedings of Congress, including bills (i.e., draft legislation being considered by the House and/or Senate) that have been proposed or enacted by Congress, are published in the *Congressional Record*, the official journal of all actions taken by Congress.

2. The designated executive branch agency develops proposed regulations, following the requirements of the Administrative Procedures Act. In general, the agency must publish in the *Federal Register*, which is the federal government's journal of daily announcements, its intent to issue regulations in compliance with a specific statute. Meetings held during the rulemaking process must generally be open to the public. The public has the opportunity to submit data to the agency during the rulemaking process. Draft and final rules must be published in the *Federal Register* and on the agency's web site.
3. Final rules take effect upon publication in the *Federal Register*, but often provide a time schedule for compliance by the regulated community. For example, the EPA's regulations on underground storage tanks gave owners 10 years to inspect, repair, or replace their tanks. Final regulations are incorporated into the Code of Federal Regulations, which can be accessed through the Internet. Failure to be in compliance with a regulation can result in penalties that are specified in the enabling legislation.

3.8 SUMMARY

Described in this chapter are the roles of the PHS and EPA. The PHS, dating from the PHSAct, was the U.S. Government agency first tasked by Congress to investigate health hazards in water, air, food, and sanitation. During most of the first half of the twentieth century, states had primacy in controlling pollution and other environmental hazards within their borders. The PHS provided states with advice, services, and guidelines for controlling levels of contaminants in outdoor air, water supplies, and municipal waste. By the late 1960s, critics of the PHS approach of laissez-faire response to environmental hazards had begun to advocate for a regulatory approach to hazard control.

In 1970, the EPA was established by the Nixon administration, in effect, supplanting the PHS as the federal government's primary agency for protection of the environment and public health. This created a dichotomy of federal and state environmental protection agencies (with public health ethos) and public health agencies (with environmental hazards of interest). This awkward dichotomy has been replicated as policy by most U.S. states and some countries. The awkwardness derives from environmental regulatory agencies that have public health responsibilities, but without the requisite public health resources and experience. On the other side, some public health agencies have environmental health responsibilities, but without the necessary resources in environmental science and experience. This kind of dichotomy can produce uncoordinated programs of environmental research and services to the public.

As described in this chapter, in addition to the PHS and EPA, many other federal departments have environmental programs that impact segments of the U.S. public. These programs are agency specific and generally respond to statutory requirements such as hazardous waste management. Because federal statutes on control of environmental hazards are generally based on the development of environmental standards and regulation of environmental hazards, the chapter concluded with a discussion of the federal rulemaking process that must be followed when federal agencies develop regulations.

This and the preceding chapter have discussed how humankind has come to grips with the nature of environmental hazards, the evolution of environmental health, and the emergence of government as the key player in the control of environmental hazards and the process of policymaking. Given this background, the next chapter will begin a discussion of basic federal environmental statutes.

3.9 POLICY QUESTIONS

1. Assume that the traditional public health approach toward preventing disease and disability is through science (i.e., problem identification), consensus-formation (i.e., problem resolution), and services (to affected organizations and at-risk populations). Using this paradigm, discuss the current roles of any two agencies of the Department of Health and Human Services in preventing adverse health effects of environmental hazards.
2. Discuss the roles of public health agencies at the federal, state, and local levels. Is any more important than the other? Would you recommend any changes in how the delegation of roles of these three levels of public health? Provide details of your recommended changes, if any are recommended. If no changes are suggested, detail why you are satisfied with the current three-levels of public health practice.
3. Given the discussion about the historical role of the U.S. Surgeon General, discuss whether or not the Surgeon General's former primacy in public health leadership, including environmental hazards, should be restored.
4. Referring to Figure 3.2, describe how common law impacts environmental policies that affect you personally.
5. Assume that reports have arrived at the CDC and FDA of persons in the southeastern U.S. who have died from an unknown cause, accompanied by requests from several state health departments for federal investigation of possible food poisonings.

Further assume that CDC epidemiologists and FDA microbiologists have identified salmonella contamination of undercooked chicken as the cause of food illnesses, with a common factor of only one source of poultry supply. Given these circumstances, what federal departments are likely to take action?

6. Why did the U.S. PHS lose it primacy in leading the nation's environmental health programs? What could the Surgeon General have done to preserve PHS primacy?
7. The EPA's first Administrator, William Ruckelshaus, made enforcement of the EPA's federal regulations as his top priority. Assume that he had made science and services his first priority. Speculate on how the EPA might have evolved as a federal regulatory agency.
8. Referring to Figure 3.1, select any one of the three branches of the U.S. federal government and discuss some of its policymaking implications for environmental health policy.
9. In regard to environmental health, discuss the key differences between statutory law and administrative law.
10. Why do governments care about the public's health?
11. As a thought exercise, assume only local governments have the authority to enact environmental policies and that federal and state governments are denied by federal legislation to have any regulatory status. Discuss in an essay of appropriate depth how development of policy and enforcement might be affected by this kind of policy.
12. This chapter has discussed the structure and role of the federal judiciary. Federal judges are appointed for life terms, whereas members of Congress must be re-elected every few years and the U.S. president is bound by term limits. Using critical thinking, discuss in an essay of appropriate depth both the advantages and disadvantages of term limits for federal judges.
13. There have been occasional proposals that the EPA should be elevated to cabinet-rank status, e.g., Department of Environmental Protection or similar nomenclature. Discuss in an essay of appropriate depth the potential benefits and disadvantages of making such a change.
14. Amendments to the U.S. Constitution have occasionally occurred when significant social changes have occurred in the nation's social fabric. For example, the 19th amendment gave women the right to vote in U.S. elections. Assume that you are a member of the Right to Healthful Environment Society and your group desires to amend the Constitution in order to assure each American the right to a healthful environment. (a) Discuss the process of amending the Constitution. (b) Provide the language your group advocates for inclusion as the amendment.
15. Parliamentary forms of government were discussed in this chapter. The U.S.'s geographically closest parliamentary country is Canada. Using Internet resources, ascertain how environmental policymaking occurs at the federal level in Canada.
16. Review the structure and functional organization of the United Nations. Is it structured as a federation or confederation? Provide specifics in support of your analysis.
17. Discuss with you grandparents or with persons of similar age the times and social events in the U.S. during the decade of the 1960s. In their opinion what was the most significant event of that period and why?
18. Consider the cabinet-rank departments listed in Table 3.1. In your opinion, which one has the most significant environmental program that directly benefits you? Discuss in an essay of appropriate depth the basis for your selection.
19. Good news! Providence has smiled on you. You have been promoted to the position of director of the office of impenetrable regulations for unavoidable litigious encounters (OIRULE). Provide details on the requirements for federal rulemaking under the Administrative Procedures Act that you must follow.
20. Great work! You have completed Chapter 3. Discuss in an essay of appropriate depth the most important new information that you learned. Be sure to explain why this new knowledge is important to you.

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4 General U.S. Federal Environmental Statutes

4.1 INTRODUCTION

Commencing in the 1950s, a gradual awareness arose in the U.S. public's mind that environmental hazards might be harmful to human health, an awareness that helped in the enactment of various federal and state laws to control environmental hazards. The enactment of individual laws that now constitute the main body of U.S. federal environmental law has occurred over a half century of public concern, legislative enactment, executive branch implementation, and judicial interpretation. This body of law did not occur without heated debate and impassioned feelings. In particular, environmental groups and business organizations were often at odds as how to deal with specific environmental hazards, usually leading legislative bodies like the U.S. Congress to seek legislative language that negotiated the differences between business and environmental groups. This chapter will describe several general statutes of relevance to environmental health policies. Subsequent chapters will relate environmental health statutes to specific environmental hazards, e.g., air pollution.

Over the decades that began in the 1950s, environmental laws were enacted for reasons that differed across time. To be more specific, the impetus for legislation in the earlier years differed from what occurred later in the twentieth century. In particular, four conditions that contributed to the passage of specific environmental laws are listed in Table 4.1. The individual statutes identified primarily by abbreviations will be described in subsequent sections, but examples of the operative conditions shown in Table 4.1 are presented in the following sections.

4.1.1 Public Health Tradition

The earliest federal environmental legislation was drawn from the traditions of public health. This tradition comprised of conducting scientific research on specific environmental hazards and assessing the public health significance of scientific data, fostering consensus on the public health significance of scientific information, and providing services to states tasked with controlling environmental hazards. Legislation for the Clean Air Act (CAAct); Clean Water Act (CWAct); Safe Drinking Water Act (SDWAct); Federal Insecticides, Fungicides, and Rodenticide Act (FIFRAct); and Resource Conservation and Recovery Act (RCRAct) were developed through application of the public health tradition. For example, consider the example of the CAAct. As will be described in the following section, in 1955, the U.S. Congress enacted the Air Pollution Control Act, which provided the Public Health Service (PHS) with funds and authorities to research the effects of air pollutants on human health and to provide technical assistance to states' air pollution programs.

Over the next decade, Congress gradually gave the Surgeon General, as head of the PHS, additional authorities and resources to further investigate the effects of air pollution on human health and to commence the development of air quality standards. An advantage of this public health tradition as a foundation for environmental legislation is the development of a body of science that in turn guides specific statutory language. As policy, this is an early legislative example of what is now called the Precautionary Principle, which was discussed in Chapter 2. A disadvantage is the time required to develop both the body of science and infrastructure for providing services, most often to state health programs as part of a public health federalism compact.

Few concerns motivate elected officials as quickly as fear. No legislator or policymaker wants to be accused of ignoring conditions that could produce a catastrophic event.

4.1.2 Fear of Catastrophic Events

Few concerns motivate action by elected officials as quickly as fear. No legislator or other policymaker wants to be accused of ignoring conditions that could produce a catastrophic event. This is particularly true of catastrophes of anthropogenic cause. Consider the body of legislation that almost immediately followed the September 11, 2001 terrorist events that occurred in New York City, Washington, DC, and Pennsylvania. No member of Congress wanted to be accused of delaying legislation that would strengthen airport security, identification of terrorists, and improve the nation's resources in managing biological and chemical agents that could be used by terrorists.

A product of public fear can therefore be quickly enacted legislation that attempts to control a hazard before feared events occur. Perhaps the premiere example of federal environmental legislation is the the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLAct) also called the Superfund law. This law was enacted in response to the public's concerns that toxic waste was leaking into homes and environmental media (e.g., groundwater), exposing human populations to substances that could cause cancer, birth defects, and other fearful outcomes. These concerns were broadcasted and amplified by news media across the U.S. landscape. Because toxic waste was viewed as insidious,

TABLE 4.1
Impetus for Various U.S. Federal Environmental Statutes

Impetus	Environmental Statutes
Public health tradition	CAAct, CWAct, SDWAct, FIFRAct, RCRAct, FDCAct, FMIA, noise control
Fear of catastrophic events	CERCLAct, Oil Pollution Act, Medical Waste Tracking Act, Bioterrorism Preparedness Act
Opportunistic conditions	FMIA, NEPAct, Title III of CERCLAct, Information Quality Act
Confluence of special interests	FQPA, TSCA, OSHA

FMIA, Federal Meat Inspection Act; TSCA, Toxic Substances Control Act.

silent, and a threat to children, it was feared and characterized as such, even in the absence of causal scientific research. This means of legislative operation was clearly different from the public health tradition approach, where policy was based on a persuasive body of existing scientific data. However, using the limited scientific data available, Congress, in effect, acted upon the Precautionary Principle, concluding that the small amount of scientific data was adequate to enact precautionary legislation.

4.1.3 Opportunistic Conditions

Sometimes legislation occurs simply because the conditions were opportune. An example of such legislation is the Emergency Response and Community Right to Know Act of 1986, which is Title III of the CERCLAct. This act established community-based requirements for emergency response teams, requiring in particular, that local responders (often fire departments) be provided information by companies and others about hazardous materials stored on their premises. Such information provides emergency responders with advance information about chemicals that could be harmful to them and to communities if released into the environment. Further, Title III established the Toxics Release Inventory (TRI), an Environmental Protection Agency (EPA) database of substances released by industrial sources into the environment. Moreover, the act stipulates that the TRI be made available to the public, thereby providing the public with information that they could use in managing their own exposure to environmental hazards.

Passage of the Emergency Response and Community Right to Know Act had failed to gain Congressional support until 1986. While the act was strongly supported by national environmental groups and local government, business interests energetically opposed the legislation, objecting in particular to reporting of chemical stocks and releases to government agencies and the public. These objections were couched as trade secret information that if released could give competitors an edge in producing commercial products. However, supporters of the act were able to overcome these objections by attaching the act to the CERCLAct amendments of 1986. The public at that time remained very supportive of preventing releases from uncontrolled hazardous waste sites and emergency chemical releases were considered a similar chemical threat, albeit acute in nature. Support for the CERCLAct legislation was strong within Congress, and the conditions were opportune for attaching the Emergency Response and Community Right to Know Act to the Superfund Amendments and Reauthorization Act of 1986. What wasn't previously possible became possible when the act was piggybacked onto popular legislation that had broad-based support in 1986.

4.1.4 Confluence of Vested Interests

The election of Ronald Reagan as U.S. President in 1980 commenced two decades of political separation between the political party of the incumbents of the White House and the political party controlling the U.S. Congress. Republican Reagan served during a period when Democrats controlled both houses of Congress, as was the situation with President George H.W. Bush, a Republican. Similarly, commencing in 1994, Democrat Bill Clinton found himself working with a Republican-controlled Congress, a condition that continued for President George W. Bush until 2001, when Democrats regained control of the U.S. Senate. President George W. Bush is the exception, working with a Congress controlled by the Republican Party. A political consequence of this method of "separation of power" is the necessity for negotiation and compromise if legislation is to successfully navigate the political waters. Confluence of vested interests can assist in the legislative process.

The Food Quality Protection Act (FQPA) of 1996 is an example of legislation that resulted from the confluence of vested interests. Environmental groups and children's health advocates were concerned that America's young children were experiencing exposure to pesticides in food in amounts deleterious to their health. At the same time, producers of pesticides and related substances had long sought relief from the Delaney Clause,* a provision in the Food and Drug Act that required the Food and Drug Administration (FDA) to ban any carcinogen found added to food. The Delaney Clause became, in effect, an environmental health policy of zero cancer risk from carcinogens in food. The producers' prevailing attitude was that the Delaney Clause was inflexible and out of date, given the emergence of risk assessment as the principal method for determining the risk of environmental hazards. Although the interests of pesticide producers and environmental and children's health advocates were different, there was a confluence of desire to change how pesticides were regulated by the U.S. Government. This desire led to enactment, without a dissenting vote in

* Named after Congressman James Delaney (D-NY), who in 1958 authored an amendment to § 409 of the Food, Drug and Cosmetic Act, which stated "the Secretary shall not approve for use in food any chemical additive found to induce cancer in man, or, after tests, found to induce cancer in animals."

either the House of Representatives or Senate, of the FQPA of 1996. As will be subsequently described, this act materially altered federal pesticide statutes, which are described in Chapter 11.

4.2 REGULATIONS AND STANDARDS

Before launching into a presentation of the major federal environmental—or environmentally relevant—statutes and policies, it is useful to repeat some material from Chapter 2. In particular, the primary environmental health policy, command and control (also called regulations and standards), merits reiteration, since this policy is operative in many of the statutes to be discussed. In particular, the distinction between quality and emission standards needs elaboration.

As reminder, *quality standards* are the maximum levels of contaminants to be permitted in specific environmental media, such as air, water, and food. Quality standards are established by regulatory agencies through a process of review of scientific literature, risk estimation, and health impact. In distinction, *emission standards* prescribe the amount of contaminant discharges that can be released from significant emission sources, such as industrial facilities, municipal discharges into water, and landfills. It is important to understand the meanings of both kinds of standards and their essential interrelation.

Emissions standards and quality standards are essential partners for controlling environmental quality. Consider the simple act of showering. Assume that the temperature of the water is the quality factor to be controlled. Some persons prefer a tepid temperature; others find a hot shower to be preferable. The quality of the showering event can be controlled through setting of the water's temperature. A comfortable water temperature is therefore the quality standard. The quality standard in this example is based upon a set of data (i.e., previous showering) that was evaluated by a knowledgeable expert (i.e., the person showering). Water coming from the showerhead can be considered as the emission source. Its volume and temperature can be controlled to achieve the quality standard. As this example suggests, a quality standard is only a goal if an emissions standard is lacking.

While the showering example may be a simple illustration of the relationship between quality and emission standards, application of these standards to large geographic areas is very complex and challenging. Consider the problem posed by a regional air shed, i.e., a geographic area such as a city and its outlying metropolitan areas. Assuming that quality standards have been established for individual air pollutants (e.g., particulate matter), how can emission standards be established to control sources of pollution within the air shed? Setting emission standards to apply to an air shed requires authorities, normally state agencies acting under federal law (e.g., the CAAct), to identify sources of air pollution, to derive emission standards for polluting sources, and to work through a regulatory apparatus to implement the emission standards. The process is complicated by uncertainties in characterizing sources of pollution and computer modeling of air shed pollutants. Moreover, producers of pollution will resist those emission standards they consider as too costly. Protracted litigation is often the result.

4.3 ENFORCEMENT AND PENALTIES

Federal statutes that require U.S. federal agencies to develop regulations, standards, and control of environmental hazards in general also contain enforcement authorities. The enforcement authorities are normally accompanied by penalties for failure to comply with specific statutory requirements. For example, under the CAAct, §113, the EPA is authorized, in ascending order of severity, to (1) issue an administrative penalty order, (2) issue an order of compliance, (3) bring a civil action, or (4) request the U.S. Attorney General to commence a criminal action. Examples of EPA enforcement actions and penalties are found in Chapters 8 through 12. The examples are given for the purpose of showing the seriousness of federal enforcement authorities and illustrate the civil (monetary penalties) and criminal (felony actions) consequences of failure to meet statutory directives.

Having discussed how federal environmental legislation has evolved according to the conditions of the times and a brief discussion of regulations and standards, the following sections will describe some of the U.S. federal statutes that contain broad environmental health purposes and policies, together with statutes that are important for understanding larger policy issues such as information quality. The nine federal statutes that follow in this section are presented in an ascending order by year of congressional enactment. A perusal of the years of enactment shows that six of the nine laws were enacted during the 1960s and 1970s, a period of considerable congressional interest in environmental concerns. Moreover, several of the major environmental statutes, as described in subsequent chapters, were also enacted during this same time span. Ensuing chapters of this book will describe the key federal environmental statutes that address air pollution, water quality and security, food safety and security, waste management, toxic substances and pesticides, as well as statutes that pertain to endangered species, tobacco products, climate change, genetically modified organisms, and environment-related diseases. Each statute or emerging policy is described in terms of its history, key provisions pertinent to public health, and public health and ecosystem impacts.

4.4 PUBLIC HEALTH SERVICE ACT, 1912

Protection of the American population's health has not always been a concern of the U.S. federal government. Not until the early twentieth century did the U.S. Congress commence the acts of legislation that were purposed for protecting the health of the nation's residents. Of the various acts, none was more important for the public health than the PHSAct, which will be described in this section.

4.4.1 History

The PHSAct and subsequent revisions constitute the basis for several environmental health programs. As background, prior to 1912, the Marine Hospital Service, formed in 1870, provided health care for merchant mariners and gradually expanded its services over the next 30 years. These expanded services included the control of infectious disease and quarantine responsibilities. In 1912, Congress enacted the PHSAct, which brought under one statute the various federal health authorities and programs. As described by a PHS historian, "The PHSAct made explicit what had been an increasingly important element of the work of the Service from 1887 when the Hygienic Laboratory opened—the all-out exploration of disease in the laboratory and in the field" [1]. The PHSAct and its subsequent numerous amendments are the bedrock federal public health legislation, whose various authorities impact the full breadth of the U.S. society. The act of 1912 consisted of only two brief sections. § 1 of the act is relevant to environmental health concerns. The language of that section follows [2].

"AN ACT To change the name of the Public Health and Marine-Hospital Service to the Public Health Service, to increase the pay of officers of said service, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress Assembled, That the Public Health and Marine-Hospital Service of the United States shall hereafter be known and designated as the Public Health Service, and all laws pertaining to the Public Health and Marine-Hospitals Service of the United States shall hereafter apply to the Public Health Service, and all regulations now in force, made in accordance with law for the Public Health and Marine-Hospital Service of the United States shall apply to and remain in force as regulations of and for the Public Health Service until changed or rescinded. The Public Health Service may study and investigate the diseases of man and conditions influencing the propagation and spread thereof, *including sanitation and sewage and the pollution either directly or indirectly of the navigable streams and lakes of the United States* (emphasis added), and it may from time to time issue information as publications for use by the public."

The PHSAct and its subsequent numerous amendments are the bedrock federal public health legislation, whose various authorities impact the full breadth of the U.S. society.

The PHSAct of 1912 was significant in regard to environmental health policy and practice. For example, the act authorized surveys and studies of the impact of water pollution on human health. The act further directed the PHS to develop the first national water standards [3], which materialized in 1914. The standards introduced the concept of maximum contaminant limits for drinking water supplies. However, because they were intended to protect the traveling public, the standards applied only to water supplies that served interstate transportation [3]. These fledgling steps to establish national water quality standards did not lead to true national standards for another 60 years when Congress enacted the SDWAct of 1974.

The same act also initiated the first federal policy concerning the disposal of human wastes. The act provided technical advice and assistance to communities and commenced federal support for research and technical studies on the sanitary disposal of human wastes. Sanitary disposal of human wastes, like protecting the quality of drinking water, was a public health success, eliminating one major source of disease-producing pollution in the environment. The policy of federal involvement in reducing or preventing environmental hazards in states and local communities was wise and timely, although not without some opposition by those who maintained these responsibilities lay exclusively with the states. That federal-state argument over jurisdiction continues today, a product of the U.S. Constitution which limits the role of federal government and assigns to states those responsibilities not specifically specified as federal authorities in the U.S. Constitution. Federal court decisions over the years have elaborated and further defined the roles of federal government and state/tribal governments, generally holding that the federal government has primacy on matters of environmental pollution.

The 1912 PHS legislation remained intact until the years preceding World War II. Some members of Congress and the PHS leadership—in particular, Surgeon General Thomas Parran—foresaw the need to reorganize the country's health resources in advance of a likely global war. Two acts of Congress reshaped the PHS and the nation's health needs [4]. Congressman Alfred Bulwinkle (D-NC) and Senator Elbert Thomas (D-UT) were the leaders in Congress who spearheaded the legislation. The first act, signed into law in November 1943, organized the PHS Commissioned Corps along military lines and cobbled PHS functions into four subdivisions: the National Institute of Health, the Office of the Surgeon General, the Bureau of Medical Services, and the Bureau of State Services.

The second act, signed on July 3, 1944, was of great significance for the PHS's future. It codified all of the PHS's responsibilities and further strengthened the role of the Surgeon General in public health policymaking [4]. According to Snyder [4], the act of 1944 established the PHS Commissioned Corps as the leadership cadre of the PHS and included "[f]inancial, technical, and advisory support to State and local health departments, the funding of extramural research through grants-in-aid, the provision of construction funds for hospitals and other facilities, and continued clinical services for a wide range of federal beneficiaries." The act also expanded the PHS tuberculosis program to include support to state and local health departments.

4.4.2 Key Provisions of the PHSAct Relative to Public Health

The PHSAct of 1944 became the framework upon which the modern public health programs in the U.S. are built.

Various environmental health programs are authorized and funded through the PHSAct, as was discussed in Chapter 3. These include programs of biomedical research at the National Institute of Environmental Sciences, National Cancer Institute, and the FDA; the Center for Disease Control and Prevention (CDC) surveillance of environmental exposures to toxicants and health effects of environmental hazards; and toxicity testing programs under the auspices of the National Toxicology Program. Environmental education programs, physician education credits, and grants to states for their environmental health programs (e.g., exposure to lead prevention efforts) are other examples of environmental health programs funded through the PHSAct, as amended.

4.5 NATIONAL CONTINGENCY PLAN, 1968

Of relevance to several federal statutes to be subsequently discussed, the National Oil and Hazardous Substances Pollution Contingency Plan, more commonly called the National Contingency Plan (NCP), is the federal government's blueprint for responding to both oil spills and hazardous substance releases. The NCP resulted from efforts to develop a national response capability and promote overall coordination among the hierarchy of government and private sector emergency responders and contingency plans [5].

According to the EPA [5], the first NCP was developed and published in 1968 in response to a massive oil spill from the oil tanker *Torrey Canyon*, which had ruptured off the coast of England the prior year. More than 37 million gallons of crude oil spilled into the water, causing massive environmental damage. To avoid the problems faced by European response officials involved in the incident, U.S. officials developed a coordinated approach to cope with potential spills in U.S. waters. The 1968 plan provided the first comprehensive system of accident reporting, spill containment, and cleanup, and established a response headquarters, a national reaction team, and regional reaction teams, which are now called the National Response Team and Regional Response Teams.

The National Contingency Plan is the federal government's blueprint for responding to both oil spills and emergency releases of hazardous substances.

Over the ensuing years, Congress has broadened the scope of the NCP. As required by the CWAct of 1972, the NCP was revised the following year to include a framework for responding to hazardous substance spills as well as oil discharges. Following the passage of the CERCLAct in 1980, the NCP was broadened to cover releases from those hazardous waste sites that require emergency removal actions. Over the years, additional revisions have been made to the NCP to keep pace with the enactment of legislation. The latest revisions to the NCP were finalized in 1994 in order to reflect the oil spill provisions of the Oil Pollution Act of 1990. The details of the NCP can be found elsewhere [5], but include provisions such as establishment of the National Response Team, establishment of the Regional Response Teams, establishment of general responsibilities of federal on-scene coordinators, the provision of funding for responses under the Oil Spill Liability Fund, and authorization of the lead agency to initiate appropriate removal action in the event of a hazardous substance release.

As environmental health policy, the NCP provides the means, resources, and legal framework to quickly respond to emergency conditions that involve the release of oil or hazardous substances. Because the NCP is based on law, it brings together the coordination between federal government agencies and others in order to protect the public's health and the well-being of ecosystems. Yoking government agencies in legally binding ropes of coordination serves the public well, since such cooperation is often difficult to achieve in the absence of law due to bureaucratic inertia and uncertainty of legal authority.

4.6 NATIONAL ENVIRONMENTAL POLICY ACT, 1969

The National Environmental Policy Act (NEPAct) is a relatively brief, concise statute that articulates U.S. national policy on the environment and establishes goals for federal programs in terms of their impact on the environment.

4.6.1 History

The NEPAct is an administrative procedures act, that is, it directs federal executive agencies to do specified actions. One source considers the NEPAct to have had a profound impact in the sense that the act focused the U.S. federal government's attention on environmental consequences and forced government agencies to assess the impact of their actions on the environment [6]. Of note, the NEPAct's concepts have been emulated by many state statutes and some national governments.

The NEPAct created the Council on Environmental Quality (CEQ) and requires federal agencies to prepare environmental impact statements.

According to one source, "Few statutes of the United States are intrinsically more important and less understood than is the National Environmental Policy Act of 1969" [7]. The basis for this assertion is the fact that the NEPAct firmly established the nation's endorsement of the importance of environmental quality and protection. Further, the NEPAct established the policy of individuals' responsibility, "[e]ach person should enjoy a healthful environment and that each person has a responsibility to contribute to the preservation and enhancement of the environment" [7].

According to Caldwell [7], the enactment of the NEPAct was the culmination of 10 years of effort in Congress, which began in 1959, when Senator James E. Murray (D-MT) introduced the Resources and Conservation Act in the 86th Congress. Murray's bill contained several provisions that

were ultimately included in the NEPAct, including a declaration of national environmental policy, the creation within the Executive Office of the President of an advisory CEQ, and the preparation of an annual report on the nation's environmental quality. Congressional hearings in 1960 on Murray's bill were important because they brought forward dialog on protecting the environment.

As noted by Caldwell, "environment," as understood today, had very limited meaning prior to the 1960s [7]. The prevailing perspective was conservation of natural resources, with recognition of an endangered environment only slowly emerging in the early 1960s. Murray's bill was opposed by the Eisenhower administration, by many federal agencies, and by business trade associations. This opposition stemmed from the Eisenhower administration's general reluctance to expand the role of federal government, federal agencies' fear of loss of authorities and resources, and recognition by business groups that the Murray bill might have an deleterious economic impact on them [7].

Following the failure of Murray's bill to get sufficient Congressional support to enable its passage, alternative bills on the environment were introduced during the 1960s. During this period, the environmental movement began coming to the forefront, supporting congressional efforts to protect the environment. Moreover, a scientific literature, which had begun in the 1930s, increased in amount and gravity of findings through the 1960s. This literature, which included *Silent Spring* by Rachel Carson [8] and *The Quiet Crisis* by Stewart Udall (D-AZ) [9], helped raise an environmental awareness by the U.S. public and the public's political representatives. In particular, *Silent Spring* made environmentalism a middle-class issue. Carson's book described in detail how Dichlorodiphenyltrichloroethane (DDT) enters the food chain and accumulates in the fatty tissues of animals and humans. She concluded that DDT and other pesticides had poisoned the world's food chain. The book was widely circulated and engendered environmental concerns in people who had moved from cities to suburban areas in search of better environmental conditions. Environmentalism was no longer simply a concern only to conservation groups; the new environmental movement was focused on environmental quality and protection. This wider interest soon became apparent to elected officials and contributed to legislative support for new, more protective environmental policies.

In 1966, Senator Henry Jackson (D-WA) and Congressman John Dingell (D-MI) prepared bills on environmental policy that included several features of the Murray bill of 1959. These legislative efforts came to fruition in December 1969 when both houses of Congress passed a House-Senate conference bill, resulting in enactment of the NEPAct. President Richard Nixon signed the act into law on January 1, 1970. With Nixon's signature came fulfillment of a decade's labor in Congress to make environmental protection a matter of national policy.

The NEPAct states four important purposes: (1) to declare a national policy that will encourage productive and enjoyable harmony between man and his environment, (2) to promote efforts that will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man, (3) to enrich the understanding of the ecological systems and natural resources important to the nation, and (4) to establish a CEQ.

Concerning national policy the act states, "The Congress, recognizing the profound impact of man's activity on the interrelations of all components of the natural environment, particularly the profound influences of population growth, high-density urbanization, industrial expansion, resource exploitation, and new and expanding technological advances and recognizing further the critical importance of restoring and maintaining environmental quality to the overall welfare and development of man, declares that it is the continuing policy of the Federal Government, in cooperation with state and local governments, and other concerned public and private organizations, to use all practicable means and measures, including financial and technical assistance, in a manner calculated to foster and promote the general welfare, to create and maintain conditions under which man and nature can exist in productive harmony, and fulfill the social, economic, and other requirements of present and future generations of Americans."

4.6.2 Key Provisions of the NEPAct Relevant to Public Health

The NEPAct comprises two titles [10].

Title I—*Congressional Declaration of National Environmental Policy*—states, "[i]t is the continuing responsibility of the Federal Government to use all practicable means, consistent with other essential considerations of national policy, to improve and coordinate Federal plans, functions, programs, and resources to the end that the Nation may

1. fulfill the responsibilities of each generation as trustee of the environment for succeeding generations*;
2. assure safe, healthful, productive, and aesthetically and culturally pleasing surroundings for all Americans;
3. attain the widest range of beneficial uses of the environment without degradation, risk to health and safety, or other undesirable and unintended consequences;
4. preserve important historic, cultural, and natural aspects of our national heritage, and maintain, wherever possible, an environment which supports diversity and variety of individual choice;
5. achieve a balance between population and resource use which will permit high standards of living and a wide sharing of life's amenities†; and
6. enhance the quality of renewable resources and approach the maximum attainable recycling of depletable resources."

* This statement can be construed as an early commitment to what is now called the *Precautionary Principle*.

† This statement can be construed as an early commitment to what is now called *Sustainable Development*.

Title I also requires that an environmental impact statement (EIS) must be prepared by all agencies of the federal government to "[i]nclude in every recommendation or report on proposals for legislation and other major federal actions significantly affecting the quality of the human environment." The EIS is to include: "[a] the environmental impact of the proposed action, [b] any adverse environmental effects which cannot be avoided should the proposal be implemented, [c] alternatives to the proposed action, [d] the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and [e] any irreversible and irretrievable commitments of resources which would be involved in the proposed actions should it be implemented [10]". The EIS process involves participation and review at all levels of federal government and allows interested public groups to be involved.

Title II—*Council on Environmental Quality*—creates the CEQ, which is placed in the Executive Office of the President, and defines its responsibilities. The CEQ is to assist and advise the President in the preparation of an annual Environmental Quality Report to Congress. The report must include (1) the status and condition of the major natural, man-made, or altered environmental classes of the nation; (2) current and foreseeable trends in the quality, management, and utilization of such environments; (3) the adequacy of available natural resources; (4) a review of government and nongovernment programs as to their effect on the environment and on the conservation, development, and utilization of natural resources; and (5) a program for remedying the deficiencies of programs, together with recommendations for legislation [10]. In addition, CEQ advises the President on policies and legislation, gathers timely information concerning trends in environmental quality, and conducts studies related to environmental quality and ecological systems.

Technical amendments to the NEPAct occurred in 1970, 1975, and 1982. Of note, the Environmental Quality Improvement Act of 1970 established the Office of Environmental Quality within the Executive Office of the President. The director of the Office is stipulated to be the Chairman of the CEQ. The Office is authorized to conduct administrative actions and information collection attending the responsibilities of the CEQ.

In a more practical context, the White House's CEQ provides political leadership on environmental issues, including environmental health. The council interacts with federal agencies and private sector organizations to help shape environmental policies and represents the administration in interactions with the Congress. In theory, the CEQ is an advocate for an administration's policies and practices on environmental affairs.

4.6.3 Public Health Implications of the NEPAct

In a policy sense, the public health implications of the NEPAct are found in statements of purpose in the act's Title I:

"2. Assure safe, *healthful* (emphasis added), productive, and aesthetically and culturally pleasing surroundings for all Americans;
3. Attain the widest range of beneficial uses of the environment without degradation, *risk to health* (emphasis added) and safety, or other undesirable and unintended consequences."

These two statements codify in law the nation's commitment to preventing adverse health effects from environmental hazards. The public's health, it can be argued, must be preserved and the NEPAct serves as an anchor for this protection.

4.7 OCCUPATIONAL SAFETY AND HEALTH ACT, 1970

Unsafe work conditions can cause workplace injuries and lack of adequate industrial hygiene can contribute to some workers' diseases. The primary U.S. federal legislation that addresses workplace safety and health issues is the Occupational Safety and Health Act (OSHAct) of 1970, as described herein.

4.7.1 History

The Occupational Safety and Health Act requires OSHA to develop and enforce workplace standards and the National Institute for Safety and Health to research and investigate workplace hazards.

Workers' health and safety have been concerns of long standing. Since antiquity, the nature of human activity called work has always had the potential to cause harm to those who do it. Our earliest human ancestors, whether stalking feral animals for food or growing grain for consumption, were subject to injury from predatory animals, wildfires, and traumatic events. As agriculture became the principal commercial human endeavor, farm workers fell victim to injuries caused by domestic animals, farm equipment, and weather hazards.

The Industrial Revolution replaced agriculture as the main economic engine in most countries. This development brought new kinds of hazards to workers, who found themselves subjected to chemicals (e.g., tars, solvents, metals), physical agents (e.g., heat, noise), particulates (e.g., soot, silica), and musculoskeletal trauma (e.g., loss of limbs, lower back disorders). As the Information Age gradually succeeded the Industrial Age, computer-based technology and information management brought their own kind of workplace problems, including musculoskeletal disorders (e.g., carpal tunnel syndrome) associated with repetitive body motion from work at computer keyboards, eyestrain from staring at video displays, and stress from challenging work schedules and economic pressure.

In the U.S., workplace safety became an issue with trade unions in the 1930s. Improved workplace conditions, job security, better pay, and other benefits were cornerstones for

organized labor's bargaining in the U.S. Organized labor, as it grew in national political influence, lobbied Congress to enact legislation to protect workers' safety and health. These efforts, usually opposed by trade associations and business interests, culminated in the passage of the OSHAct of 1970.

The OSHAct was the first U.S. federal legislation to deal comprehensively with health and safety problems in the workplace. The declared purpose and policy of the statute is "[t]o assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources" [11]. To effectuate this goal, the OSHAct created three new government agencies. OSHA, which was placed in the Department of Labor, is directed to develop workplace safety and health standards, conduct workplace inspections, enforce regulatory actions developed by the agency, help set up state occupational safety and health programs and monitor their effectiveness, and conduct education and training programs for safety and health professionals. As discussed in Chapter 3, the National Institute for Occupational Safety and Health (NIOSH) was placed in the Department of Health, Education, and Welfare, which became the Department of Health and Human Services (DHHS) in 1979. NIOSH is tasked with conducting scientific research, performing workplace health evaluations, and developing criteria documents that contain recommendations for safety and health exposure conditions. The third agency created by the OSHAct is the Occupational Safety and Health Review Commission, which was established to adjudicate disputes arising from enforcement of the act.

The most consequential OSHA responsibility under the OSHAct is the development and promulgation of safety and health standards. This is done through regulatory action, taking into account all relevant scientific information and public concerns. OSHA standards affect most workplaces, large and small. Employers convicted of willful violation of OSHA standards can face civil or criminal penalties, depending on the seriousness of the infraction. OSHA's inspectors conduct inspections of workplaces to assess compliance with OSHA safety and health standards. Since 1977, OSHA has attempted to direct most of its inspections toward high-hazard industries—construction, petrochemicals, and manufacturing [13]. Where no specific standards exist for a workplace condition, the OSHAct directs each employer to provide "[a] place of employment which is free from recognized hazards that are causing harm to employees." This "general duty" clause is used by OSHA to control workplace hazards that are obvious and for which no specific standard exists [11, 12].

An OSHA standard of particular importance is the Hazard Communication Standard (HCS). This standard covers more than 32 million U.S. workers exposed to an estimated 650,000 hazardous chemicals in all industrial sectors [13]. It requires that the hazards of all chemicals imported into, produced or used in U.S. workplaces are evaluated and that the hazard information is disseminated to affected employers and exposed employees. The hazard information is conveyed by means of labels on containers and material safety data sheets (MSDSs). All employers covered under the HCS must have a communications program that includes labels on containers, MSDSs, and employee training [13]. One organized labor source considers it the most significant job safety and health regulatory action ever adopted [11]. The HCS is known as the "Right-to Know" standard and its concept has been widely adopted by numerous states and some local governments.

Language related to waste management is found in the 1986 amendments to the CERCLAct, which directs OSHA to promulgate standards for the health and safety protection of employees engaged in hazardous waste operations. The CERCLAct amendments stipulate that the OSHA regulations pertaining to hazardous waste workers must include the following: (1) site analysis (each hazardous waste site is to have a specific plan for worker protection), (2) training requirements for contractors to provide workers with training in hazardous waste operations, (3) medical surveillance of workers, (4) protective equipment requirements, (5) engineering controls concerning the use of equipment, (6) maximum exposure limits for workers, (7) information programs informing workers of hazards, (8) handling of hazardous waste, (9) new technology that would maintain worker protections, (10) decontamination procedures, and (11) emergency response requirements [10]. The subject OSHA regulations were promulgated in final form in 1990.

The OSHAct of 1970 was amended in 1990 by Public Law 101–552 and in 1998 by Public Laws 105–198 and 105–241. The 1990 amendments raised OSHA fines sevenfold over their corresponding amounts specified in 1970 [14]. The amendments in 1998 required: (1) the Secretary of Labor to establish a program under which employers may consult with state officials in respect to compliance with occupational safety and health requirements, and (2) directed the Secretary of Labor not to use the results of enforcement activities to evaluate employees directly involved in enforcement activities under the OSHAct or to impose quotas or goals with regard to the results of such activities. Other amendments have been for the purpose of clarifying specific sections of the act.

4.7.2 Public Health Implications of the OSHAct

Job-related deaths are normally separated into two categories: (1) deaths due to workplace injuries and (2) deaths attributable to occupational diseases. The former includes deaths due to causes such as electrocutions, motor vehicle accidents, falls, homicides, and machinery-related events. The latter category includes deaths due to diseases such as asbestosis, silicosis,* and cancer. According to the CDC, in 2008, an estimated 3.7 million workers in private industry and 940,000 in state and local government had a nonfatal occupational injury or illness; 40–50% of these workers were transferred, placed on work restrictions, or took time away from work. In that year, a total of 5071 U.S. workers died from occupational injuries, and 49,000 deaths annually are attributed to work-related illnesses [15].

* Asbestosis and silicosis are lung diseases caused by inhalation of asbestos fibers and silica particles, respectively.

In an earlier work, Herbert and Landrigan [16] summarized occupational mortality data from several sources. They cite data showing a total of 88,622 deaths from work-related injuries during the period 1980 through 1994. The number of deaths per year decreased from 7405 in 1980 to 5406 in 1994, with the annual death rate declining from 7.5 per 100,000 workers in 1980 to 4.5 per 100,000 workers in 1994. More recent fatality data indicate a lesser decline in death rates: 5.3 per 100,000 in 1994 and 4.5 per 100,000 in 1998 [16]. These figures are based on injury surveillance systems; no similar systems exist in the U.S. on deaths from occupational diseases.

The Bureau of Labor Statistics, U.S. Department of Labor, conducts surveys annually to estimate the incidence rates of occupational injuries and illnesses. The data in Figure 4.1 indicate that between the years 2003 through 2013, nonfatal injury and illnesses incidence rates have steadily declined over the years [16a]. As a matter of environmental policy, do decreases of this magnitude portray changes in U.S. workplaces due merely to the nature of work (e.g., fewer manufacturing jobs or how work is performed)? Or are they due to the effectiveness of the OSHAct? Or, most likely, due to both? This dilemma illustrates the difficulty in policy analysis of changes that occur over extended periods of time.

The number of fatal injuries in the U.S. for the years 2003–2015 is shown in Figure 4.2 [16b]. An examination of the figure reveals that injury fatalities were relatively constant until 2008 and 2009, and then decreased to approximately 4600 annual fatalities until 2014 and 2015, when increases again occurred. The variation in the numbers of fatalities is difficult to attribute to any single factor. But one of the important factors is the state of the national economy; during periods of economic depression, fewer jobs are available, hence fewer workers are at risk of injury. The Bureau of Labor Statistics notes for the fatal injury data of 2015

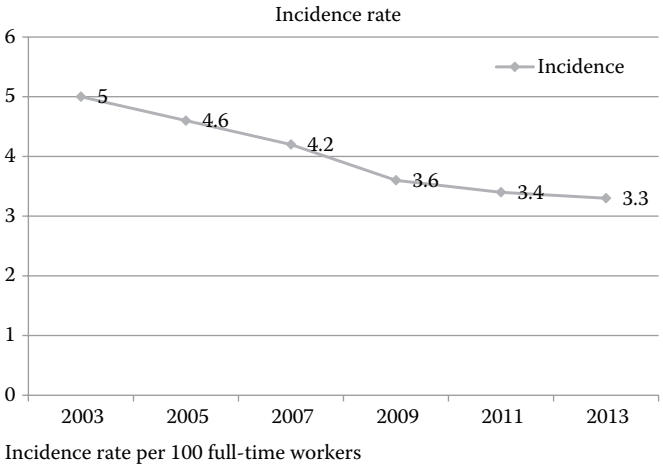

FIGURE 4.1 Yearly U.S. nonfatal occupational injury and illnesses incidence rates, private industry. (From Bureau of Labor Statistics, Chart 1, News release: Employer-reported workplace injuries and illnesses, USDL-16-2056. Washington, DC: U.S. Department of Labor, Office of Public Affairs, 2016.)

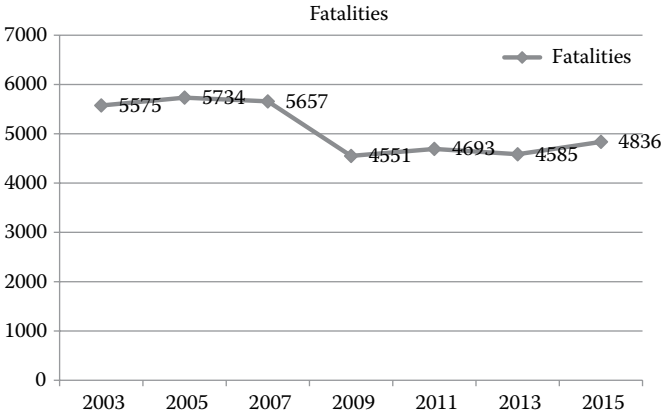

FIGURE 4.2 Yearly number of fatal work injuries in U.S. (From Bureau of Labor Statistics, Chart 1, News release: National census of fatal occupational injuries in 2015, USDL-16-2304. Washington, DC: U.S. Department of Labor, Office of Public Affairs, 2016)

some of the following characteristics of relevance to public health policies [16b]:

- The annual total of 4836 fatal workplace injuries in 2015 was the highest since 5214 fatal injuries in 2008.
- Roadway incident fatalities were up 9% from 2014 totals, accounting for more than one-quarter of the fatal occupational injuries in 2015.
- Workplace suicides decreased 18% in 2015; homicides were up 2% from 2014 totals.
- Heavy and tractor-trailer truck drivers recorded 745 fatal injuries, the most of any occupation.

4.7.2.1 Perspective

These and similar data provide insight for implementing health and safety interventions, e.g., equipment, education, to reduce roadway incident fatalities. For sake of comparison, the CDC reported that in 2014 there were 18,893 deaths in the U.S. caused by overdoses of opioid analgesics and 10,574 from heroin overdoses [16c]. In the same year, the National Safety Council estimated 38,300 people were killed on U.S. roads [16d]. These comparisons with workers' fatalities are not intended to minimize the loss of life due to workplace conditions, but do suggest public health priorities in education and practice.

4.8 CONSUMER PRODUCT SAFETY ACT, 1972

The Consumer Product Safety Act (CPSAct) is somewhat different from other environmental health statutes discussed in this book. The act's focus is on safety, rather than health. Further, the act's statutory architecture is rather different in the context of permitting voluntary remedial actions by industry, rather than proceeding directly to regulatory action. The act's history provides some background for why these differences exist.

4.8.1 History

Of the four major federal regulatory agencies, the smallest in resources and perhaps least visible to the public is the Consumer Product Safety Commission (CPSC), headquartered in Bethesda, Maryland, and with regional offices in New York City, Chicago, and Oakland, California. Other regulatory agencies (e.g., EPA, FDA) are arguably better known to the U.S. public, with broader environmental responsibilities. However, the CPSC fills an important public health role, protection against hazardous consumer products.

The CPSAct's purpose is to protect the public "against unreasonable risks of injuries associated with consumer products."

The CPSC was created by Congress under the CPSAct of 1972. The legislation occurred in the early 1970s, a period of energetic congressional and White House environmental activism, although reasons for the activism differed between the two major political parties. Republicans, particularly President Nixon, were interested in expanding their political base by attracting suburban voters interested in environmental protection. Democrats supported environmental legislation as being consistent with their view of the use of federal government to advance social programs. The act directs the CPSC to protect the public "against unreasonable risks of injuries associated with consumer products" [17].

The CPSC is an independent federal agency, not part of any federal department or agency. Five commissioners head the Commission. They serve 7-year terms, appointed by the President and confirmed by the U.S. Senate. The Chairman of the Commission serves as the principal executive officer of the Commission. The CPSC's FY 2015 annual appropriation was $123.0 million. Additional funds brought the sum of all operating funds available for obligation in FY 2015 to be $126.0 million [18].

The purposes of the act are stated to be [19] as follows:

1. To protect the public against unreasonable risks of injury associated with consumer products,
2. To assist consumers in evaluating the comparative safety of consumer products,
3. To develop uniform safety standards for consumer products and to minimize conflicting state and local regulations, and
4. To promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.

Of these four purposes, two (#1, #3) are particularly germane to prevention of injuries and deaths from consumer products, as discussed below.

4.8.2 Key Provisions of the CPSAct Relevant to Public Health

While the CPSC has statutory authority to develop safety standards for products under their jurisdiction, voluntary standards are mandated by the Act, which states, "The Commission shall rely upon voluntary consumer product standards rather than promulgate a consumer product safety standard prescribing requirements [w]henever compliance with such voluntary standards would eliminate or adequately reduce the risk of injury addressed and it is likely that there will be substantial compliance with such voluntary standards" [17]. According to the Commission, since 1990, their cooperative work with industry has resulted in 214 voluntary standards. During the same period, 35 mandatory rules were issued [18]. By law, the CPSC can issue a mandatory standard only when a voluntary standard has been determined by the Commission not to have eliminated or adequately reduced the risk of injury or death or if a voluntary standard is unlikely to have substantial compliance. In 2002, the Commission issued 950 corrective actions that included 387 recalls involving about 50 million consumer product units that either violated mandatory standards or presented a substantial risk of injury to the public [18]. This is an impressive body of public health accomplishment, particularly in view of the modest amount of federal resources made available to the Commission.

4.8.3 Public Health Implications of the CPSAct

Consumer products can injure some of those who use them. According to CPSC data, product-related deaths and injuries in the U.S. annually average 23,900 deaths and 32.7 million injuries [18]. This is a heavy public health burden on the U.S. public, a burden not reflected in the Commission's authorities and resources. The deaths, injuries, and property damage associated with consumer products cost the nation more than $700 billion annually. These kinds of injuries are investigated by the CPSC when the weight of evidence supports a follow-up. The Commission has jurisdiction over more than 15,000 kinds of consumer products used in and around the home, in sports, recreation, and schools. However, the CPSC has no jurisdiction over many of the most hazardous consumer products. The excluded products include automobiles, other on-road vehicles, aircraft, tires, boats, alcohol, tobacco, firearms, food, drugs, cosmetics, pesticides, and medical devices [18]. While some of these products are covered by other federal statutes (e.g., FDCAct, TSCAct), many escape regulatory coverage (e.g., firearms, tobacco) due to pressure brought on Congress by vested interest groups. In a public health context, exclusion of hazardous products like tobacco from CPSC jurisdiction is not good environmental health policy.

The Commission uses a variety of tools to reduce the risk of hazardous consumer products. "[T]he tools include: (1) developing and strengthening voluntary and mandatory safety standards, (2) initiating recalls and corrective actions of hazardous products and enforcing existing regulations, and (3) alerting the public to safety hazards and safe practices" [18]. The CPSC has authority to direct recall of specific products that have been found to present an "unreasonable hazard" to consumers. Under recall manufacturers are required to remove the designated products from commerce until revisions are made to remove the product's hazardous features.

The act also requires the Commission to maintain an Injury Information Clearinghouse to "[c]ollect, investigate, analyze, and disseminate injury data, and information, relating to the causes and prevention of death, injury, and illness associated with consumer products" [17]. The CPSC's recalls are notices available to the public and are archived on their website (www.cpsc.gov).

The CPSC relies heavily on injury data submitted by consumers. This leads to *post hoc* investigations and regulatory actions such as recall of products. While such hazard elimination or reduction can serve as prevention actions, they are triggered only after injuries have already occurred.

As a matter of policy, the CPSAct encourages the development of voluntary standards through industry and CPSC cooperation. This approach can expedite the development of voluntary standards, hastening the introduction of actions that can prevent injury or death caused by consumer products. However, implementing voluntary standards is largely a matter of industry responsibility. Although the Commission has statutory authority to convert a voluntary standard into a mandatory standard if compliance with a voluntary standard is inadequate, mandatory standards are subject to the same challenges and litigation that often delay regulatory actions undertaken by other federal regulatory agencies.

4.9 NOISE CONTROL ACT, 1972

Unique among the federal environmental statutes is the Noise Control Act of 1972. It is unique because it is an existing law, but has not been funded by Congress since 1981. Lack of funds means an agency is prohibited from conducting programs in support of authorities in law. This renders a statute impotent. How did this happen in regard to federal noise control?

4.9.1 History

As background, the Noise Control Act of 1972 was signed into law by President Nixon on October 28, 1972. The act gave the EPA the primary role for controlling environmental noise. It had been submitted in 1971 to Congress as part of the Nixon administration's environmental package [20]. Under the provisions of the 1972 statute, the EPA has the responsibility for coordinating all federal programs in noise research and control. The EPA must be consulted by other federal agencies prior to publishing new regulations on noise. If the agency feels that any proposed new or existing federal regulations do not adequately protect the public health and welfare, the agency can call for public review of them. Further, the EPA has the authority to set standards for any product or class of products that have been identified as a major source of noise. Categories of equipment covered by the Noise Control Act include construction, transportation, motors or engines, and electrical and electronic devices.

The Noise Control Act authorizes the EPA to conduct and coordinate noise research, review noise control regulations, and set standards for major sources of noise.

Under the act, the EPA created the Office of Noise Abatement and Control (ONAC). It had the overall responsibility for administering EPA's responsibilities under the Noise Control Act of 1972. In 1978, Congress amended the 1972 act to require coordination between federal agencies on matters of noise control and abatement, primarily with the intent of facilitating better coordination between EPA and the Federal Aviation Administration on issues of aircraft noise regulations [20]. The 1978 amendments, called the Quiet Communities Act of 1978, also authorized EPA to provide grants to state and local governments for noise abatement.

In 1981, funding for the ONAC was eliminated by Congress in response to a proposal from the Reagan administration. The proposal was part of the Reagan administration's antiregulatory agenda, an agenda that included the proposed elimination of EPA, OSHA, the Department of Education, and the downsizing of the Department of Interior. This agenda soon foundered because of adverse public reaction and eventual opposition by the Democrat-controlled Congress. However, the administration's proposal to eliminate noise control regulations did not result in Congressional repeal of the Noise Control Act and its amendments. Rather, Congress left the act stand, but eliminated funding of the ONAC. In 1997, a bill to restore funding for the ONAC was introduced in Congress. Called the Quiet Communities Act of 1997, it failed to generate sufficient support for passage by either body of Congress.

As an environmental policy matter, this action by Congress to not repeal the Noise Control Act makes it relatively easy to restart the EPA program of noise control and abatement. Restored funding provided through the appropriations process would be all that is required, since the existing law already provides the necessary authorizing language that appropriations committees require.

4.9.2 Public Health Implications of the Noise Control Act

There are few environmental hazards as pervasive as noise pollution. Noise is defined as unwanted sound, which, in some instances, may be considered desired sound by others, e.g., loud music. One source observes that noise affects millions of people globally on a daily basis [21]. The same source cites highway noise alone affecting more than 18 million people in the U.S. and 100 million worldwide. In the U.S., it is estimated that community noise levels have increased more than 11% during the decade of the 1990s [22]. Most urban noise is caused by automobile traffic, an environmental problem on the rise globally. Internationally, noise control and abatement has gained more attention as countries set their own national noise standards [21]. No similar federal government actions are underway in the U.S. However, some local governments in the U.S. have established noise control ordinances.

The adverse health effects of noise have been summarized by the World Health Organization (WHO) [23]. The WHO considers the health significance of noise pollution to include noise-induced hearing impairment, interference with

speech communication, disturbance of rest and sleep, effects on residential behavior and annoyance, and interference with intended activities. For public health purposes, two adverse health effects are further described herein.

Noise-induced hearing loss is no doubt the first recognized adverse effect of noise pollution. Noise in workplaces was early recognized as a major occupational hazard and remains so in both industrialized and developing countries. The principal social consequence of hearing loss is an inability to understand speech. Interpersonal communication is made more difficult, contributing to frustration and stress in hearing-impaired individuals. More recently, community noise pollution has become a concern in regard to hearing loss [23]. One source estimates that 120 million people worldwide suffer from disabling hearing difficulties [23].

Effects on the cardiovascular system are the second public health effect of note due to exposure to noise pollution. WHO notes, "Many studies in occupational settings have indicated that workers exposed to high levels of industrial noise for 5–30 years have increased blood pressure and statistically significant increases in risk for hypertension, compared to workers in control areas. In contrast, only a few studies on environmental noise have shown the populations living in noisy areas such as airports and noisy streets have an increased risk for hypertension. The overall evidence suggests a weak association between long-term environmental noise exposure and hypertension, and no dose-response relationships could be established" [23].

Data are limited on the health costs associated with exposure to excessive noise. Research in Germany has estimated that the annual cost of noise on public health is approximately \$500 to \$1900 million ECU* (approximately \$725 million to \$2.7 billion) per year for road noise and \$100 million ECU per year for rail noise (cited in [23]). In summary, workplace and community environmental noise is an environmental hazard of global importance. High levels can impair hearing, cause hypertension, and other health consequences. Moreover, noise levels in the U.S. and other countries have continued to increase. Many countries, both industrialized and developing, have developed noise control and abatement programs, while in the U.S. the federal government noise control program is frozen in time, owing to failure of Congress in 1981 to fund the provisions of the Noise Control Act of 1972.

4.10 ENVIRONMENTAL RESEARCH AND DEVELOPMENT DEMONSTRATION AUTHORIZATION ACT, 1976

Many federal statutes that pertain to environmental protection and concern for effects of environmental hazards on public health contain provisions for research and development. The intent of Congress has been to encourage research that advances scientific knowledge about specific environmental hazards and their consequences. According to an analysis by the Congressional Research Service, the EPA's statutory mandate for research and development grew piecemeal from parts of many environmental protection laws, enacted and amended over the years, involving at least 12 separate federal environmental statutes [24].

4.10.1 History

The Environmental Research, Development, and Demonstration Authorization Act of 1976 (ERDDA Act) coalesced the EPA's research and development programs under one authorization statute. ERDDA Act was enacted annually through 1980, ending in 1981 when Congress did not enact an authorization for fiscal year 1982. The lack of current authorization means that, in the House, bills appropriating funds for those programs are potentially open to objections because they do not comply with the rule that money cannot be appropriated without prior authorization. This problem has not been unique to ERDDA Act. During the 1980s, authorization for appropriations for many of the EPA's programs expired for a time. In the absence of ERDDA Act, the EPA's current and continuing authority for research and development derives from the combination of authorization provisions in basic environmental protection statutes, requirements and precedents established by the laws that authorized appropriations for the EPA's overall R&D program annually, and annual (unauthorized) appropriations for the EPA [24].

The Environmental Research and Development Demonstration Authorization Act authorized all EPA research and development programs.

Although not covered by ERDDA Act, several other federal departments conduct research and development on environmental hazards and conditions. This includes the DHHS, Department of Energy, Department of Defense, and Department of Interior. These departments' appropriations are authorized through various authorizing statutes that are specific to each department.

Of policy note, amendments in 1978 to ERDDA Act established the EPA Science Advisory Board (SAB) [25], an independent (i.e., nongovernment) committee of scientists and other specialists. The SAB provides advice to the EPA on matters of science that include reviews of EPA draft criteria documents, risk assessment methods, emerging environmental problems, global environmental hazards, and risk communication issues. The SAB's work has influenced the EPA's environmental policies that rely on science-based risk assessment and judgment.

As policy, many government agencies have formed advisory committees to advise them on matters of science and other issues. Federal government agencies must construct their advisory committees, e.g., the EPA's SAB, in compliance with the Administrative Procedures Act (Chapter 3), which requires that committee meetings must be announced

* ECU: the former official monetary unit of the European Union, used to evaluate the exchange rates and reserves of members of the European Monetary System on a common basis and in trading Eurobonds. It was replaced by the euro.

in advance and held as public meetings. (Committees, however, can convene in executive session, which is not open to the public.) Agencies are encouraged to create advisory committees that contain racial, gender, and geographic diversity. Committee members from academic institutions often constitute the majority of advisory committees, owing to their perceived expertise and objectivity on matters of science.

Federal agencies that choose not to form an advisory committee for a specific issue of science or public health practice often turn to the National Academies for advice. The Academies comprise the National Academy of Medicine, National Academy of Sciences (NAS), and the National Academy of Engineering. The Academies can create committees to advise federal agencies on matters of medicine, engineering, and science. Federal agencies, e.g., the EPA, commission the Academies to create a committee to address a particular matter of interest. As an example, the NAS has often been asked to advise federal agencies on such subjects as risk assessment, toxicology, and epidemiology.

Agencies are not obliged to accept the advice proffered by advisory committees, since it is the agency, not the committee, which is legally accountable under a particular federal or state law. However, agencies that ignore the advice from advisory committees run the risk of criticism from the lay public, vested interest groups, and science organizations, depending on the science issue at hand. It is good environmental health policy for government agencies to accept advice and recommendations from their advisory committees and document to the public why any specific recommendations were not adopted.

4.10.2 Public Health Implications of the ERDDA Act

Understanding the effects of environmental hazards on human and ecological health has been, and continues to be, a matter of "catch-up." Unlike the considerable body of human health data that clearly, and unequivocally, causally links specific infectious agents (e.g., HIV) with corresponding diseases (e.g., AIDS), research on the effects of specific environmental stressors (e.g., climate change) with potential health consequences (e.g., famine) is often equivocal and fraught with uncertainties. Some of the complicating factors in ascertaining associations between the environment and human health impacts include uncertain exposure regimens, nonhomogeneous study populations, lack of basic mechanisms of toxicity or other biological action, poorly established records of environmental contaminants, and reliance on risk assessment methods that can be blunt instruments when characterizing human risk.

Notwithstanding the previous pessimistic comments, a considerable body of research now exists on the effects of environmental hazards and their remediation or control. This can be attributed, in part, to the ERDDA Act, which was enacted as an answer on how to authorize the EPA's need to conduct research on environmental hazards and protection of the environment. This was a statement from Congress that environmental research was important and would be pursued by federal agencies. The EPA and several other federal agencies currently sponsor or conduct serious and sometimes ambitious programs of basic and applied research on the effects of the environment on humans and ecological systems. Although the ERDDA Act has not been reauthorized since 1981, it remains as a policy reminder that environmental research programs must accompany programs of environmental protection and public health.

4.11 INFORMATION QUALITY ACT, 2001

Unique among the federal statutes that are described in this book is the Information Quality Act of 2001. While this act is not a major work of Congressional legislation, it is nonetheless important in terms of its origin in Congress, as detailed by the act's history.

4.11.1 History

The federal statutes discussed in this chapter are, with the exception of what is called the Information Quality Act of 2001, the products of congressional hearings, public debates, and congressional authorizing committees' action. This process makes public the business of making legislation. For environmental legislation, the outcome is a statute that *authorizes* federal agencies to take regulatory or other actions on a specific environmental problem, e.g., air pollution. Authorizing legislation such as the CAAct contains language that permits *appropriating* funds from the U.S. Treasury in support of agencies' programs. Without Congressional appropriations that are specific to an authorizing statute, federal agencies can take no action. Each year Congress must enact appropriations bills for each federal department and agency.

Appropriations bills have sometimes contained language that some argue is actually authorizing language. Such language is called a *rider*, since it rides along with a bill that has a primary purpose different from the rider. Appropriations bills are a favorite vehicle for members of Congress to place riders, given that such bills are seldom vetoed by the President, since that could lead to federal agencies going without funds, in effect, a shutdown of government. Adding a rider to a bill typically requires only the assent of the chairperson of the responsible congressional committee. Hearings and public debate do not usually occur, thereby denying the visibility and democratic embrace that accompany authorizing legislation.

The Information Quality Act's stated purpose is to enhance the quality of information used by federal agencies in science-based decision making.

In 2000, Congress enacted legislation that addressed the alleged problem of inadequate information quality used in federal regulations and other policy decisions. Although the Information Quality Act is not an environmental law, its implications for regulatory agencies such as the EPA can be substantial, which is why the act is included in this chapter.

As described by Weiss [26], the Information Quality Act* was the brainchild of a Washington, DC, corporate lobbyist working for the Center for Regulatory Effectiveness who had worked in the White House's Office of Management and Budget (OMB) during the Reagan administration. The lobbyist drafted what became the Information Quality Act and gained the support of a Congresswoman who agreed to insert the draft into a massive appropriations bill. The Congresswoman was a former lobbyist and former director of communications for the National Republican Congressional Committee. Congress held no hearings to discuss the act, nor was the public informed of the act and its implications. As policy, this was the legislative process at its worst. It is an example of stealth legislation.

Further background information on the evolution of the Information Quality Act was provided by Baba et al. [27], who discovered the role played by the tobacco company Philip Morris. The company, which was concerned about the EPA's risk assessment of the carcinogenicity of secondhand tobacco smoke, retained the Center for Regulatory Effectiveness, a Washington, DC advocacy firm, to draft language that eventually became the backbone of the Act. This link between a major cigarette company and its promotion of government policies to frustrate scientific rigor in public health standards was discovered in court documents in litigation brought against the tobacco industry.

The Information Quality Act of 2001 was quietly enacted as 27 lines in the Treasury and General Appropriations Act for Fiscal Year 2001. § 515 of the act states the following:

> § 515. (a) IN GENERAL—The Director of the Office of Management and Budget shall, by not later than 30 September 2001, and with public and Federal agency involvement, issue guidelines under § 3504(d)(1) and 3516 of title 44, United States Code, that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of Chapter 35 of title 44, United States Code, commonly referred to as the Paperwork Reduction Act.
>
> (b) CONTENT OF GUIDELINES—The guidelines under subsection (a) shall—
>
> 1. apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and
> 2. require that each Federal agency to which the guidelines apply—
>
> [A] issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a);
>
> [B] establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and
>
> [C] report periodically to the Director—(i) the number and nature of complaints received by the agency about the accuracy of information disseminated by the agency; and (ii) how such complaints were handled by the agency.

The Information Quality Act rode along with the rest of the appropriations bill and was signed into law by President Clinton. OMB's final guidelines were published in the *Federal Register* in January 2002, with a corrected version appearing in February 2002 [28].

The act met with the U.S. Chamber of Commerce's approval and that from other business interests. In support of the Act, the Chamber of Commerce stated, "Federal law has not historically required that information used by agencies to support regulations meet particular quality standards. This omission has frequently resulted in politically motivated regulations that would not, if tested, withstand scientific or statistical scrutiny. However, as a result of the Information Quality Act, which became effective on 1 October 2002, a new and exciting opportunity exists to bring to a close the days of such poorly supported regulations" [29]. In essence, the Chamber asserted that federal regulations had frequently been based on flawed science. As policy, alleged "imperfect or unnecessary" regulations have long been a target of regulated enterprises, primarily because of alleged economic impacts.

In compliance with the Information Quality Act, on October 15, 2002, the EPA published its *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity Disseminated by the Environmental Protection Agency* [30]. The guidelines state that the EPA will use a graded approach to establish the appropriate level of quality, utility, and integrity of information based on the intended use of the information. The more important the information (e.g., an epidemiology investigation used in a proposed water quality standard), the higher the quality standards to which it will be held by the agency. EPA guidelines specify how persons who believe the EPA information does not meet the requirements of the Information Quality Act can submit a Request for Correction (RFC) to the agency. Presumably, the EPA's denial of a RFC can be litigated.

* * *

In December 2004, OMB released its final guidelines on how federal agencies must conduct peer reviews of scientific documents [31]. In the Information Quality Act (§515a), Congress directed OMB to issue guidelines to "[p]rovide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility and

* Originally called the Data Quality Act (e.g., [26]). The name was apparently changed by the White House's Office of Management and Budget (OMB).

integrity of information" disseminated by federal agencies. The OMB guidelines note that *peer review* "[i]s a form of deliberation involving an exchange of judgements about the appropriateness of methods and the strength of the author's inferences." Peer review is conducted on draft documents for purpose of identifying errors and flaws prior to the document becoming final. Two forms of peer review are acknowledged: *internal*, where members of a federal agency who were not involved with the preparation of a draft document conduct the peer review, and *external*, where the reviewers are not affiliated with the agency that has prepared the draft document.

The OMB guidelines exempt various types of information from their requirements for peer review, leaving the decision to the agency that is developing a scientific document. For example, time-sensitive health and safety determinations could be excluded from peer review, depending on an agency's determination that the public's welfare would be disserved by the time delay inherent in any peer review. In contrast, "highly influential scientific assessments" are required to be peer reviewed and under specific conditions, EPA's development of a risk assessment for an air pollutant would be an example of a highly influential scientific assessment, which would be required to follow OMB's peer review guidelines.

Under the OMB guidelines, "[i]n general, a federal agency conducting a peer review of a highly influential scientific assessment must ensure that the peer review process is transparent by making available to the public the written charge to the peer reviewers, the peer reviewers' report(s), and the agency's response to the peer reviewers' report(s). The agency selecting peer reviewers must ensure that the reviewers possess the necessary expertise. In addition, the agency must address reviewers' potential conflicts of interest (including those stemming from ties to regulated businesses and other stakeholders) and independence from the agency" [31].

The OMB guidelines are required policy for all federal agencies that produce scientific information. The peer review requirements, since they cut across all federal agencies, will bring about a more uniform approach to the preparation, review, and dissemination of scientific information. Better science translates into better public policy.

* * *

When environmental legislation gets enacted into law, some opponents shift their attention to combating agency regulations that flow from specific environmental statutes (e.g., the CAAct). This opposition can include lawsuits that take issue with how an agency has developed or implemented a particular regulation. Another kind of opposition includes providing agencies with written comments in response to an agency's published, proposed regulations. One can argue that changing how an agency develops its regulations is also a path to opposing environmental statutes. Some will assert that the Information Quality Act is such an impediment.

Whether delays in effectuating government decision-making are a problem depends on whose policy ox is being gored. Those interests that have eschewed government regulations will likely be pleased with delays in promulgating—and possibly achieving less onerous—regulations. Some organizations will trumpet that the Information Quality Act has lessened the government's reliance in rulemaking on the now tiresome term "junk science." However, other groups will use the Information Quality Act to delay or overturn government decisions they think are not stringent enough. Recall that the mature ox has two horns and is adept at goring with either or both horns. And that's the predictable impact of the Information Quality Act: more litigation, more lawyers, delayed public policies, more contentious debates over science, and heightened cynicism about government's failure to protect the environment, environmental quality, ecosystems, and public health.

4.11.2 Public Health Implications of the Information Quality Act

Given the newness of the Information Quality Act, it is not clear if the act will deleteriously impact the public's health. As environmental health policy, it would be unfortunate if the act were used simply by vested interests to delay or otherwise impede the issuance of federal regulations and standards that would decrease environmental risks and improve public health. Some would argue that delay of flawed regulations is a contribution to public health and environmental policy. Critics would argue that regulations based on alleged poor science impose an unjustified economic burden on the public, decreasing resources that could be used for higher social priorities. The allegation of poor science inherent in federal government regulations has historically not been verified when outside scientific reviews have been conducted of, e.g., EPA science reviews. For example, the NAS has often been asked by Congress to review the science that underpins specific proposed federal regulations. Examples of NAS reviews include the toxicity of arsenic and mercury. Both reviews supported the EPA analysis of the published literature pertaining to the two toxicants.

Just how the Information Quality Act will impact the traditional practice of public health is not yet known. Presumably, such actions (e.g., federal quarantine of ocean vessels with passengers presenting symptoms of illness) might be subject to provisions of the Information Quality Act. The possible impact would be delay of public health interventions and second-guessing of public health policies. Moreover, the very core of public health practice, which is prevention of disease and disability, might be severely hampered if information quality considerations must precede taking public health actions. Also, it is uncertain to what extent the Information Quality Act might euthanize the adoption of the Precautionary Principle in U.S. environmental policy, which requires acting on incomplete information if a public health threat is sufficiently compelling.

4.12 PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT, 2002

Few factors spur elected policymakers into action as does the occurrence of a disaster. This book cites examples of celerity by the U.S. Congress. Examples include the enactment of the Food and Drug Act of 1906 (Chapter 10) in response to deaths due to impure food and harmful medicines; the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 in response to hazardous waste found leaking into private residences in New York and Missouri (Chapter 12), and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 in response to terrorists' attacks on the U.S. on September 11, 2001. In all three instances, the U.S. Congress moved swiftly to craft and enact legislation in response to widespread public concern.

The third act listed above was a component of a set of actions by the U.S. Congress in reaction to the 9/11 terrorist attack on the U.S. The first major act was the USA Patriot Act of 2001, which gave law enforcement officials sweeping new powers to conduct searches without warrants, monitor financial transactions and eavesdrop, and detain and deport, in secret, individuals suspected of committing terrorist acts. But by far the most far-reaching and significant measure enacted after September 11 was the Department of Homeland Security Act (DHS) of 2002, which established the Cabinet-level DHS and created the position of Secretary of Homeland Security. This new federal government department was vested with the principal responsibility of protecting the U.S. from terrorist attacks. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 was enacted as a measure of protection against bioterrorism attacks on the U.S.

4.12.1 History

The U.S. has been fortunate to have sustained only a few homeland attacks on its national security. In substantial measure this has been due to the nation's geography—sheltered by two major oceans—and good relations with its hemispheric neighbors. That is not to say that attacks on the U.S. homeland have not occurred. In 1814, British forces burned the public buildings in Washington City (now called Washington, DC) during the War of 1812. In 1941, Japanese forces bombed the U.S. Navy base at Pearl Harbor, Hawaii, precipitating the U.S.'s entry into World War II. And on September 11, 2001, terrorists hijacked four commercial airplanes and flew two planes, with their passengers, into the twin World Trade Towers in New York City; one plane was flown into the Pentagon in Washington, DC, and the fourth plane crashed in Pennsylvania. In total, approximately 3000 persons were killed by this act of terrorism [32]. In each of these three examples, the nation came together, united in response to threats to its national security.

America's response to the terrorists' attacks of September 11, 2001 was swift and multifaceted. Of relevance to environmental health policy was the enactment of federal legislation to strengthen the nation's public health structure in order to be prepared for any future acts of terrorism on the U.S. In concert with Congress, the President George W. Bush administration participated in the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (hereafter shortened to Bioterrorism Preparedness Act). The Act's titles are listed in Table 4.2. They portray an act that provides protections, through federal and state public health agencies, of food, drugs, and drinking water supplies through enhanced programs of advance planning and preparedness. A discussion of each of the Act's titles follows.

TABLE 4.2
Public Health Security and Bioterrorism Preparedness and Response Act Titles

Title Number	Name of Title
I	National Preparedness for Bioterrorism and Other Public Health Emergencies
II	Enhancing Controls on Dangerous Biological Agents and Toxins
III	Protecting Safety and Security of Food and Drug
IV	Drinking Water Security and Safety
V	Additional Provisions

The Bioterrorism Preparedness Act of 2002 is a comprehensive public health plan to be used if acts of bioterrorism occur within the U.S.

4.12.2 Key Provisions of the Bioterrorism Preparedness Act Relevant to Public Health

4.12.2.1 Title I—National Preparedness for Bioterrorism and Other Public Health Emergencies

This title is aptly named. Title I is built upon the traditional public health infrastructure, which requires federal, state, and local public health authorities to coordinate in programs to prevent disease and disability. Title I is focused on preparedness in response to acts of bioterrorism and related public health emergencies.

Title I directs the Secretary of DHHS to develop and implement a coordinated health-related plan for use in responding to acts of bioterrorism. The plan must be coordinated with states and local governments. A new position, Assistant Secretary for Public Health Response Emergency Preparedness, appointed by the President, is established under Title I, with responsibility for the Act's newly established National Disaster Medical System, which is to provide healthcare services, health-related social services, other human services, and auxiliary services needed to respond to the needs of victims of a public health emergency. Five subtitles specify the actions to be taken under Title I:

Subtitle A—National Preparedness and Response Planning, Coordinating, and Reporting—§101 [§2801(a) of Public Health Service Act] "The Secretary shall further develop and implement a coordinated strategy, building upon the core public health capabilities established pursuant to Section 319A, for carrying out health-related activities to prepare for and respond effectively to bioterrorism and other public health emergencies, including the preparation of a plan under this section. The Secretary shall periodically thereafter review and, as appropriate, revise the plan." §2801(a)(2) "In carrying out paragraph (1), the Secretary shall collaborate with the States toward the goal of ensuring that the activities of the Secretary about bioterrorism and other public health emergencies are coordinated with activities of the States, including local governments." §2801(a) (3) "Developing and maintaining medical countermeasures (such as drugs, vaccines and other biological products, medical devices, and other supplies) against biological agents and toxins that may be involved in such emergencies." §2801(a)(5) "Enhancing the readiness of hospitals and other health care facilities to respond effectively to such emergencies."

Subtitle B—Emergency Preparedness and Response—§2811(a)(1) "There is established within the Department of Health and Human Services the position of Assistant Secretary for Public Health Response Emergency Preparedness. [..]."§2811(b)(1) "The Secretary shall provide for the operation in accordance with this section of a system to be known as the National Disaster Medical System. The Secretary shall designate the Assistant Secretary for Public Health Emergency Preparedness as the head of the National Disaster Medical System [...]."§2811(b)(2)(A) "National Disaster Medical System shall be a coordinated effort by the Federal agencies specified in subparagraph (B), working in collaboration with the States and other appropriate public or private entities, to carry out the purposes described in paragraph (3)." […]§2811(b)(2)(A) "The Secretary may activate the National Disaster Medical System to (I) provide health services, health-related social services, other appropriate human services, and appropriate auxiliary services to respond to the needs of victims of a public health emergency [...]."§121(1) "The Secretary of Health and Human Services [i]n coordination with the Secretary of Veteran Affairs, shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable [t]o provide for the emergency health security of the United States [...]."

Subtitle C—Improving State, Local, and Hospital Preparedness for and Response to Bioterrorism and Other Public Health Emergencies—§131[§319C-1(a) of Public Health Service Act] "To enhance the security of the United States with respect to bioterrorism and other public health emergencies, the Secretary shall make awards of grants or cooperative agreement to eligible entities to enable such entities to conduct the activities described in subsection (d)." […]

Subtitle D—Emergency Authorities; Additional Provisions—§142 Streamlining and Clarifying Communicable Disease Quarantine Provisions "This section streamlines and clarifies communicable disease quarantine provisions; emergency waiver of Medicare, Medicaid, and SCHIP requirements; and provision for expiration of public health emergencies"

Subtitle E—Additional Provisions—§153 "The Secretary of Health and Human Services [a]cting through the Director of the National Institute of (sic) Occupational Safety and Health, shall enhance and expand research as deemed appropriate on the health and safety of workers who are at risk for bioterrorist threats or attacks in the workplace [...]."

4.12.2.2 Title II—Enhancing Controls on Dangerous Biological Agents and Toxins

This title provides authorities to the Departments of Health and Human Services and Agriculture for purpose of controlling dangerous biological agents and toxins through registration and enforcement requirements of those persons in possession of biological agents and toxins. The following four subtitles contain Title II's principal authorities:

Subtitle A—Department of Health and Human Services (DHHS)—§351A(a)(1)(A) "The Secretary shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety." (b) "The Secretary shall by regulation provide for—(1) the establishment and enforcement of safety procedures for the transfer of listed agents and toxins [...]."

Subtitle B—Department of Agriculture (USDA)—This subtitle parallels Subtitle A, but with the Secretary of Agriculture responsible for developing a list of biological agents and toxins, with the requirement to develop regulations for transportation and use of the listed agents and toxins.

Subtitle C—Interagency Coordination Regarding Overlap Agents and Toxins—§221(a)(1) "The Secretary of Agriculture and the Secretary of Health and Human Services shall in accordance with this section coordinate activities about overlap* agents and toxins."

Subtitle D—Criminal Penalties Regarding Certain Biological Agents and Toxins—§231(a)(1) "Whoever transfers a select agency to a person who the transferor knows or has reasonable cause to believe is not

* Overlap refers to agents and toxins that are common to the lists developed by DHHS and the USDA.

registered as required by regulations under subsection [b] or [c] of section 351A of the Public Health Service Act shall be fined under this title, or imprisoned for not more than 5 years, or both." (C)(1) "Whoever knowingly possesses a biological agent or toxin for which such person has not obtained a registration required by regulations under section 31A of the Public Health Service Act shall be fined under this title, or imprisoned for not more than 5 years, or both."

4.12.2.3 Title III—Protecting Safety and Security of Food and Drug Supply

This title established extra protections for the U.S. food and drug supplies. Title III requires the development of a communications and education strategy when there are bioterrorism threats to the U.S. food security. Further, the Secretary of Agriculture is directed to register food production facilities and to increase the number of food inspections of such facilities. Similar to authority to register food production facilities, foreign producers of drugs must be registered. The following three subtitles contain the primary public health authorities under Title III:

Subtitle A—Protection of Food Supply—§301 "The President's Council on Food Safety (as established by Executive Order No. 13100) shall, in consultation with the Secretary of Transportation, the Secretary of the Treasury, other relevant Federal agencies, the food industry, consumer and producer groups, scientific organizations, and the States, develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply. [...]." §305 Registration of food facilities—"The Secretary shall by regulation require that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary [..]."§313 "The Secretary of Health and Human Services, through the Commissioner of Food and Drugs and the Director of the Centers for Disease Control and Prevention, and the Secretary of Agriculture shall coordinate the surveillance of zoonotic diseases."

Subtitle B—Protection of Drug Supply—§321 Annual registration of foreign manufacturers; shipping information; drug and device listing—"[o]n or before December 31 of each year, any establishment shall, through electronic means in accordance with the criteria of the Secretary, register with the Secretary the name and place of business of the establishment, the name of the United States agent for the establishment, and the name of each person who imports or offers for import such drug or device to the United States for purposes of importation."

Subtitle C—General Provisions Relating to Upgrade of Agricultural Security—§331 "The Secretary of Agriculture [m]ay utilize existing authorities to give high priority to enhancing and expanding the capacity of the Animal and Plant Health Inspection Service to conduct activities to (1) increase the inspection capacity of the Service at international points of origin; [E]nhance methods of protecting against the introduction of plant and animal disease organisms by terrorists [...]."

4.12.2.4 Title IV—Drinking Water Security and Safety

This title provides added protections for public water supplies and for their customers. At the heart of these protections are vulnerability assessments, which are required of all public drinking water systems that serve 3300 or more persons. The assessments, which are required to be secured by the EPA Administrator, must be used by water suppliers to design and implement an emergency response system to protect against acts of terrorists, as stipulated in §1433.

§1433(a) "Vulnerability Assessments—Each community water system servicing a population of greater than 3300 persons shall conduct an assessment of the vulnerability of its system to a terrorist attack or other intentional acts intended to substantially disrupt the ability of the system to provide a safe and reliable supply of drinking water. […] §1433(a)(2) "Each community water system referred to in paragraph (1) shall certify to the Administrator that the system has conducted an assessment complying with paragraph (1) and shall submit to the Administrator a written copy of the assessment. [...]."

4.12.2.5 Title V—Additional Provisions

This title has, in truth, little to do with the purpose of the Bioterrorism Preparedness Act. These subtitles were riders submitted by vested interest groups. One subtitle provides the FDA with extra funds that can be used to further reduce the time required by FDA to approve new drug applications from pharmaceutical companies. Another subtitle concerns digital television transmission.

4.12.3 Public Health Implications of the Bioterrorism and Preparedness Act

The Public Health Security and Bioterrorism Preparedness and Response Act was enacted by Congress in response to terrorist acts against the U.S. The act provides authorities and resources to federal government agencies, in coordination with state and local agencies, to prepare for, and respond to, acts of bioterrorism. The act requires actions to protect food, drug, and drinking water supplies and registration of food production facilities and foreign drug manufacturers of drugs imported into the U.S. Further, the act directs the development of the National Disaster Medical System, which would be called into deployment in instances of bioterrorism. The beneficial implications to the public's health are obvious.

The challenge to public health authorities will be to maintain the Act's preparedness programs and resources

over extended periods of time, since the potential for bioterrorism is not likely to diminish for many years. Experience shows that today's public health crisis can become tomorrow's humdrum activities unless care is taken to refresh the responses to the crisis. This is why public health campaigns to reduce tobacco smoking, prevent the spread of HIV infection, and abolish children's exposure to lead all need periodic reinforcement in terms of public education and awareness raising.

4.13 PANDEMIC AND ALL-HAZARDS PREPAREDNESS ACT, 2006

In December 2006, Congress enacted and President George W. Bush signed into law the Pandemic and All-Hazards Preparedness Act (PAHPA), Public Law No. 109–417 [33]. The purpose of the act is "to improve the Nation's public health and medical preparedness and response capabilities for emergencies, whether deliberate, accidental, or natural." The act amended the PSHAct to establish within the DHHS a new Assistant Secretary for Preparedness and Response (ASPR). The act also authorized new programs and initiatives concerning medical surge capacity, the development of countermeasures to biological threats, and the capacity of states and localities to prepare for and respond to public health emergencies. Further, the establishment of a quadrennial National Health Security Strategy is required [33]. The ASPR has overall responsibility for these program areas and is based at DHHS headquarters, Washington, DC [33].

In March 2013, Congress enacted and President Obama signed into law the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law No. 113–5 [34]. The 2013 law builds on the PAHPA of 2006 reauthorized DHHS programs that include funding for public health and medical preparedness programs, such as the Hospital Preparedness Program and the Public Health Emergency Preparedness Cooperative Agreement, amending the PHSAct to grant state health departments flexibility in dedicating staff resources to meeting community needs in a disaster, authorizing funding through 2018 for purchasing medical countermeasures under the Project BioShield Act, and increasing the flexibility of BioShield to support advanced research and development of potential medical countermeasures. The PAHPRA also enhances the authority of FDA to support rapid responses to public health emergencies. The DHHS ASPR has overall responsibility for these program areas.

4.14 SUMMARY

The U.S. federal environmental statutes described in this and subsequent chapters constitute the skeleton for the body of U.S. environmental health programs, policies, and practices. Concern for public health is a characteristic of most of these laws. The 1970s were a watershed period for Congressional legislation to control environmental contaminants in outdoor ambient air, bodies of water, and drinking water supplies. Much of this legislation was predicated on human health concerns and enacted without an existing body of causal science and public health data. In a very real sense, this was an act of Precautionary Action, i.e., legislating without complete scientific data and information. As noted in this chapter, a scientific body of published reports has reinforced the importance of having in place environmental statutes that protect human health and quality of environment.

The statutes discussed in this and the chapters that follow have often been emulated in other countries. Moreover, some of the U.S. environmental health policies (e.g., polluters pay for the costs of their pollution) have been adopted by regional governments and individual nations. In particular, the UN is playing an increasingly important role in developing policies for controlling environmental hazards, especially in developing countries, as described in Chapter 5. As the UN and the EU continue to implement environmental health policies, such as the management of hazardous waste, they will impact how the U.S. interacts with global partners in trade, commerce, and risk management of environmental hazards.

4.15 POLICY QUESTIONS

1. Let us assume that you are working for a member of your state's legislature. As an elected official, she/he has been asked by several community groups to get a law enacted that would regulate traffic noise, which the groups believe has gotten out of control and is deleteriously affecting their quality of life, and possibly causing adverse health effects. (a) Your assignment is to provide the following: (1) name of the proposed act, (2) create a policy statement to be included in the act, (3) define the purpose of the act, (4) write titles (or subtitles if you prefer) in the act, and (5) author key provisions in each title (or subtitle). (b) Discuss what you anticipate to be the key issues in getting the proposed legislation adopted by the state legislature. NOTES: Assume a "command and control" regulatory structure, and assume the traffic noise comes from only three sources: vehicle tires, vehicle mufflers, and vehicle radios. SUGGESTION: A useful document on community noise levels can be found at www.who.int/peh/.
2. Discuss the historical significance of the PHSAct. Does that act from the early twentieth century have any relevance to you today? If so, how? Be specific.
3. What in your personal opinion is the practical importance of the NEPAct? Review the NEPAct's policy statement that begins, "The Congress, recognizing the profound impact [...]," and rewrite the statement in terms of sustainable development, as discussed in Chapter 2.
4. Using Internet resources, determine which state and local agencies are responsible for emergency

preparedness in your area. Ascertain the details of how the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 have improved your state's preparedness to respond to bioterrorism.

5. The CPSAct requires the CPSC to first rely upon voluntary consumer product standards developed in concert with industry in lieu of CPSC mandated standards. Discuss the benefits and disadvantages of this policy.
6. The Noise Control Act of 1972 is a federal statute without an annual Congressional appropriation, which makes the statute inoperative. Are there benefits to keeping the act "on the books," rather than its outright repeal by Congress? Be specific.
7. The OSHAct of 1970 provides the authority for federal government agencies to develop standards and regulations for the purpose of controlling workplace hazards. Discuss the pros and cons of having federal government intervention in private sector workplaces.
8. What are the differences between emission standards and quality standards? Why are both needed for control of environmental pollution? In your opinion, which standard is more protective of public health?
9. The Information Quality Act came into law without going through the process of developing authorizing legislation. Rather, it was added as a rider to an appropriations bill. Discuss the pros and cons of this method of legislation.
10. Choose any statute from Table 4.1 and discuss its impetus for enactment into a statute.
11. The Delaney Clause was described in this chapter. Should it have been deleted from federal law? Provide three arguments for its reinstatement as a requirement under the Food, Drug and Cosmetic Act.
12. Access the CPSC website and select three product cautions/warnings issued recently by them. Discuss any implications of the selected cautions to you as a public health specialist working at a local health department.
13. Discuss in an essay of appropriate depth the pros and cons of allowing legislative riders to be permitted under legislative rules. Begin your essay by defining and illustrating a rider to an appropriations bill.
14. What is the OMB? In an essay of appropriate depth describe its mission, organizational placement, and role in environmental policymaking.
15. What is the BioShield? Describe its purpose and any implications for your personal well-being.
16. What is the Oil Spill Liability Trust Fund? What federal law authorized its collection and from whom? Is the liability tax in current collection? Who administers the trust fund?
17. Review the provisions of the NEPAct and select the provision that most applies to you. State your reasons for the selection. Also opine on whether NEPAct has lost its prominence in the domain of environmental health policies.
18. Review the excerpted provisions of the Bioterrorism Preparedness Act and select the provision that in your opinion gives the U.S. public the greatest preparedness benefit. Be specific and justify your selection.
19. Use the Internet to access the Office of ASPR, DHHS. Describe in an essay of appropriate depth the primary purposes and functions of the office. To what extent does the existence of this office affect you?
20. Good work! You've completed another chapter. After considering the material in this chapter, discusses the three most important lessons you learned. Was your personal environmental health behavior changed by the content of this chapter? If so, how? If not, why?

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5 Global Environmental Health Programs and Policies

5.1 INTRODUCTION

Pollution of air, water, soil, and food respects no geographic boundaries. For instance, untreated chemical waste released into a river will eventually add to the pollution load of the ocean receiving the river's outflow. Ocean currents will distribute what began as local pollution across the planet. In the course of pollution migration, contaminants can cross international boundaries. How cross-boundary pollution is prevented or otherwise managed can therefore require the involvement of regional [e.g., European Union (EU)] and/or global (e.g., UN) agencies. This involvement often includes technical assistance and support.

Because we live in an increasingly political world and complex environment, knowledge of laws, regulations, and agreements that control or influence the management of environmental hazards is topically important. Global political systems have changed remarkably in recent years because of the restructuring of many national governments, greater regional collaboration in trade (e.g., the North American Free Trade Agreement), and increased international trade competition.

Furthermore, as global geopolitical systems have become more complex and integrated across national borders, the world community has broadened what it considers to be the "environment." For example, the World Commission on Environment and Development (sometimes called the Brundtland Commission) noted the importance of infectious diseases and the link to poverty as a global *environmental* (emphasis added) concern [1]. They stated, "[C]ertain infectious diseases show signs of new gains as a result of increasing poverty and an inability to meet persons's basic needs. Malnutrition remains a serious obstacle to health and to the development of human resources." For others, the "environment" includes the areas stated by the UN's World Health Organization (WHO): "Environmental health comprises those aspects of human health, including quality of life, that are determined by physical, chemical, biological, social and psychosocial factors in the environment. It also refers to the theory and practice of assessing, correcting, controlling and preventing those factors in the environment that can potentially affect adversely the health of present and future generations" [2]. Regardless of differences in definitions, the world community has indicated through national legislation and international treaties its concern over environmental conditions that can adversely affect the health and well-being of humans and ecological systems.

This chapter will describe international agencies' roles in administering environmental health programs, in particular, the programs of the UN, as well as the roles of two non-UN organizations, the World Bank and the World Trade Organization (WTO). In addition, one regional organization, the EU, is discussed in terms of its environmental health activities. This chapter concludes with a presentation of international environmental health rankings.

5.2 UNITED NATIONS

The United Nations (UN) is a global organization that has its roots in efforts to prevent war and preserve peace among nations. It is unique as the only global organization banded together for peaceful purposes. That is not to say that the UN has always been successful in preventing conflicts between nations and peoples. The continuing conflicts in several regions of the world illustrate the problems faced by UN peacekeeping goals. A more successful aspect of the UN has been its humanitarian programs, including those for environmental protection and human health enhancement. Specific examples of these accomplishments are discussed in the sections that follow.

The UN's history includes efforts in the nineteenth century to find ways to peacefully settle disputes across national borders. In 1899, the International Peace Conference was convened in The Hague, The Netherlands, to explore ways to settle disputes peacefully, prevent wars, and codify rules of warfare [3]. An outcome of the conference was the adoption of the Convention for the Pacific Settlement of International Disputes and established the Permanent Court of Arbitration. These outcomes failed to prevent World War I, a particularly nasty war among several European nations (primarily, Austria, France, Germany, Great Britain and its Commonwealth allies, Italy, Russia). The war eventually drew the U.S. into World War I as a combatant. In 1919, the Treaty of Versailles brought World War I to an end. The terms of settlement imposed on Germany eventually contributed to economic collapse in that country, a condition that fostered resentment in Germany and contributed to the start of World War II.

The Treaty of Versailles in 1919 established the League of Nations. Its purpose was "[T]o promote international cooperation and to achieve peace and security" [3]. It was headquartered in Geneva, Switzerland, chosen because of that country's history of political neutrality in world conflicts. Although U.S. President Woodrow Wilson was a principal in the League's establishment, the U.S. did not become a member; owing to concern in Congress that membership could bring international entanglements not in the best interests of the U.S. This stance was part of a political policy of isolationism, i.e., a belief that the U.S. should isolate itself from the

problems of Europe and other regions. In time, the League of Nations ceased operations after failing to prevent World War II. In 1946, the League of Nations was officially dissolved with the establishment of the UN.

In 1945, following the conclusion of World War II, representatives of 50 countries met in San Francisco to convene the United Nations Conference on International Organization. The name United Nations had been coined in 1942 by President Franklin D. Roosevelt, although he died prior to the San Francisco meeting. President Harry Truman represented the U.S. The global representatives to the conference drafted the United Nations Charter. It was signed on June 26, 1945, by representatives of the 50 countries. The UN officially came into existence on October 24, 1945, after the Charter had been ratified by China, France, the Union of Soviet Socialist Republics (USSR), the UK, the U.S., and by a majority of other signatories [3]. New York City was selected as the UN's headquarters. As of 2015, the UN's membership consisted of 193 countries.

Of note, in September 2000, the member states of the UN met in New York City to set its international agenda for the start of the twenty-first century. The resulting Millennium Declaration established measurable goals in seven key areas, one of which is specific to protecting the environment [4]. Under this environmental goal is stated the following:

1. "We must spare no effort to free all of humanity, and above all our children and grandchildren, from the threat of living on a planet irredeemably spoilt by human activities, and whose resources would no longer be sufficient for their needs.
2. We reaffirm our support for the principles of sustainable development, including those set out in Agenda 21, agreed upon at the United Nations Conference on Environment and Development.
3. We resolve therefore to adopt in all our environmental actions a new ethic of conservation and stewardship and, as first steps, we resolve:
   - To make every effort to ensure the entry into force of the Kyoto Protocol, preferably by the tenth anniversary of the United Nations Conference on Environment and Development in 2002, and to embark on the required reduction in emissions of greenhouse gases (GHSs).
   - To intensify our collective efforts for the management, conservation and sustainable development of all types of forests.
   - To press for the full implementation of the Convention on Biological Diversity and the Convention to Combat Desertification in those Countries Experiencing Serious Drought and/or Desertification, particularly in Africa.
   - To stop the unsustainable exploitation of water resources by developing water management strategies at the regional, national and local levels, which promote both equitable access and adequate supplies.
   - To intensify cooperation to reduce the number and effects of natural and man-made disasters.
   - To ensure free access to information on the human genome sequence" [4].

This collection of objectives is a powerful commitment to improved global environmental conditions, within the architecture of sustainable development. Specifically, the UN member states commit to actions to reduce GHSs, conserve forests, reduce the creeping expansion of deserts, protect water resources, and reduce the number of environmental disasters. As a matter of environmental health policy, these objectives would make a notable improvement in human and ecological health. However, the objectives must face the reality of global political challenges. For example, as will be described, enforcing the Kyoto Protocol in order to reduce emissions of GHSs has yet to achieve full approval by the U.S. government.

Component organizations of the UN are located in several countries, including those that specialize in environmental protection, human health, and labor issues. For the purposes of this book, four UN agencies—United Nations Environment Programme (UNEP), WHO, the International Labour Organization (ILO), and the Food and Agriculture Organization (FAO)—are of particular relevance and are discussed in the following sections.

5.2.1 United Nations Environment Programme

UNEP was found in 1972. Its mission is stated as, "To provide leadership and encourage partnership in caring for the environment by inspiring, informing, and enabling nations and peoples to improve their quality of life without compromising that of future generations" [5]. The headquarters of UNEP are based in Nairobi, Kenya, with offices in Paris, France; Geneva, Switzerland; Osaka, Japan; The Hague, The Netherlands; Washington, DC; New York, NY; Bangkok, Thailand; Mexico City, Mexico; Manama, Bahrain; Montreal, Canada; and Bonn, Germany. UNEP's activities span a wide spectrum of environmental issues, including protection of atmospheric and terrestrial ecosystems, promotion of environmental science acquisition and dissemination of information, and systems to respond to natural and anthropogenic emergencies and disasters [5]. UNEP's midterm 2010–2013 priorities and program goals are as follows:

- "*Climate change*: Strengthen the ability of countries, in particular developing countries, to integrate climate change responses into national development processes.
- *Disasters and conflicts*: Minimize threats to human well-being from the environmental causes and consequences of existing and potential natural and man-made disasters.
- *Ecosystem management*: Ensure that countries use the ecosystem approach: the holistic management of land, water and living resources to promote

conservation and sustainable use to enhance human well-being.
- *Environmental governance*: Ensure that environmental governance and interactions at the country, regional and global levels are strengthened to address environmental priorities.
- *Harmful substances and hazardous waste*: Minimize the impact of harmful substances and hazardous waste on the environment and people.
- *Resource efficiency – sustainable consumption and production*: Ensure that natural resources are produced, processed and consumed in an environmentally sustainable way, paving the way to the Green Economy, in which environmental impact is decoupled from economic growth and social cobenefits are optimized." [6]

UNEP's mission: "To provide leadership and encourage partnership in caring for the environment by inspiring, informing, and enabling nations and peoples to improve their quality of life without compromising that of future generations" [5].

Within each priority program are data collection, education, research, and sociopolitical efforts and projects pursuant to program goals.

UNEP, like other UN agencies, has developed information networks and databases that are available through the Internet. These include the Global Resource Information Database, the International Register of Potentially Toxic Chemicals, and UNEP.Net, a web-based interactive catalog that provides access to environmentally relevant geographic, textual, and pictorial information. Like other UN resources, these UNEP environmental networks are particularly useful and relevant to the needs of developing countries [5]. The Pollutant Emission Register is intended to report about 90% of point source pollution released by Europe's major industrial facilities. In this regard, the policy of using emissions data, such as in the EU database and the Toxics Release Inventory (TRI), to bring pubic pressure on industrial sources of pollution will continue to be effective.

Of note, UNEP has had major involvement in the two global environmental summits on the environment. Summit meetings are those represented by heads of state (e.g., presidents, prime ministers). The United Nations Conference on Environment and Development (UNCED) was held in Rio de Janeiro, Brazil in 1992. The other summit, the World Summit on Sustainable Development (WSSD), was held in Johannesburg, South Africa, in 2002. Both summit meetings are discussed in subsequent sections of this chapter. Also to be discussed are several international treaties of importance to national environmental health policies. These include the Basel Convention for management of hazardous waste and the convention on Persistent Organic Pollutants (POPs).

UNEP has also led global efforts to confront the effects of climate change and to develop global policies to mitigate the effects. These efforts at policymaking will be described in Chapter 6 (Climate Change).

5.2.1.1 The Basel Convention, 1989

The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (referred to as the Basel Convention) is influencing waste management on an international scale [7, 8]. Negotiated under the auspices of UNEP, the Basel Convention was adopted in 1989 [9]. It covers transboundary movements of hazardous waste and household waste ash and prohibits movement between nonparties to the convention, unless the countries have a separate agreement that ensures sound waste management. The convention specifies that government-to-government notice must be given, and consent obtained, before hazardous waste is exported. It sets an "environmentally sound management" standard as the basis for all transboundary movements of hazardous waste. Countries that export waste must not allow a shipment to proceed, even if an importing country has agreed to accept it, if evidence suggests that wastes will not be managed in an environmentally sound manner.

According to UNEP, the Basel Convention is the response of the international community to problems caused by the annual global production of 400 million tonnes of hazardous wastes. The primary principles of the Basel Convention are [9]:

- Transboundary movements of hazardous wastes should be reduced to a minimum consistent with their environmentally sound management.
- Hazardous wastes should be treated and disposed of as close as possible to their source of generation.
- Hazardous waste generation should be reduced and minimized at the source.

The convention entered into force as an international treaty 90 days after the 20th signatory country, Australia, ratified it on May 5, 1992. As of October 1996, 100 parties (i.e., member states of the UN or political/economic organizations) had ratified the Basel Convention [9]. Ratification of the treaty signals a party's readiness to fully implement the convention, including having the necessary legislative authorities to enforce its terms. On March 21, 1990, the U.S. signed the Basel Convention, indicating that the U.S. will not take any action that would defeat the objective and purpose of the convention [10]. Each signatory to the treaty must ratify it through legislative action. Although the U.S. Senate has ratified the Basel Convention [11], no Congressional actions have provided the authorizing legislation necessary to implement the Convention's provisions.

The impact of the Basel Convention on the U.S. and other industrialized countries is unclear, in part because the amount of exported waste is uncertain. According to the EPA, <1% of the hazardous waste generated in the U.S. and <10% of that generated in European countries are exported [12]. Legislation in support of implementing the conditions of the Basel Convention, together with further amendments to the Resource Conservation and Recovery Act (Chapter 12), would give the EPA additional regulatory authorities to control the

export of nonhazardous solid waste, limit exports of solid waste based on the management of exported waste in the receiving country, limit imports of certain solid waste, and administer a registration or permit program for waste exports and imports [12].

Some business groups in the U.S. oppose U.S. ratification of the Basel Convention, asserting it would restrict free trade. Environmental organizations argue that free trade agreements lead to the dumping of hazardous waste in poor nations [13]. These trade and environmental issues will influence any future U.S. congressional action on implementing the Basel Convention.

5.2.1.2 UN Conference on Environment and Development, 1992

The member states of the UN met in Rio de Janeiro, Brazil, from June 3–14, 1992, to conduct the UNCED, also called the Earth Summit. On June 14, 1992, the conference approved Agenda 21, which is a comprehensive statement of concerns, findings, and recommended actions in specific environmental areas [14]. Agenda 21 is a significant agreement among the nations of the world. It is a statement of global consensus and political commitment at the highest level for economic development and environmental cooperation. Agenda 21 is organized into 40 chapters, commencing with a preamble, which states, "Humanity stands at a defining moment in history. We are confronted with a perpetuation of disparities between and within nations, a worsening of poverty, hunger, ill health and illiteracy, and the continuing deterioration of the ecosystems on which we depend for our well-being [14]." Of note to global environmental health policy, Agenda 21's Chapter 5, Protecting and Promoting Human Health Conditions, addresses environmental hazards as contributors to adverse human health conditions. Objective 6.40 states the following [15]:

"The overall objective is to minimize hazards and maintain the environment to a degree that human health and safety is not impaired or endangered and yet encourage development to proceed. Specific programme objectives are:

A. By the year 2000, to incorporate appropriate environmental and health safeguards as part of national development programmes in all countries;
B. By the year 2000, to establish, as appropriate, adequate national infrastructure and programmes for providing environmental injury, hazard surveillance and the basis for abatement in all countries;
C. By the year 2000, to establish, as appropriate, integrated programmes for tackling pollution at the source and at the disposal site, with a focus on abatement actions in all countries;
D. To identify and compile, as appropriate, the necessary statistical information on health effects to support cost/benefit analysis, including environmental health impact assessment for pollution control, prevention and abatement measures" [15].

Agenda 21 is a significant agreement among the nations of the world. It is a statement of global consensus and political commitment at the highest level for economic development and environmental cooperation.

To implement these four objectives would have cost about $3 billion, according to the UN Secretariat in 1992. To give perspective to this global public health cost, the cost of one U.S. B-2 stealth bomber is about $1.2 billion [16].

Additional objectives in Agenda 21 and plans for implementation address specific environmental hazards, including protection of the atmosphere and freshwater resources, combating deforestation, managing fragile ecosystems, promoting sustainable agriculture, and rural development; conservation of biological diversity; protection of the oceans; and sound management of toxic chemicals, hazardous wastes, and solid wastes [15].

Of relevance to environmental health policy, proper management of hazardous waste was of importance to the preparers of Agenda 21. Several chapters relate to hazardous waste and human health issues; two are particularly germane. Chapter 20, Environmentally Sound Management of Hazardous Wastes Including Prevention of Illegal International Traffic in Hazardous Wastes, opens by stating, "Effective control of the generation, storage, treatment, recycling and reuse, transport, recovery, and disposal of hazardous wastes is of paramount importance for proper health, environmental protection and natural resource management, and sustainable development. This will require the active cooperation and participation of the global community." Furthermore, "Prevention of the generation of hazardous wastes and the rehabilitation of contaminated sites are the key elements, and both require knowledge, experienced people, facilities, financial resources and technical and scientific capacities."

The four targets established in Chapter 20 of Agenda 21 are as follows: (1) preventing or minimizing the generation of hazardous wastes as part of an overall integrated production approach; eliminating, or reducing to a minimum, transboundary movements of hazardous wastes, consistent with the environmentally sound and efficient management of those wastes; and ensuring that environmentally sound hazardous waste management options are pursued to the maximum extent possible within the country of origin; (2) ratification of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal and the expeditious elaboration of related protocols; (3) ratification and full implementation of regional agreements bearing on transboundary shipments of hazardous wastes; and (4) elimination of the export of hazardous wastes to countries that prohibit the import of such wastes [14]. Chapter 20 of Agenda 21 details a series of recommended policies and actions that support each overall target.

In a similar voice of concern, Chapter 16 of Agenda 21, Environmentally Sound Management of Biotechnology, contains the following statement: "Despite increasing effort to prevent waste accumulation and to promote recycling, the amount

of environmental damage caused by overconsumption, the quantities of waste generated and the degree of unsustainable land use appear likely to continue growing" [14].

An emphasis on biotechnology is relevant to hazardous waste management because biotechnology can be used under certain circumstances to destroy hazardous waste. Agenda 21 defines biotechnology as "[a] set of enabling techniques for bringing about specific man-made changes in deoxyribonucleic acid (DNA), or genetic material, in plants, animals and microbial systems, leading to useful products and technologies" [14]. Biotechnology is specifically recommended to increase the availability of food, feed, and renewable raw materials; improve human health; and enhance protection of the environment. Bioremediation is also described as a means "[t]o prevent, halt, and reverse environmental degradation through the appropriate use of biotechnology in conjunction with other technologies, while supporting safety procedures as an integral component of the program" [14]. This statement conveys international support for bioremediation as a means to reduce hazardous wastes and as a method for waste site remediation.

These statements from Chapters 16 and 20 of Agenda 21 commit UN member states to a cradle-to-grave approach for reducing the volume of hazardous wastes, and the need to take an ecological perspective and sustainable development approach toward reducing the impacts of hazardous wastes.

How the nations of the world implement Agenda 21 and other agreements from the Rio Conference will shape future impacts of environmental hazards on ecological systems, environmental quality, and human health. However, little will be achieved if national governments do not commit to actions that support the UNCED agreement and effect collaborative actions across national borders.

5.2.1.3 Convention on POPs, 2000

A significant public health and ecological problem is the presence of chemicals that persist in the environment for long periods of time. In response to this problem, UNEP has led the development of a global treaty to ban or severely restrict the production and use of what are called persistent organic pollutants (POPs). POPs are a set of chemicals that are toxic, persist in the environment for long periods of time, and biomagnify as they move up through the food chain. They have been linked to adverse effects on human health and animals, such as cancer, damage to the nervous system, reproductive disorders, and disruption of the immune system. Because they circulate globally through the atmosphere, oceans, and other pathways, POPs released in one part of the world can travel to regions far from their source of origin [17].

In 1997, UNEP was asked by several governments to commence negotiations of treaties to reduce and/or eliminate releases of POPs into the environment. At the same time, academic and government scientists and various environmental organizations also suggested similar action by UNEP. On December 10, 2000 in Johannesburg, South Africa, diplomats from 122 countries completed the text of a legally binding treaty for control of POPs, the convention on POPs, which was adopted on May 22, 2001, in Stockholm, Sweden, covering 12 chemicals. The convention is linked to the 1992 Rio Summit, stating in the Stockholm Convention's Article 1 as its objective, "Mindful of the precautionary approach as set forth in Principle 15 of the Rio Declaration on Environment and Development, the objective of this convention is to protect human health and the environment from persistent organic pollutants" [18]. The Stockholm Convention represents an international treaty, requiring signatory countries to the treaty to ratify it through treaty approval mechanisms. The treaty requires all parties to the treaty to stop production and new uses of intentionally produced POPs, with limited country-specific and general exceptions. All new manufacture of Polychlorinated biphenyls (PCBs) is banned, and parties are to take steps to reduce use of existing PCBs. DDT use is restricted to vector control (e.g., to control malaria-bearing mosquitoes) and is slated for ultimate elimination as cost-effective alternatives become available. Parties will also be required to implement rigorous controls on sources of POP by-products to reduce releases. The treaty also includes requirements for safe handling and disposal of POPs in an environmentally sound manner [17].

In a sense, the POPs treaty continues the work advocated by Rachael Carson in her book *Silent Spring*, published in 1962. Carson's concerns about the persistence of DDT in the environment are echoed in the POPs treaty, together with concerns for the ecological and human health effects of 11 other POPs.

The treaty also includes provisions restricting trade of POPs for which uses or production continue to exist and bans all export of POPs, except for environmentally sound management once there are no longer any uses allowed. In addition, a strong financial and technical assistance provision in the agreement provides support to developing countries and countries in economic transition to assist them in implementing the obligations under the treaty. Finally, the treaty includes a science-based procedure to allow for the addition of other chemicals to the agreement [17].

The POPs treaty took effect on May 17, 2004, after 50 signatory countries gave their ratification [19]. The U.S. signed the convention on POPs on May 23, 2001. On April 11, 2002, the administration submitted the treaty to the U.S. Senate for ratification [20]. But as of 2016 the POPs treaty has not been ratified by the U.S. Congress.

5.2.1.4 World Summit on Sustainable Development, 2002

As a follow-up to the 1992 Earth Summit, the WSSD was held from August 26 to September 4, 2002 in Johannesburg, South Africa, to elaborate on Agenda 21. In 1992, Agenda 21 represented a significant agreement among the nations of the world. It remains a statement of global consensus and political commitment at the highest level for economic development and environmental cooperation. However, in the decade that followed the Earth Summit, progress in meeting the objectives of Agenda 21 was disappointing, according to the UN Secretary-General. In 2002, prior to the WSSD meeting, the Secretary-General stated, "Attempts to promote human development and to reverse environmental degradation have not, in

Agenda 21's grand dreams of sustainable development, environmental protection, and elimination of poverty can only be made into international and national policies if there is political resolve, accompanied by monetary funds and other resources.

general, been effective over the last decade. Too few resources, a lack of political will, a piecemeal and uncoordinated approach and continued wasteful patterns of production and consumption have conspired to thwart efforts to implement sustainable development, or development that is balanced between people's economic and social needs and the ability of the earth's resources and ecosystems to meet present and future needs" [21].

Agenda 21's grand dreams of sustainable development, environmental protection, and elimination of poverty can only be made into international and national policies if there is political resolve, accompanied by monetary funds and other resources. A primary objective of the 2002 summit was to develop detailed steps and to identify quantifiable targets for better implementation of Agenda 21. In attendance were heads of state and other senior government officials, national delegates, and leaders from nongovernment organizations (NGO), businesses, and other major concerned groups. Two areas of focus at the summit were alleviation of global poverty and protection of the natural environment and human health.

Only time will reveal the true worth of the WSSD. However, as a matter of environmental health policy, having an agenda, stated goals, and targets for global improvement is an important resource for long-range national and international planning. According to the UN [22], highlights of commitments and implementation initiatives from the WSSD Plan of Implementation pertinent to environmental health policy are as follows:

- "Water and Sanitation – Commitment to halve the proportion of people without access to sanitation by 2015; this matches the goal of halving the proportion of people without access to safe drinking water by 2015.
- Energy – Commitments: To increase access to modern energy services increase energy efficiency and to increase the use of renewable energy; To phase out, where appropriate, energy subsidies; To support the NEPAct's objective of ensuring access to energy for at least 35% of the African population within 20 years.
- Health – Commitments: By 2020, chemicals should be used and produced in ways that do not harm human health and the environment; To enhance cooperation to reduce air pollution; To improve developing countries' access to environmentally sound alternatives to ozone depleting chemicals by 2010.
- Agriculture – Commitments: The Global Environmental Facility will consider inclusion of the Convention to Combat Desertification as a focal area for funding; In Africa, development of food security strategies by 2005.
- Biodiversity and Ecosystem Management – Commitments: To reduce biodiversity loss by 2010; To reverse the current trend in natural resource degradation; To restore fisheries to their maximum sustainable yields by 2015; To establish a representative network of marine protected areas by 2012; Undertake initiatives by 2004 to implement the Global Programme of Action for the Protection of the Marine Environment from Land Based Sources of Pollution."

The UN's Secretary-General Kofi Annan stated at the conclusion of the Johannesburg Summit, "This Summit makes sustainable development a reality. This Summit will put us on a path that reduces poverty while protecting the environment, a path that works for all peoples, rich and poor, today and tomorrow. Governments have agreed here on an impressive range of concrete commitments and action that will make a real difference for people in all regions of the world" [23]. The Secretary-General's statement seems to portend hope for the future, but also bears the ring of hyperbole, given the history of broken promises from the Rio Summit. Moreover, what isn't stated is the level of effort and resources that will have to be mobilized in order for the Summit's commitments to become reality in their implementation. Also, it should be noted that the Summit's agreements are not legally binding, which lessens any nation's resolve to act to implement the agreements.

Some environmental organizations have expressed disappointment that the Summit did not result in more definitive commitments and resources. For example, the World Wildlife Federation stated, "The Summit failed to address energy issues, the harmful effects of trade liberalization and subsidies, made lukewarm statements to support the Biodiversity Convention, and compromised on toxic chemicals to the extent that the outcome was weaker than previous international agreements" [24]. While this criticism is harsh, perhaps appropriately so, the Summit's agreements, if implemented, would lead to significant improvements in global water quality, sanitation, and fisheries protection. As a matter of environmental health policy, considerable pressure will need to be brought on national governments in order to make the Summit's Plan of Implementation become a reality. Failure of the nations of the world to implement the agreements from the Rio Summit should serve as a warning about implementing the Johannesburg agreements.

Perspective: UNEP has become the global leader on environmental health policies as a consequence of environmental hazards becoming more widespread and more globally consequential to human and ecosystem health.

5.2.2 World Health Organization

WHO is the UN agency that specializes in human health issues. It was created on April 7, 1948 with headquarters in Geneva, Switzerland, and regional offices in Brazzaville, Republic of the Congo; Copenhagen, Denmark; New Delhi, India; Washington, DC; Cairo, Egypt; and Manila, the Philippines.

WHO states that its objective is "the attainment by all peoples of the highest possible level of health. Health is defined as a state of complete physical, mental, and social well-being, not merely the absence of disease or infirmity" [25]. WHO is governed by the UN's member states (currently 193 countries) through the World Health Assembly, which meets biennially to consider major policy questions about WHO's programs and priorities. WHO has two sources of funding. Its regular budget derives from dues paid by the UN's member states. The regular biennial budget for 2016–2017 was approximately $4.4 billion. The second, and larger, source of funds comes from donor countries. These are voluntary funds (called extrabudgetary) and amount to about $1 billion per budget period [26]. For purpose of comparison, the budget for the U.S. National Institutes of Health was approximately $32.3 billion for fiscal year 2016 [27].

WHO defines "Health as a state of complete physical, mental, and social well-being, not merely the absence of disease or infirmity."

WHO is the UN's lead international political body for global, regional, and national responses to major threats to human health. It provides technical assistance, research, and special services on matters of disease and disability. Perhaps the most notable success of WHO was its leadership in global eradication of the scourge of smallpox. This was achieved by mobilizing medical talent and resources from many countries and energetic application of disease prevention principles. While industrialized countries had already conquered smallpox through vaccination of national populations, many developing countries lacked the resources to vaccinate their people. WHO's teams of specialists worked with health professionals in countries with endemic smallpox outbreak to isolate new cases of the disease, quarantine affected populations, and vaccinate those at risk. In time, the strategy reduced the new cases of smallpox to zero.

WHO maintains a global disease surveillance network, operates regional laboratories and investigates outbreaks, such as the Avian Flu. It compiles and evaluates epidemiological data provided by its 193 member countries. In recent years it has produced ambitious analyses of the global burden of specific diseases, as well as estimates of the contribution that various modifiable "risk factors"—such as unclean water, smoking, obesity, and unsafe sex practices—make to illness and the world's 55 million annual deaths.

In the developing world, WHO provides advice to ministries of health and provides technical services that many nations cannot do on their own, such as establishing standards for exposure to hazardous chemicals. It promulgates treatment guidelines for specific diseases, compiles an "essential medicines" list for governments and public agencies, and promotes optimal—and often underused—disease-fighting strategies, such as the use of insecticide-treated sleeping nets in areas where mosquitoes carry malaria.

WHO operates under three-decade-old regulations that established its responsibilities for combating global health problems. WHO's regulations were established during the era when yellow fever, cholera, and the plague were the infectious diseases of global concern [28]. In combating such diseases, WHO then, and now, works in cooperation with affected member states of the UN. In this mode, WHO can request health information from a particular country or propose specific interventions. However, the affected country is under no binding arrangement to provide the requested information or accept the proposed intervention.

To take action against a recalcitrant country would require WHO to refer the problem to the UN Security Council, a politically complicated proposition with an uncertain outcome. Rather, it relies on a "bully pulpit" approach for its global health effectiveness. Much like the U.S. Surgeon General, who now has relatively little direct control over U.S. public health programs, WHO can bring pressure on a country by making public their concerns about a particular health problem. Whether WHO should have greater authority to intercede in a sovereign nation's affairs is, of course, a serious policy issue. One can argue that a nation must have the authority to reject intercessions from WHO and others. After all, shouldn't a country be in the best position to know what is in its own best interests? On the other hand, modern day diseases can easily and rapidly emigrate from one country to another. Shouldn't a global body, such as WHO, have the authority to interdict disease outbreaks before they become an epidemic or pandemic? These are questions being debated by WHO and the member nations of the UN.

5.2.2.1 WHO's Global Health Risk Factors

In 2002, WHO made a major contribution to a better understanding of global health risk factors [29]. Following a 3-year study of 25 risk factors, WHO published a ranked list, with supporting documentation, of the 10 leading global health risk factors. While the factors were found to vary by region of the world, the list shown in Table 5.1 represents a global integration of regional risk factors. The principal metric used by WHO to compare risk factors was the DALY (disability-adjusted life year). One DALY is equal to the loss of one healthy year of life. The concept of the DALY comes from the World Development Report [30, 31], an endeavor of the World Bank. Some have criticized the DALY concept, arguing that its information data set consists of sex, age, disability status, and time period, but not socioeconomic status. Incorporation of socioeconomic data, critics assert, would give greater weight to the illness of more disadvantaged populations [26].

The following narrative about the 10 leading health factors is excerpted from the WHO report [29]. Each health factor is accompanied there by proposed public health interventions, which are not discussed here, but available at the cited reference.

Underweight/Undernutrition—Childhood and maternal underweight was estimated to cause 3.7 million deaths in 2000, about 1.8 million in Africa. This accounted for about one in 14 deaths globally. Undernutrition was a contributing factor in more than half of all child deaths in developing countries. Since deaths from undernutrition all occur among

TABLE 5.1
WHO's 10 Leading Health Risk Factors

Risk Factor	DALYs (millions)	Number of Premature Deaths (in millions)
Underweight	138	3.7
Unsafe sex	92	2.9
High blood pressure	64	7.1
Tobacco consumption	59	5.0
Alcohol consumption	58	1.8
Unsafe water, sanitation, and hygiene	54	1.7
High cholesterol	40	4.0
Indoor smoke	39	—
Iron deficiency	35	1.0
Obesity	33	0.5

Source: Adapted from Table 3.11 in WHO (World Health Organization), The world health report 2002, Geneva, Switzerland, Office of the Director-General, Media Centre, 2002.

young children, the loss of healthy life years is even more substantial: about 138 million DALYs, 9.5% of the global total. *Undernutrition* is mainly a consequence of inadequate diet and frequent infection, leading to deficiencies in calories, protein, vitamins, and minerals. Underweight remains a pervasive problem in developing countries, where poverty is a strong underlying cause, contributing to household food insecurity, poor childcare, maternal undernutrition, unhealthy environments, and poor health care.

Unsafe Sex—HIV/AIDS caused 2.9 million deaths in 2000 or 5.2% of the global total. It also caused the loss of 92 million DALYs (6.3% of all) annually. Life expectancy at birth in sub-Saharan Africa is currently estimated at 47 years; without AIDS it is estimated that it would be around 62 years. Current estimates suggest that 95% of the HIV infections prevalent in Africa in 2001 are attributable to unsafe sex. In the rest of the world the estimated percentage of HIV infections prevalent in 2001 that are attributable to unsafe sex ranges from 25% in Eastern Europe to 90% or more in parts of South America and the developed countries of Western Pacific.

High Blood Pressure and Cholesterol—Worldwide, high blood pressure is estimated to cause 7.1 million deaths, about 13% of the global fatality total. Across WHO regions, research indicates that about 62% of strokes and 49% of heart attacks are caused by high blood pressure. High blood pressure levels damage the arteries that supply blood to the brain, heart, kidneys, and elsewhere. Cholesterol is a fat-like substance found in the bloodstream that is a key component in the development of atherosclerosis, the accumulation of fatty deposits on the inner lining of arteries of the heart and brain. High cholesterol is estimated to cause a loss of 4.4 million deaths (7.9% of global total) and a loss of 40.4 million DALYs (2.8% of total), although its effects often overlap with high blood pressure. This amounts to 18% of strokes and 56% of global ischemic heart disease.

Tobacco Consumption—WHO estimates that tobacco caused about 4.9 million deaths worldwide in 2000, or 8.8% of the total, and was responsible for 4.1% of lost DALYs (59.1 million). In 1990, it was estimated that tobacco caused just 3.9 million deaths, demonstrating the rapid evolution of the tobacco epidemic and new evidence of the size of its hazard, with most of the increase in developing countries.

Alcohol Consumption—Alcohol consumption has health and social consequences via intoxication (drunkenness), dependence (habitual, compulsive, long-term heavy drinking), and other biochemical effects. Intoxication is a powerful mediator for acute outcomes, such as vehicle crashes or domestic violence, and can also cause chronic health and social problems. Alcohol consumption causes 1.8 million deaths annually deaths (3.2% of global) and 4.0% of DALYs (58 million). Most of all the increase in alcohol consumption is occurring in developing countries.

Unsafe Water and Sanitation—WHO estimates that approximately 1.7 million deaths annually (3.1% of global deaths) and 3.7% of DALYs (54.2 million) worldwide are attributable to unsafe water, sanitation, and hygiene. Of this burden, about one-third occurred in Africa and one-third in Southeast Asia. Overall, 99.8% of deaths associated with these risk factors are in developing countries, and 90% are deaths of children. Various forms of infectious diarrhea make up the main burden of disease associated with unsafe water, sanitation, and hygiene.

Indoor Smoke from Solid Fuels—Cooking and heating with solid fuels such as dung, wood, agricultural residues, or coal are likely to be the largest source of indoor air pollution globally. When used in simple cooking stoves, these fuels emit substantial amounts of pollutants, including respirable particulates, carbon monoxide, nitrogen and sulfur oxides, and benzene. According to WHO, nearly half of the world cooks with solid fuels. This includes more than 75% of people in India, China, and adjacent countries, and 50–75% of people in parts of South America and Africa. In total, 2.7% of DALYs globally are attributable to indoor smoke from burning solid fuels.

Iron Deficiency—Iron deficiency is one of the most prevalent nutrient deficiencies in the world, affecting an estimated

two billion people with consequences for maternal and perinatal health and child development. In total, 800,000 (1.5%) of deaths worldwide are attributable to iron deficiency, 1.3% of all male deaths and 1.8% of all female deaths. Attributable DALYs are even greater, amounting to the loss of about 25.9 million healthy life years (2.5% of global DALYs) because of the nonfatal outcomes like cognitive impairment.

Obesity, Overweight, and High Body Mass—Overweight and obesity lead to adverse metabolic effects on blood pressure, cholesterol, triglycerides, and insulin resistance. Risk of coronary heart disease, ischemic stroke, and type-2 diabetes mellitus steadily increase with increasing body mass index (BMI). In the WHO study, 58% of diabetes mellitus globally, 21% of ischemic heart disease, and 8–42% of certain cancers were attributable to BMI greater than 21 kg/m^3.

The WHO health risk factors study of 2002 is a remarkable contribution to global public health. Its findings, which ranked health risk factors, constitute a road map for regional and national programs of interventions that would reduce DALYs and premature loss of life. To follow the road map will require international cooperation, national resources, and political resolve. National environmental health policies will need to be articulated and adopted. Absent national resolve and policy infrastructure, WHO's health risk factors will languish much like the recommendations in Agenda 21.

There are major political challenges facing the implementation of interventions to reduce the impact of health risk factors identified in the WHO report. For example, some have questioned WHO's management structure. The criticisms include allegations that WHO's headquarters in Geneva and its six regional offices do not effectively coordinate programs, leading to too little impact of disease prevention efforts, particularly in developing countries [26]. Contributing to the alleged lack of cooperation is the fact that WHO regional directors are selected by the member states of their region, not by WHO's Secretary-General, nor the WHO World Health Assembly. Because of how regional directors are selected, WHO regions have a degree of autonomy from the Geneva headquarters. Another challenge to WHO is the emergence of other organization, in particular the World Bank, that are receiving funds from donors in support of global health projects.

5.2.2.2 WHO's Environmental Health Programs

WHO's priorities have traditionally focused on preventing infectious and, to a somewhat lesser extent, chronic diseases. Human health consequences of environmental hazards have received lesser attention and have suffered from lack of resources. As will be discussed subsequently, WHO has provided leadership in organizing and promoting the activities of the International Agency for Research on Cancer (IARC) and the International Programme on Chemical Safety. The mission and work of these two programs is discussed in Chapter 11 (Hazardous Chemical Substances). Further, WHO has taken significant actions to reduce the global devastation caused by tobacco usage.

In support of action on WHO's global health risk factors (Table 5.1), WHO has led the development of a global tobacco control program. The WHO Framework Convention on Tobacco Control is the first international treaty solely addressed to an environmental health issue. The convention, which is an international treaty, was adopted during WHO's 56th World Health Assembly, on May 28, 2003, in Geneva, Switzerland. The convention was opened for signature by all members of WHO, or members of the UN, and by regional economic interest organizations. The treaty will go into effect after 40 governments have ratified it.

Concerning global environmental health policy, in 1989, WHO's Regional Office for Europe, located in Copenhagen, issued a significant statement about the environment in their European Charter on Environment and Health [32]. The charter was a product of the First European Conference on Environment and Health. The conference was convened by government ministers and other senior representatives from the environment and health administrations of 29 European countries and the Commission of the European Communities. The charter established a series of entitlements and responsibilities for governments and individuals, articulated principles for public policy, set strategic elements in support of public policies, and stated priorities for actions needed to protect human health and the environment [32].

The European Charter also contains principles relevant for public policy; three are particularly germane to hazardous waste issues. Principle 8 states, "The entire flow of chemicals, materials, products and waste should be managed in such a way as to achieve optimal use of natural resources and to cause minimal contamination." Principle 9 avers, "Governments, public authorities and private bodies should aim at both preventing and reducing adverse effects caused by potentially hazardous agents and degraded urban and rural environments." And Principle 11 declares, "The principle should be applied whereby every public and private body that causes or may cause damage to the environment is made financially responsible." This latter principle parallels the philosophy and liability provisions in the CERCLAct: polluters must pay for the consequences of their pollution (Chapter 12). Statements from WHO are important because some countries adopt them as principles to help shape national legislation.

5.2.3 International Labour Organization

The ILO was founded in 1919 as a provision of the Treaty of Versailles. It is based in Geneva, Switzerland, with regional offices in other regions of the world. According to the ILO history, there were three primary motivations for ILO's establishment [33]. One motivation was humanitarian. Specifically, the unhealthy, unsafe, and economically exploited condition of workers was deemed unacceptable. Second, there was a political motivation for ILO's creation. Industrialists of that era were concerned that workers would create social unrest, perhaps even revolution, given the Russian Revolution of 1917, which was led by V.I. Lenin, and involved large numbers of workers and Russian peasants. Third, there was an economic motive to the creation of ILO. Industrialists and some national leaders were concerned that some nations might adopt social

policies of workers' welfare that would put themselves at economic disadvantage if other nations did not adopt similar reforms [33]. "The ILO formulates international labour standards in the form of Conventions and Recommendations setting minimum standards of basic labour rights: freedom of association, the right to organize, collective bargaining, abolition of forced labour, equality of opportunity and treatment, and other standards and regulation conditions across the entire spectrum of work related issues" [33]. Unique among the UN agencies, ILO operates as a tripartite structure with workers and employers participating as equal partners with governments in the organization's work. This structure forces consensus-seeking on matters of workplace policies and practices. ILO labor standards do not override national standards; they are advisory unless adopted by national governments. For example, ILO workplace standards do not replace the Occupational Safety and Health Act standards that are in force in the U.S.

The ILO provides technical assistance in several areas related to labor and workplace conditions, including the areas of employment policy, vocational training, labor administration, working conditions, labor statistics, and occupational safety and health. The technical services offered by the ILO have particular relevance in developing countries, where national labor and work environment resources may not exist.

5.2.4 Food and Agriculture Organization

The UN's FAO was created in 1943, when 44 nations, meeting in Hot Springs, Virginia, committed themselves to founding a permanent organization for food and agriculture [34]. FAO is headquartered in Rome, Italy, with regional offices in Accra, Ghana; Bangkok, Thailand; Cairo, Egypt; and Santiago de Chile, Chile. The FAO functions as an organization representing 193 member countries of the UN. FAO's mandate is "[t]o raise levels of nutrition, improve agricultural productivity, better the lives of rural populations and contribute to the growth of the world economy" [34].

Serving both developed and developing countries, FAO acts as a neutral forum where all nations can meet as peers to negotiate agreements and debate policy. FAO is also a source of knowledge and information, helping developing countries and countries in transition to modernize and improve agriculture, forestry, and fisheries practices and to ensure good nutrition for all. The focus of FAO since its creation has been on the needs of developing rural areas, where 70% of the world's poor and hungry people reside [34]. FAO "[p]rovides the kind of behind-the-scenes assistance that helps people and nations help themselves. If a community wants to increase crop yields but lacks the technical skills, we introduce simple, sustainable tools and techniques. When a country shifts from state to private land ownership, we provide the legal advice to smooth the way. When a drought pushes already vulnerable groups to the point of famine, we mobilize action. And in a complex world of competing needs, we provide a neutral meeting place and the background knowledge needed to reach consensus" [34].

FAO's mandate is "to raise levels of nutrition, improve agricultural productivity, better the lives of rural populations and contribute to the growth of the world economy" [34].

The FAO is a significant global policymaker on issues that include food, agriculture, pesticides, and fisheries. The work and responsibilities of the FAO are quite likely to increase in both magnitude and importance as challenges arise in food production, combating hunger, control of pesticides and hazardous substances, and ocean pollution, among others. These problems will be exacerbated due to increased global population and the effects of global climate change.

5.2.5 United Nations Economic Commission for Europe

The United Nations Economic Commission for Europe (UNECE) was established in 1947 to encourage economic cooperation among its member states. The commission was established to foster economic recovery in Europe after World War II. It is one of five regional commissions under the administrative direction of UN headquarters. The ECE has 55 member states and reports to the UN Economic and Social Council. The U.S. is a member. The UNECE's headquarters are located in Geneva, Switzerland. "The UNECE strives to foster sustainable economic growth among its 55 member countries. To that end UNECE provides a forum for communication among States, brokers international legal instruments addressing trade, transport and the environment, and supplies statistics and economic and environmental analysis" [35].

Of environmental health policy note, there is a treaty on water quality that was developed under the auspices of the UNECE. The convention on the Protection and Use of Transboundary Watercourses and International Lakes was agreed upon at Helsinki, Finland, on March 17, 1992 [36]. The convention's general provisions provide insight into its environmental health polices:

- "The parties shall take all appropriate measures to prevent, control and reduce any transboundary impact.
- The parties shall, in particular, take all appropriate measures:
  - To prevent, control and reduce pollution of waters causing or likely to cause transboundary impact.
  - To ensure that transboundary waters are used with the aim of ecologically sound and rational water management, conservation of water resources and environmental protection;
  - To ensure that transboundary waters are used in a reasonable and equitable way, taking into particular account their transboundary character, in the case of activities which cause or are likely to cause transboundary impact;
  - To ensure conservation and, where necessary, restoration of ecosystems.

- Measures for the prevention, control and reduction of water pollution shall be taken, where possible, at source.
- These measures shall not directly or indirectly result in a transfer of pollution to other parts of the environment.
- In taking the measures referred to in paragraphs 1 and 2 of this article, the Parties shall be guided by the following principles:
  - The precautionary principle, by virtue of which action to avoid the potential transboundary impact of the release of hazardous substances shall not be postponed on the ground that scientific research has not fully proved a causal link between those substances, on the one hand, and the potential transboundary impact, on the other hand;
  - The polluter-pays principle, by virtue of which costs of pollution prevention, control and reduction measures shall be borne by the polluter;
  - Water resources shall be managed so that the needs of the present generation are met without compromising the ability of future generations to meet their own needs.
- The Riparian Parties shall cooperate on the basis of equality and reciprocity, in particular through bilateral and multilateral agreements, in order to develop harmonized policies, programmes and strategies covering the relevant catchment areas, or parts thereof, aimed at the prevention, control and reduction of transboundary impact and aimed at the protection of the environment of transboundary waters or the environment influenced by such waters, including the marine environment.
- The application of this Convention shall not lead to the deterioration of environmental conditions nor lead to increased transboundary impact.
- The provisions of this Convention shall not affect the right of Parties individually or jointly to adopt and implement more stringent measures than those set down in this Convention" [36].

A perusal of these eight provisions reveals several policies that correspond to five of the public's policy expectations that were discussed in Chapter 1: (1) prevention of pollution is strongly emphasized in the provisions, (2) rational water management can be interpreted as a matter of accountability, (3) the Precautionary Principle is advocated as a key policy, (4) the polluter-pays principle is endorsed, and (5) reference to present and future generations is consistent with a policy of sustainable development. It is interesting to observe the incorporation of the public's policy expectations into a major regional environmental treaty.

In order to implement the general provisions of the convention required the development of the Protocol on Water and Health. The Protocol entered into force on August 4, 2005, following ratification by the minimum 16 countries [37]. The Protocol calls on the ratifying countries to strengthen their health systems, improve planning for and management of water resources, improve the quality of water supplies and sanitation services, address future health risks, and ensure safe recreational water environments. Each country has the responsibility for its implementation of the Protocol.

According to WHO, the Protocol on Water and Health is the world's first legally binding international agreement that expressly intends to reduce water-related diseases [37]. The U.S. is not a signatory to the protocol, relying on domestic water safety and security policies (Chapter 9).

5.3 WORLD BANK

At the end of World War II, the victorious Allies (the UK, U.S., and USSR) were faced with the reality of rebuilding the Axis powers they had defeated (Germany, Italy, and Japan). Other countries in Europe caught up in the war also needed rebuilding of their national economies and physical infrastructure. Only the U.S. mainland had remained relatively isolated from the wounds of World War II. Protected by the vast Atlantic and Pacific oceans, the U.S. had been largely immune to the presence of foreign troops and damage to the country's infrastructure.

Under the Truman administration, the Marshall Plan poured financial and technical aid into Europe. In 1947, U.S. Secretary of State George C. Marshall had proposed a solution to the widespread hunger, unemployment, and housing shortages in Europe. Marshall proposed that the European nations themselves set up a program for reconstruction, with U.S. help. This proposal led to Congressional enactment of the Economic Assistance Act of 1948. Over the 4 years of the Marshall Plan's life, about $13.3 billion was appropriated by Congress [38]. A component of the plan to rebuild Europe was the creation in 1944 of the International Bank for Reconstruction and Development (IBRD), known more simply then as the World Bank. Following the rebuilding of Europe, the Bank engaged the needs of the world's poorest countries, which became known as developing countries.

During the decade of the 1990s, the World Bank became increasingly important in global programs of health and environmental protection. Based in Washington, DC, the World Bank Group currently consists of five institutions that are owned by member countries. Two of the institutions, the IBRD and the International Development Association (IDA), constitute what is now called the World Bank [39]. The World Bank functions as a bank in the sense that it raises capital from its investment in global financial markets (e.g., national stock exchanges) and makes loans to national governments. Funds invested by the Group come from member countries and individual donors.

The World Bank makes loans to national governments. Funds come from member countries and individual donors. Loans help provide access to better basic services (such as education, health care, and clean water and sanitation).

Of the two groups constituting the World Bank, The IDA "[h]elps provide access to better basic services (such as education, health care, and clean water and sanitation) and supports reforms and investments aimed at productivity growth and employment creation" [39]. The IDA was established in 1960 to provide assistance to countries that are too poor to borrow at commercial rates. They issue interest-free loans (called IDA credits), which borrowers must repay in 35–40 years. Contributions to the IDA constitute $6–$7 billion annually, deriving from approximately 40 countries, including a mix of industrialized countries (France, Germany, Japan, the UK, and U.S.) and some developing countries (e.g., Botswana, Turkey) [39]. The IDA has become a significant source of funds for public health and environmental projects in developing countries that qualify for IDA credits. The IDA cites the following accomplishments for the period 2011–2015: Over 400 million people received essential health services; 17 million pregnant women received prenatal care from a health-care provider; 50 million people received access to better water services; over 100,000 km of roads were constructed, rehabilitated, or upgraded; 5 million teachers were recruited and/or trained; and 205 million children were immunized [39].

The World Bank's monetary credits to developing countries in support of environmental health projects have grown over time, in part because of donors' increased funding. As a matter of policy, some donor countries view the World Bank as preferable to UN agencies because of the Bank's more stringent control over how funds are allocated and spent. Another matter of political importance is whether developing countries should be permitted to forego repayment of World Bank credits. Some environmentalists and social activists have argued that unless debt relief is given to poor countries, they will remain in debt, chilling any prospects of social and economic development. There is merit in this argument, but such debt relief would have to be managed in ways that do not prompt irresponsible borrowing in the future.

5.4 WORLD TRADE ORGANIZATION

Environmental issues and trade in goods and services are intertwined in ways both good and bad. Trade in goods has historically generally brought economic prosperity to individuals, cities, and nations. Indeed, trade was essential for the economic growth of the fledgling U.S. Economic prosperity promotes social development and cultural growth. Social development includes such positive benefits as job creation, more capital to invest in business enterprises, and more banking services. Economic prosperity can contribute to cultural growth by establishing educational institutions, libraries, fine arts, civil rights, and access to health care. In a positive environmental context, economic prosperity provides, through taxation, philanthropy, and other means, the resources to help finance the infrastructures needed for sewage treatment, air pollution control, water purification, food safety, waste management, and public health programs. On the negative side, numerous examples exist of abuses accompanying the production of goods to be traded. Of course, the most egregious, vile example was (and sadly, still is) the trade in human slaves. Other negative examples include pollution generated by production of goods, disease caused by international transportation of goods, and occupational health and safety problems, including child labor, found in some workplaces.

Following the end of World War II, nations were eager to stabilize economic development and trade. War had ravaged much of Europe, the USSR, Japan, and China. Even the U.S., which largely had been spared physical damage to its infrastructure, needed economic recovery to pay for the monetary cost of World War II. The mechanism chosen for trade stabilization was the Global Agreement on Trade and Tariffs (GATT), created in 1947 by 23 trade-dependent nations, and including the U.S. GATT provided the forum for resolving trade issues, e.g., tariff disputes over goods traded between the U.S. and Europe.

GATT was replaced by the WTO, which came into existence on January 1, 1995. Like GATT, the WTO, which is based in Geneva, Switzerland, functions as a voluntary body of nations. The WTO generally operates by seeking consensus among its member countries. Unlike GATT, WTO's decisions are binding and can be enforced by withdrawing trade benefits from a country that has violated WTO rules [40]. WTO members are expected to enact WTO policies and directions and accept findings on both general and specific trade issues. The WTO states, "The WTO is a rules-based, member-driven organization—all decisions are made by the member governments, and the rules are the outcome of negations among members" [41]. As of July 2016, the organization's membership comprised 164 countries. WTO's functions are stated to be (1) administering WTO trade agreements, (2) serving as a forum for trade negotiations, (3) handling trade disputes, (4) monitoring national trade policies, (5) providing assistance and training for developing countries, and (6) cooperating with other international organizations [41]. Settling trade disputes is an important and often quite visible function of the WTO.

Dissatisfaction with the WTO has been expressed in words and deeds, e.g., demonstrations by environmental groups and organized labor. Some environmental groups believe that WTO decisions on trade have lessened environmental protections. For example, Friends of the Earth notes that U.S. restrictions on the import of shrimp from countries where fishermen catch shrimp with nets that kill endangered sea turtles were set aside by the WTO, which found the U.S. in violation of trade rules [42]. The effect of this WTO decision was to negate U.S. protection of an endangered species, sea turtles, in favor of commercial shrimpers with no evident environmental conscience. As a matter of U.S. domestic policy, WTO's authority to negate environmental and public health protections is very troubling. Do the benefits of "free trade" exceed the costs to environmental quality and public health? This is a calculus yet to be performed.

Organized labor in the U.S. has also expressed reservations about aspects of WTO's operation. One organization asserts, "the push to reduce all trade barriers in all sectors

has exacerbated social tensions, frayed social safety nets and highlighted national differences in labor laws and environmental protection. Problems with the WTO arise because its rules are seen as too intrusive by some countries (in overriding legitimate domestic laws) and because of the absence of rules in such crucial areas as labor rights. [B]ecause workers' rights (other than prison labor) are not included in WTO rules, countries may not withdraw trade preferences from WTO members even for egregious violation of workers' rights" [40]. As policy, how will the U.S. and other industrialized countries with well-developed protections for workers' rights work to improve the WTO's record of lowering environmental and labor protections in the guise of "free trade"?

5.5 EUROPEAN UNION

The discussion to this point has focused on UN global agencies or non-UN agencies with global programs. There also exist organizations with regional focus. One of the most significant is the EU. The history of the EU derives from the need for ways to prevent wars among European nations. For centuries, Europe was the scene of frequent and bloody conflicts. In the twentieth century alone, political instability in Europe led to World Wars I and II, conflicts that spilled out of Europe and engaged the U.S. and other countries in regional and global warfare.

As noted by the EU [43], following World War II, a number of European leaders sought ways to secure a lasting peace through treaties that bound their nations through economic and political agreements. In 1950, this led the French Foreign Minister Robert Schuman to propose that the coal and steel industries of Western Europe join in a cooperative arraignment that furthered the national interests of cooperating countries. As a result, in 1951, the European Coal and Steel Community (ECSC) was established, with six members: Belgium, France, Italy, Luxembourg, The Netherlands, and West Germany. This international cooperation led to the formation of an independent, supranational body called the "High Authority," which had the authority to formulate polices and take actions on the coal and steel industries in the six member countries [43].

The ECSC was such a success that the six member countries agreed to go further in economic and political coordination. In 1957, they signed the Treaty of Rome, creating the European Atomic Energy Community and the European Economic Community. The six member states effected removal of trade barriers between themselves and forming a "common market." In 1967, a single Commission, a single Council of Members, and the European Parliament were created. Since that year, the number of member countries has steadily increased in number.

The EU, which was created by the Treaty of Maastricht, came into existence in November 1993. In 1995, the European Community was renamed the EU when the organization grew from 12 to 15 Member States [44]. Ten more Member States joined the EU in 2004. As of 2017, the member states were Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the UK.* The EU has adopted a common currency, the Euro, which is used across Member States.

The EU serves as an umbrella for its member countries to cooperate in areas that include a single trade market, unified foreign policy, mutual recognition of national credentials, and exchange of information bases. This cooperation is pursued through a complex organization structure, consisting of five EU institutions and flanked by four other important bodies [45]. The four EU institutions are the following:

- "European Parliament (elected by the peoples of the Member States);
- Council of the European Union (representing the governments of the Member States);
- European Commission (driving force and executive body);
- Court of Justice (ensuring compliance with the law);
- Court of Auditors (controlling sound and lawful management of the EU budget)" [45].

The other four bodies of importance to the EU's organization and its program of work are the following:

- "European Economic and Social Committee (expresses the opinions of organised civil society on economic and social issues);
- Committee of the Regions (expresses the opinions of regional and local authorities);
- European Central Bank (responsible for monetary policy and managing the euro);
- European Investment Bank (helps achieve EU objectives by financing investment projects)" [45].

The EU and its predecessor European Community and some member states have generated a substantial amount of environmental legislation and legal acts. The aims set out in the EU treaties are achieved by several types of legal act. Some are binding, others are not. Some apply to all EU countries, others to just a few. The forms of legal act are as follows [46]:

"Regulations: A "regulation" is a binding legislative act. It must be applied in its entirety across the EU. For example, when the EU wanted to make sure that there are common safeguards on goods imported from outside the EU, the Council adopted a regulation.

The EU serves as an umbrella for its member countries to cooperate in areas that include a single trade market, unified foreign policy, mutual recognition of national credentials, and exchange of information bases.

* The British electorate voted in 2017 to exit the EU.

Directives: A "directive" is a legislative act that sets out a goal that all EU countries must achieve. However, it is up to the individual countries to devise their own laws on how to reach these goals. One example is the EU consumer rights directive, which strengthens rights for consumers across the EU by, for example, eliminating hidden charges and costs on the Internet, and extending the period under which consumers can withdraw from a sales contract.

Decisions: A "decision" is binding on those to whom it is addressed (e.g., an EU country or an individual company) and is directly applicable. For example, the commission issued a decision on the EU participating in the work of various counterterrorism organizations. The decision related to these organizations only.

Recommendations: A "recommendation" is not binding. When the commission issued a recommendation that EU countries' law authorities improve their use of videoconferencing to help judicial services work better across borders, this did not have any legal consequences. A recommendation allows the institutions to make their views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed.

Opinions: An "opinion" is an instrument that allows the institutions to make a statement in a nonbinding fashion; in other words without imposing any legal obligation on those to whom it is addressed. An opinion is not binding. It can be issued by the main EU institutions (Commission, Council, and Parliament), the Committee of the Regions, and the European Economic and Social Committee. While laws are being made, the committees give opinions from their specific regional or economic and social viewpoint. For example, the Committee of the Regions issued an opinion on the clean air policy package for Europe" [46].

Regulations and directives are the two most common outcomes of EU legislation. Regulations become law throughout the EU on their effective date, generally enforceable in each Member State. EU directives, in distinction, are not directly and generally enforceable in Member States [47]. Rather, directives set goals for the EU's Member States to achieve through national legislation.

Of note, as discussed in Chapter 1, the EU has adopted the Precautionary Principle as policy. This is not surprising, given its origins in Sweden and Germany. Moreover, the slow adoption in Europe of quantitative risk assessment, in contrast to the U.S., created something of a void in how to prevent adverse public health and environmental consequences of environmental hazards. In 2000, the European Commission, which is the administrative arm of the EU, published Precautionary Principle guidelines for the EU'S Member States [48]. The guidelines were discussed in Chapter 1.

The EU's adoption of the Precautionary Principle as policy has already had public health and economic consequences. An example of the former is found in an EU-proposed program of chemical testing. In October 2003, the European Commission adopted legislation for a new EU regulatory framework for chemicals [49]. Called the Registration, Evaluation and Authorisation of Chemicals (REACH) framework [50], the proposal would require chemical manufacturers to conduct extensive safety tests over a span of 11 years on approximately 30,000 of the most common chemicals in the EU market for which toxicity data are lacking [51]. The Precautionary Principle was the driving force behind REACH, which has been opposed by the U.S. government [52], asserting that the U.S. Toxic Substances Control Act (Chapter 11) was adequate for testing chemicals that reach the U.S. The global chemical industry also opposes REACH, primarily because of the high cost of conducting toxicity tests. In November 2005, the European Parliament approved a modified version of REACH. The amended REACH program reduced the overall number of chemicals that would be required for testing by chemical producers [53]. EU's Member States must approve the Parliament's legislation before a final REACH program is adopted throughout the EU. As environmental health policy, better toxicological databases of substances already in commerce will help make better regulatory decisions and provide improved programs of public health.

The EU's body of environmental legislation covers a broad range of environmental concerns and issues, including air and water pollution, solid and hazardous wastes, noise pollution, radioactive waste, conservation of wild fauna and flora, urban waste treatment, freedom of information on the environment, expanded waste regulations, conducting environmental impact statements of projects, and establishment of the European Environment Agency (EEA) [46]. As of the end of 2004, the EU has adopted more than 200 environmental protection directives that are applied in all Member States. Most of the directives are designed to prevent air and water pollution and encourage waste disposal. Other major issues include nature conservation and the supervision of dangerous industrial processes. The EU "[w]ants transport, industry, agriculture, fisheries, energy and tourism to be organised in such a way that they can be developed without destroying our natural resources-in short, sustainable development. We already have cleaner air because of the EU decisions in the 1990s to put catalytic converters into all cars and to get rid of the lead added to petrol" [45]. Waste management is an example of one set of EU environmental directives.

5.5.1 European Environmental Agency

In 1990, the EU created the EEA, which is based in Copenhagen and has been operational since 1994. The agency does not have regulatory authority but is designated by the EU to collect and disseminate information about the environment. The EEA's information resources are used by the EU's Member States, the European Commission, the European Parliament, and the public, among others, when developing adopting, implementing, and evaluating environmental policies [54]. The EEA states its mission as, "[t]o support sustainable development and to help achieve significant and measurable improvement in Europe's environment through the provision of timely, targeted, relevant and reliable information to policy making agents and the public" [54].

In 2004, the EEA announced the release of Europe's first industrial pollution register, a database similar in concept and purpose to the U.S. Toxics Release Inventory. The European Pollutant Registry (EPER) contains reports from the 15 EU countries plus Norway, which is not an EU member. The first edition of the EPER provides data on emission releases of 50 pollutants to air, water, and to offsite wastewater treatment facilities by approximately 9000 industrial plants in 36 industrial sectors [55]. The report is intended to report about 90% of pollution point sources released from Europe's largest and most polluting industrial sources. According to the EEA, the EPER report is being used by environmental organizations to focus attention on specific sources of pollution. In this regard, the policy of using emissions data, such as in the EPER or the TRI, to bring pubic pressure on industrial sources of pollution will continue to be effective public policy.

Among the EEA's significant accomplishments is the preparation and distribution of an overall assessment of Europe's environment. The documents are prepared using member states' environmental data and that maintained by the EEA itself. The assessments are candid and constitute a database for EU policy development and revision. For example, the Third Assessment contains the following summary findings, "This, the third assessment, shows that most progress on environmental improvement continues to come from 'end-of-pipe' measures, actions under well-established international conventions and legislation, or as a result of economic recession and restructuring. [m]oving towards more sustainable approaches seems to be more aspiration than reality in many parts of Europe. [T]here has been less progress on implementation and substantial barriers to real progress remain, both political and financial" [56]. This kind of candid, specific analysis would be of enormous help to policymakers serious about improving environmental quality, based on a foundation of sustainable development.

5.5.2 European Chemical Agency

The European Chemical Agency (ECHA) is the driving force among regulatory authorities in implementing the EU's chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness. The ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals, and addresses chemicals of concern [57]. ECHA was established June 1, 2007 and has headquarters in Helsinki, Finland. The ECHA is the EU's principal agency on matters that pertain to the EU regulatory framework for chemicals called the REACH framework (Chapters 2, 11).

5.5.3 European Food Safety Authority

The European Food Safety Authority (EFSA) is a European agency based in Parma, Italy, funded by the EU, and functions independently of the European legislative and executive institutions (Commission, Council, and Parliament) and EU Member States. Following a series of food crises in the late 1990s, EFSA was established in 2002 to be a source of scientific advice and communication on risks associated with the food chain. The agency was legally established by the EU under the General Food Law-Regulation 178/2002 [58].

The General Food Law created a European food safety system in which responsibility for risk assessment (science) and for risk management (policy) is kept separate. EFSA is responsible for the former area and also has a duty to communicate its scientific findings to the public. As the risk assessor, EFSA produces scientific opinions and advice that form the basis for European policies and legislation. EFSA's responsibilities cover food and feed safety, nutrition; animal health and welfare; plant protection; and plant health [58]. The agency also considers, through environmental risk assessments, the possible impact of the food chain on the biodiversity of plant and animal habitats.

5.6 GLOBAL RANKINGS OF ENVIRONMENTAL STATUS

Environmental pollution is no respecter of national boundaries. It is for this reason that international agencies and between-nation treaties have been created, as described in this chapter. As national governments' environmental programs and policies mature, there will be a need to assess their effectiveness in reducing pollution and protecting the health of humans and ecosystems. Nascent efforts are underway to objectively compare environmental performance between countries. Such comparisons can presumably identify environmental programs that are succeeding and those that are not. From such analysis can come changes in international policymaking, e.g., directing funds to countries where environmental progress is deemed to be inadequate.

One source that ranks national environmental programs is the World Economic Forum, an independent international organization incorporated as a Swiss not-for-profit foundation and has NGO consultative status with the Economic and Social Council of the United Nations. A collaborative project between the Forum, Yale University, and Columbia University has developed two indexes to gauge a country's environmental status. One index, called the Environmental Sustainability Index (ESI), has been used to rank national environmental programs on the basis of five categories: "environmental systems, environmental stresses, human vulnerability to environmental risks, a society's institutional capacity to respond to environmental threats, and a nation's stewardship of the shared resources of the global commons" [59].

Twenty key indicators were calculated across the five ESI categories. Factors such as urban air quality, water, and the strength of environmental regulation are among the 20 indicators that constitute the ESI, which in turn are built upon 68 underlying databases. "The ESI distills a country's capacity for sustained environmental strength into a single number ranging from 0 to 100" [59]. The top five countries, according to ESI ranking, are Finland, Norway, Sweden, Canada, and Switzerland, with ESIs ranging from 73.9 to 66.5. Finland was top ranked because of low levels of air and water pollution, its

high institutional capacity to handle environmental problems, and its comparatively low emission of GHSs. The U.S. ranked 45th among 142 countries, achieving good marks on controlling water pollution, but lagging in controlling GHS emissions and underperforming in reducing waste [59].

A second index, called the Environmental Performance Index (EPI), is designed to measure current environmental results at the national scale [60]. The EPI is a complement to the ESI, covering "[a] broader range of conditions aimed at measuring long-term environmental prospects" [60]. Four indicators comprise the EPI: air quality, water quality, climate change, and land protection. Each indicator has two to four variables that can be calculated, e.g., dissolved oxygen, phosphorus concentrations, and biological oxygen demand comprise the variables for water quality calculations. Like the ESI, the EPI ranges between 0 and 100. Unlike the ESI, calculation of a country's EPI requires the existence of specific databases, such as concentration of sulfur dioxide in outdoor air. Few countries possess such databases, yielding a ranking of only 23 countries. The top five ranked countries were Sweden, Switzerland, Finland, Austria, and Denmark, with EPIs ranging from 74.9 to 60.6. The U.S. ranked 14th, with an EPI of 44.1, due in measure to low scores on climate change and air pollution control. In 2006, the EPI was modified to include more data on sustainability measurements. Using the modified EPI, the U.S. ranked 28th among 68 countries for which enough data were available to derive an EPI [61]. Most countries in Western Europe, as well as Japan, Taiwan, Malaysia, Costa Rica, and Chile all ranked ahead of the U.S. According to the report, "The United States placed 28th in the rankings [...] indicates that the United States is underperforming on critical issues such as renewable energy, GHS emissions, and water resources" [61].

In reflecting on the year 2002 ESI and year 2002 EPI rankings, the investigators concluded that environmental performance is strongly influenced by patterns of environmental governance, independent of levels of national wealth. Moreover, "[u]nderstanding the dynamics of environmental governance is enhanced by explicit consideration of the role of the private sector" [60]. It remains to be seen how these kinds of rankings might affect national environmental policies. Although rankings can reveal weaknesses in the performance of a country's environmental programs, it remains for each country to set its own environmental course, within the confines of international treaties. These rankings are updated annually and are available at the cited reference.

5.7 SUMMARY

It is surely now a cliché to observe that environmental pollution is no respecter of national boundaries. Filth dumped into an ocean in one region becomes part of the pollution load in another region. Similarly, the GHS CO_2 produced in abundance by industrialized countries adds to that produced in developing countries, the sum contributing to global warming. In response to the globalization of environmental hazards, the UN, acting primarily through UNEP, convened global summits on the environment and development in 1992 in Rio de Janeiro, Brazil, and in 2002 in Johannesburg, South Africa. These summits produced plans and policies to deal with environmental problems of global, regional, and national scales. The work done within the UN framework represents the best hope for controlling global environmental hazards.

One issue that has surfaced at UN environmental summits is the disparity in pollution generation between the industrialized countries and the developing world. As debated in international meetings, an issue of the disparity has been cast as environmental parity. In particular, developing countries have argued that pollution controls, as products of industrialization, should not be imposed on countries where industrialization is nascent. In effect, this is an issue of environmental justice, which will be discussed in Chapter 18.

5.8 POLICY QUESTIONS

1. This chapter has presented climate change as a global hazard to humankind. Do you agree? If so, should climate change programs aim to combat progression or create ways to adapt to it? If not, why? Discuss in detail, including any limitations in your knowledge of the position you have taken in responding to this question.
2. Consider the global health risk factors listed in Table 5.1: (1) Identify those of relevance to local health departments in the U.S. Discuss any assumptions and conditions inherent in your selection of specific health risk factors. (2) Using the material in Chapter 1 on responsibilities of local health departments, as a local health department decision-maker, discuss which of your selected risk factors would be amenable to disease and disability prevention programs. (3) Briefly discuss the elements of such prevention programs.
3. The ILO is the only UN body that operates on a tripartite policy, which requires government, industry, and labor participation in all matters of policy and practices. Discuss, using critical thinking, whether WHO could also operate on a tripartite arrangement (e.g., government, commercial interests, at-risk populations).
4. Discuss and contrast the global environmental health impacts of the World Bank and the World Trade Organization. Do either organization's policies affect you as an individual? If so, how?
5. The IARC prepares monographs on individual chemicals of public health and environmental importance. The monographs are prepared by IARC-appointed work groups. Should scientists with industrial affiliations become members of these committees? Why? Why not?
6. Using Internet resources select a specific environmental topic and track it through the EU legislative

process, including any actions taken by national legislative bodies.

7. Agenda 21 was the primary product of the 1991 UNCED, which became known as the Rio Earth Summit. Using Internet and library resources, access a copy of Agenda 21 and discuss its relevance to a local health department.
8. Discuss the convention on POPs and its public health significance.
9. This chapter has highlighted several of the UN agencies that have environmental health policymaking responsibilities. In an essay of appropriate depth, summarize the primary impacts on environmental health of each UN agency discussed in this chapter. List them in descending order of priority according to your sense of their importance.
10. As prelude to a description of the UN, the history of the League of Nations was presented in summary. In an essay of appropriate depth present your analysis of "what if" the League had been successful in its purposes. In your opinion, did the U.S. err in not joining the League?
11. Amble over to the EU or other relevant website and locate a directive of interest to you. Summarize the purpose and principal content of the directive you selected and state in an essay why you selected this directive and relate it to any corresponding regulatory or other environmental health policy in the U.S.
12. In an essay of appropriate depth, compare the authorities and missions of the U.S. FDA to those of the EU's EFSA. State in the final paragraph of your essay your opinion of which agency's authorities give you better food safety protection.
13. As noted in this chapter, the Brundtland Commission included infectious diseases and poverty as matters of global "environmental concern." WHO's definition of "environmental health" was also cited. In an essay of appropriate length and depth, contrast the two definitions and conclude your essay with your choice of definition for "environmental health."
14. This chapter's purpose was to present global environmental issues, policies, and selected resources. In an essay of appropriate depth, describe how environmental conditions in any of the seven commonly accepted continents have any impact on your personal well-being. Be specific and justify your choice of continent.
15. The IARC's mission and primary work were described. Your task is to access the IARC website and select a monograph of particular interest to you. Present a summary of your selected monograph's contents and principal finding. Conclude your summary by relating this monograph's findings to your personal well-being.
16. The UN's Millennium Declaration states, "We resolve therefore to adopt in all our environmental actions a new ethic of conservation and stewardship and, as first steps, we resolve: [...]." Six steps follow. Choose one of the six and evaluate to what extent the step has been effective in the context of environmental health policy.
17. The EPI was described in this chapter and national rankings from use of the index were cited. In your opinion, do rankings such as this one and others provide any useful data for environmental health policymaking purposes? Provide specifics on which you based your opinion.
18. The FAO includes protection of fisheries as one of its priority program areas. Access the FAO website and prepare a précis description of the organization's fisheries program. In your opinion, what is the significance of the fisheries program to your personal well-being?
19. Meander to the ILO website and seek their material on ILO Conventions and Recommendations in the field of Chemical Safety. Select one of their listed conventions (e.g., Chemicals Convention of 1990) and summarize the convention in terms of its present-day relevance.
20. Congratulations! You have successfully completed this chapter. In an essay of appropriate depth, discuss the most important new information that you gleaned from this chapter. Be sure to discuss why this information is important to you.

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Section II

Known Environmental Hazards to Public Health

6 Climate Change

6.1 INTRODUCTION

The bodies of science (e.g., meteorology, physics, chemistry, and environmental) and observable changes occurring in planet Earth signal the greatest current threat to much of life on our globe: climate change. As a reminder, climate is defined as the weather conditions prevailing in an area in general or over a long period. Many scientists and policymakers consider climate change as the current single most consequential threat to planet Earth and its living inhabitants, shown in Figure 6.1 as melting of polar ice due to temperature increase. While this strong assertion may appear to some as hyperbole, the science of climate change supports this assertion, as do signs of changes already evident in the planet's atmosphere, oceans, migratory patterns of pests, and food security. For instance, the melting of polar ice and shrinkage of glaciers, along with increased numbers and severity of episodes of extreme weather are evidence of a change in our climate.

While some naysayers may argue that these kinds of changes are a normal cycling of Earth's climate, the science of climate change disagrees. As an observation, the history of environmental health is replete with examples of denial of an existing body of science for personal or commercial reasons. These examples of denied health science include tobacco smoking, lead additives in gasoline, and workplace exposure to asbestos. Moreover, taking into consideration the body of climate change science and the observed signs of change, a precautionary stance in policymaking seems prudent.

Climate change will affect every living creature on the planet if policies to mitigate its causes are unsuccessful. Some societies will be affected more than others, but all will be affected in some way through impacts such as reduced food supply, less healthy seas, increased incidence of environmental-related diseases, increased number and duration of droughts, and disturbances in ecological systems. One example of the latter is that warmer areas of the globe will attract unwelcome carriers of disease, e.g., mosquitoes.

In addition to the adverse effects on human and ecosystem health, the global economy will be hugely injured. One study estimates that global warming will cost the world economy more than £1.5 trillion a year in lost productivity by 2030 as it becomes too hot to work in many jobs [1]. Given the global nature and impact of climate change, any effort to reverse climate change must be a global endeavor. Moreover, international forums and policymaking will be necessary. For that reason, the UN became the principal organ for addressing climate issues.

As background, technology in its various forms and climate are inextricably connected, where technology is used here in the context of "machinery and equipment developed from the application of scientific knowledge." In a historical sense, machinery and equipment came forth from the application of intuition and human experience, rather than the application of principles of science. For example, invention of the plow for purpose of land cultivation likely came in the absence of any application of science. That having been said, in addition to technology, many forces can shape local, regional, and global patters of climate. For example, forces of nature such as forest fires, volcanic eruptions, bursts of radiant energy from the Sun, and the presence of orbiting celestial materials can effect changes in climate on local to global scale. These impacts of non-anthropogenic causes of climate change have been—and will continue to be—part of Earth's climate-shaping factors. Notwithstanding the importance of nature's climate shapers, human activity has grown increasingly crucial for shaping climate change, with the impact of technology in the forefront of impact shapers.

The Industrial Revolution brought commerce, wealth, jobs, and waste products released into the environment. The path to climate change had begun.

One could assert that from our very appearance as a separate species, we have lived in ways that have affected the climate. For example, the use of fire for food preparation and protection from feral animals resulted in the release into ambient air products of incomplete combustion, carbon monoxide, and carbonaceous particles. The impacts on the climate were insignificant due to the small amounts of pollutants released into ambient air and waste into soils and water. Changes in climate were insignificant and sustainable. This benign relationship between human activity and climate began to change with the appearance of the Industrial Revolution. As described by one source, "The Industrial Revolution, which took place from the 18th to 19th centuries, was a period during which predominantly agrarian, rural societies in Europe and America became industrial and urban. Prior to the Industrial Revolution, which began in Britain in the late 1700s, manufacturing was often done in people's homes, using hand tools or basic machines. Industrialization marked a shift to powered, special-purpose machinery, factories and mass production. The iron and textile industries, along with the development of the steam engine, played central roles in the Industrial Revolution, which also saw improved systems of transportation, communication and banking. While industrialization brought about an increased volume and variety of manufactured goods and an improved standard of living for some, it also resulted in often grim employment and living conditions for the poor and working classes" [1a].

The engines of the industrial revolution were energy, raw materials, transportation, and labor. These engines produced goods, services, and waste. Products and goods

FIGURE 6.1 Melting of polar ice due to climate change. (From U.S. House of Representatives, Select Committee on Energy Independence and Global Warming, 2016.)

became matters of commerce, with corresponding increases in personal, regional, and national wealth. Jobs were created across the span of the Industrial Revolution. Steam powered machinery joined and subsequently supplanted the energy exerted by workers' heavy labor. Roads and waterways were constructed for use in transporting goods and products manufactured in factories. Trade became global as goods were shipped and exchanged across continents. The Agrarian Age came to a close in what had become known as "industrialized countries" in Europe and much of North America. But with the successes of the Industrial Revolution came a silent threat to the global climate. The threat was waste released into the environment as air pollutants, water contaminants, and food impurities.

Coal was the dominant fuel for energy production during and following industrialization of national economies. Coal was abundant in Europe, North America, China, and elsewhere. Although the process was labor intensive, coal was relatively easy to mine. Combustion of coal could heat water and thereby produce steam; steam engines delivered power to new forms of machinery that in turn manufactured goods and products for commerce. But burning coal was and remains a relatively inefficient process of combustion, resulting in tall chimneys built for release of incomplete products of coal combustion into the atmosphere. Apparently little or no thought was given to the environmental consequences of fouling the air with soot, carbon monoxide, and hydrocarbons. These consequences became global in occurrence and impact.

6.2 GLOBAL PERSPECTIVE

As a preface, Earth's climate is always changing. In the past, Earth's climate has gone through warmer and cooler periods, each lasting thousands of years. Observations show that Earth's climate has been warming. Its average temperature has risen a little more than one degree Fahrenheit during the past 100 years or so. This amount may not seem like much. But small changes in Earth's average temperature can lead to big impacts. Some causes of climate change are natural. These include changes in Earth's orbit and in the amount of energy coming from the sun. Ocean changes and volcanic eruptions are also natural causes of climate change [2].

Many scientists accept that most of the global warming that has occurred since the mid-1900s is due to the combustion of fossil fuels (coal, oil, and gas) [2]. Combusting these carbon-based fuels produces most of the energy used daily worldwide. Energy is produced, but so are products of incomplete combustion. The most consequential releases are gases that add to those already present in the atmosphere. Heat-trapping gases, such as CO_2, are emitted into the air. These gases are called greenhouse gases (GHGs).

As background, GHGs in Earth's atmosphere absorb infrared radiation (IR) from the Sun and release it. Some of the heat released reaches Earth, along with heat from the sun that has penetrated the atmosphere. Both the solar heat and the radiated heat are absorbed by the planet and released; some is reabsorbed by GHGs to perpetuate the cycle. The more of these gases that exist, the more heat is prevented from escaping into outer space and, consequently, the more Earth heats. This increase in heat is called the greenhouse effect; the increase in heat is measured as increased air temperature.

The GHGs are relatively inefficient in heat transference properties, thereby contributing to heat buildup on Earth. GHGs contribute to the greenhouse effect, which is the warming of the Earth because of a lessened ability of the Earth to radiate energy through its atmosphere. According to scientific consensus, global warming of 1°C–3.5°C will occur over the next 100 years unless GHG concentrations are decreased.

A greenhouse gas is a gas that absorbs infrared radiation (IR) and radiates heat in all directions.

Some GHGs occur naturally in the atmosphere, while others result from anthropogenic activities. Naturally occurring GHGs include water vapor, carbon dioxide, methane, nitrous oxide, and ozone. Anthropogenic activities, however, have increased the atmospheric concentrations of some GHGs. For example, carbon dioxide is formed when solid waste, fossil fuels, wood, and wood products are burned. Methane is emitted during the production and transport of coal, natural gas, and petroleum; decomposition of organic waste in landfills, and from livestock flatulence. Remarkably, it was reported in 2006 that terrestrial plants under aerobic conditions produce significant amounts of methane, estimated to be 10%–30% of annual levels of atmospheric methane. This startling finding has significant implications for control of atmospheric levels of the GHG methane. Nitrous oxide is considered a major GHG due to its long atmospheric lifetime (approximately 120 years) and radiative forcing effects. In the U.S., anthropogenic emissions of N_2O are primarily generated by agriculture soil management, mobile and stationary sources of fossil fuel combustion, adipic acid production, and nitric acid production. Other GHGs that are not naturally occurring include hydroflurocarbons, perflurocarbons, and sulfur hexafluoride. Although many factors have shaped the increase in atmospheric GHG concentrations, the most significant factors

are human population growth, fossil fuel combustion, and deforestation.

On a global scale, what are the principal GHGs released into Earth's atmosphere? According to Environmental Protection Agency (EPA) data, the key GHGs emitted by human activities are [3]:

Carbon dioxide (CO_2): Fossil fuel use is the primary source of CO_2. The way in which people use land is also an important source of CO_2, especially when it involves deforestation. CO_2 can also be emitted from direct human-induced impacts on forestry and other land use, such as through deforestation, land clearing for agriculture, and degradation of soils. Likewise, land can also remove CO_2 from the atmosphere through reforestation, improvement of soils, and other activities. The increase in CO_2 levels in the atmosphere are illustrated by NASA data shown in Figure 6.2. The historical data shown in the figure were derived from carbon measurements of fossils and polar ice. The data in the figure reveal a clear and dramatic increase in CO_2 levels that began in mid-twentieth century and show a dramatic upward trend.

Methane (CH_4): Agricultural activities, waste management, energy use, and biomass burning all contribute to CH_4 emissions.

Nitrous oxide (N_2O): Agricultural activities, such as fertilizer use, are the primary source of N_2O emissions. Biomass burning also generates N_2O.

Fluorinated gases (F-gases): Industrial processes, refrigeration, and the use of a variety of consumer products contribute to emissions of F-gases, which include hydrofluorocarbons, perfluorocarbons, and sulfur hexafluoride (SF_6).

The distribution of these GHGs in the atmosphere is illustrated in Figure 6.3. An examination of the figure indicates that CO_2 represents about 76% of the GHGs, with methane (CH_4) and nitrous oxide (N_2O) representing 16% and 6%, respectively. These percentages are important for policymaking purposes, indicating which GHGs should receive primary attention in efforts to curb climate change.

What then are the sources of GHG emissions? EPA monitors the releases in the U.S. of GHGs and lists the following primary sources of GHG emissions in 2014 [3]:

- *Electricity production* (30%): Electricity production generates the largest share of GHG emissions. Approximately 67% of U.S. electricity comes from burning fossil fuels, mostly coal and natural gas.
- *Transportation* (26%): GHG emissions from transportation primarily come from burning fossil fuel for cars, trucks, ships, trains, and planes. More than 90% of the fuel used for transportation is petroleum based, which includes gasoline and diesel.
- *Industry* (21%): GHG emissions from industry primarily come from burning fossil fuels for energy as well as GHG emissions from certain chemical reactions necessary to produce goods from raw materials.

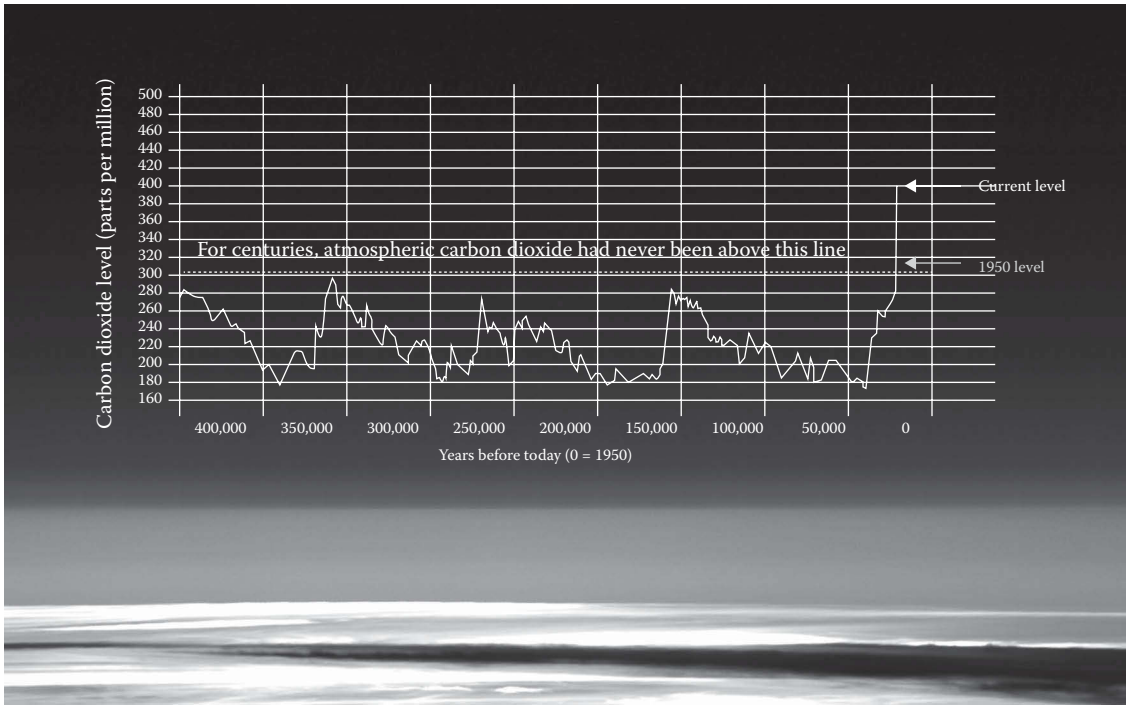

FIGURE 6.2 Historical global levels of CO_2 in Earth's atmosphere. (From Njagi, K., Extreme weather increasing level of toxins in food, scientists warn. Thomson Reuters Foundation. *Reuters*, May 21, 2016.)

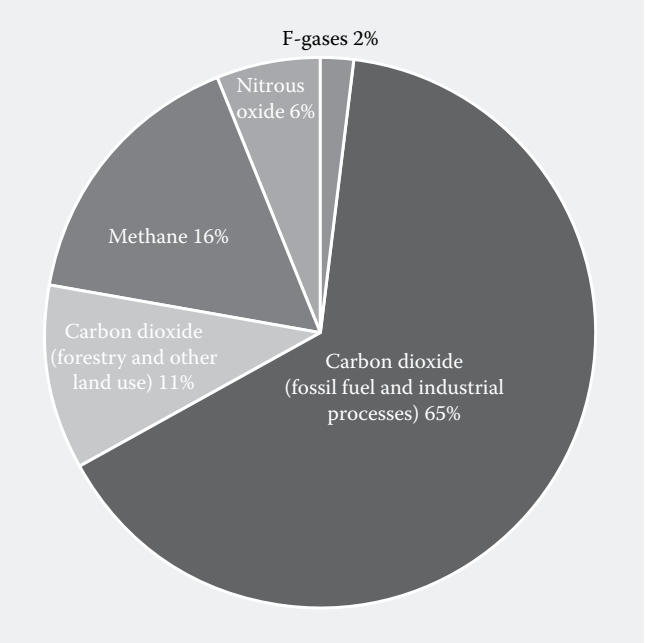

FIGURE 6.3 Distribution of greenhouse gases in Earth's atmosphere. (From EPA (Environmental Protection Agency). Sources of greenhouse gas emissions. https://www3.epa.gov/climatechange/ghgemissions/sources.html, 2016.)

- *Commercial and residential* (12%): GHG emissions from businesses and homes arise primarily from fossil fuels burned for heat, the use of certain products that contain GHGs, and the handling of waste.
- *Agriculture* (9%): GHG emissions from agriculture come from livestock such as cows, agricultural soils, and rice production.
- *Land use and forestry* (offset of 11%): Land areas can act as a sink (absorbing CO_2 from the atmosphere) or a source of GHG emissions. Since 1990 in the U.S, managed forests and other lands have absorbed more CO_2 from the atmosphere than they emit.

* * *

There may be a year or years where Earth's average temperature is steady or even decreases, but the expected overall trend is temperature increase. Earth's average temperature is expected to rise even if the amount of GHGs in the atmosphere decreases. But such a rise would be less than if GHG amounts remain the same or decreased. Some impacts already are evident, as enumerated by NASA, which provides the following pattern of signs of global climate change [2]:

Scientists use climate models to predict how Earth's climate will change. Climate models predict that Earth's average temperature will keep rising over the next 100 years.

- *Sea-level rise*: Global sea level rose about 17 cm (6.7 in.) in the twentieth century. The rate in the last decade, however, is nearly double that of the last century.
- *Global temperature rise*: Global surface temperature reconstructions show that Earth has warmed since 1880. Earth's average temperature has risen by 1.5°F over the past century, and is projected to rise another 0.5°F–8.6°F over the next 100 years. Most of this warming has occurred since the 1970s, with the 20 warmest years having occurred since 1981 and with all 10 of the warmest years occurring in the past 12 years. Even though the 2000s witnessed a solar output decline, resulting in an unusually deep solar minimum in 2007–2009, Earth's surface temperatures continue to increase.
- *Warming oceans*: The oceans have absorbed much of this increased heat, with the top 700 m (about 2300 ft) of ocean showing warming of 0.302°F since 1969.
- *Shrinking ice sheets*: The Greenland and Antarctic ice sheets have decreased in mass. Data show Greenland lost 150–250 km^3 (36–60 mi^3) of ice per year between 2002 and 2006, while Antarctica lost about 152 km^3 (36 mi^3) of ice between 2002 and 2005.
- *Declining Arctic sea ice*: Both the extent and thickness of arctic sea ice has declined rapidly over the last several decades.
- *Glacial retreat*: Glaciers are retreating almost everywhere around the world—including in the Alps, Himalayas, Andes, and Rockies, as well as within Alaska and Africa.
- *Extreme events*: The rising global temperatures have been accompanied by changes in weather and climate. Many places have seen changes in rainfall, resulting in more floods, droughts, or intense rain, as well as more frequent and severe heat waves. Since 1950 the number of record high temperature events in the U.S. has been increasing, while the number of record low temperature events has been decreasing. The U.S. has also witnessed increasing numbers of intense rainfall events.
- *Ocean acidification*: Since the beginning of the Industrial Revolution, the acidity of surface ocean waters has increased by about 30%. This increase is the result of humans emitting more carbon dioxide into the atmosphere and hence more being absorbed into the oceans. The amount of carbon dioxide absorbed by the upper layer of the oceans is increasing by about 2 billion tons per year.
- *Decreased snow cover*: Satellite observations reveal that the amount

Current Signs of Climate Change [2]:

- Sea-level rise
- Global temperature rise
- Warming oceans
- Shrinking ice sheets
- Declining Arctic sea ice
- Glacial retreat
- Extreme weather events
- Ocean acidification
- Decreased snow cover

of spring snow cover in the Northern Hemisphere has decreased over the past five decades and that the snow is melting earlier.

These observed changes in Earth's climate are caused by the buildup of GHGs.

Perspective: The nature and sources of GHGs is important for environmental health policymaking. In particular, policies to reduce the emission of GHGs can be focused on eliminating or tempering their sources and dealing with the economic and social effects of source reductions.

6.3 HISTORY OF GLOBAL CLIMATE CHANGE POLICIES

The UN [3a] provides an illuminating history of climate change, the environmental concerns, and global policymaking efforts, "To fully understand the current debate, one must look at the rise in prominence of environmental issues on the global agenda and the evolution of climate change within that context. Environmental issues, much less climate change, were not a major concern of the UN in the period following the organization's creation. During its first 23 years, action on these issues was limited to operational activities, mainly through the World Meteorological Organization (WMO), and when attention was paid to them, it was within the context of one of the major preoccupations of that time: the adequacy of known natural resources to provide for the economic development of a large number of UN members or the "underdeveloped countries," as they were then termed.

In 1949, the UN Scientific Conference on the conservation and utilization of resources (Lake Success, New York, August 17 to September 6) was the first UN body to address the depletion of those resources and their use. The focus, however, was mainly on how to manage them for economic and social development, not from a conservation perspective. It was not until 1968 that environmental issues received serious attention by any major UN organs. The Economic and Social Council on May 29 was the first to include those issues in its agenda as a specific item and decided—later endorsed by the General Assembly—to hold the first United Nations Conference on the Human Environment.

Held in Stockholm, Sweden, June 5–16, 1972, the UN Scientific Conference, known also as the First Earth Summit, adopted a declaration that set out principles for the preservation and enhancement of the human environment, and an action plan containing recommendations for international environmental action. In a section on the identification and control of pollutants of broad international significance, the declaration raised the issue of climate change for the first time, warning governments to be mindful of activities that could lead to climate change and evaluate the likelihood and magnitude of climatic effects.

The UN Scientific Conference also proposed the establishment of stations to monitor long-term trends in the atmospheric constituents and properties, which might cause meteorological properties, including climatic changes. Those programs were to be coordinated by WMO to help the world community to better understand the atmosphere and the causes of climatic changes, whether natural or the result of man's activities. The Conference also called for the convening of a second meeting on the environment and established the Governing Council of United Nations Environment Programme (UNEP), with its secretariat in Nairobi, Kenya, the Environment Fund and the Environment Coordination Board. But climate change did not become a central preoccupation of those bodies. Water resources, marine mammals, renewable energy resources, desertification, forests, environmental legal framework and the issue of environment and development took center stage.

Over the next 20 years, as part of efforts to implement the 1972 decisions, concern for the atmosphere and global climate slowly gained international attention and action. In 1979, the UNEP Governing Council asked its executive director, under the Earth Watch program, to monitor and evaluate the long-range transport of air pollutants, and the first international instrument on climate—the Convention on Long-Range Transboundary Air Pollution—was then adopted. UNEP took it to another level in 1980 when its Governing Council expressed concern at the damage to the ozone layer and recommended measures to limit the production and use of chlorofluorocarbons (CFCs) F-11and F-12. This led to the negotiation and adoption in 1985 of the Vienna Convention for the Protection of the Ozone Layer and the conclusion of a Protocol to the 1979 Transboundary Air Pollution Convention, which aimed at reducing sulfur emissions by 30%. In the meantime, palpable evidence of climate change due to air pollution was beginning to emerge in the phenomena of acid rain in Europe and North America, which resulted in various programs by UNEP and WMO for keeping it in check.

However, in 1987 the UN General Assembly gave real impetus to environmental issues, when it adopted the Environmental Perspective to the Year 2000 and Beyond—a framework to guide national action and international cooperation on policies and programs aimed at achieving environmentally sound development. The perspective underlined the relationship between environment and development and for the first time introduced the notion of sustainable development. It was disappointing, however, that such a long-term policy document, while recognizing the need for clean air technologies and to control air pollution, did not make climate change a central issue, but subsumed it under its policy directive related to energy.

In 1988, global warming and the depletion of the ozone layer became increasingly prominent in the international public debate and political agenda. UNEP organized an internal seminar in January to identify environmental sectors that might be sensitive to climate change. The Intergovernmental Panel on Climate Change (IPCC), a forum for the examination of greenhouse warming and global climate change, was established and met for the first time in November that year. The General Assembly identified climate change as a specific and urgent issue. In its resolution on the protection of global climate for present and future generations of mankind,

it asked WMO and UNEP to initiate a comprehensive review and make recommendations on climate change, including possible response strategies to delay, limit or mitigate the impact of climate change. As a result, 1989 was a watershed year for climate change, as the first significant global efforts were taken. The Assembly, in resolution 44/207, endorsed the UNEP Governing Council's request to begin preparations with WMO for negotiations on a framework convention on climate change; regional action was also being taken. In addition, the Maldives transmitted the text of the Malé Declaration on Global Warming and Sea Level Rise to the UN Secretary-General and the Helsinki Declaration on the Protection of the Ozone Layer was adopted on May 2. Also in 1989, the Montreal Protocol on Substances that Deplete the Ozone Layer entered into force.

Efforts to raise awareness of the effects of climate change were further advanced at the second World Climate Conference, held from October 29 to November 7, 1990. In its Ministerial Declaration, the Conference stated that climate change was a global problem of unique character for which a global response was required. It called for negotiations to begin on a framework convention without further delay. As the urgency for a stronger international action on the environment, including climate change, gained momentum, the General Assembly decided to convene in 1992 in Rio de Janeiro, Brazil, the United Nations Conference on Environment and Development. The Earth Summit, as it is also known, set a new framework for seeking international agreements to protect the integrity of the global environment in its Rio Declaration and Agenda 21, which reflected a global consensus on development and environmental cooperation.

Chapter 9 of Agenda 21 dealt with the protection of the atmosphere, establishing the link between science, sustainable development, energy development and consumption, transportation, industrial development, stratospheric ozone depletion and transboundary atmospheric pollution. The most significant event during the Conference was the opening for signature of the United Nations Framework Convention on Climate Change (UNFCCC); by the end of 1992, 158 States had signed it. As the most important international action thus far on climate change, the Convention was to stabilize atmospheric concentrations of "greenhouse gases" at a level that would prevent dangerous anthropogenic interference with the climate system. It entered into force in 1994, and in March 1995, the first Conference of the Parties to the Convention adopted the Berlin Mandate, launching talks on a protocol or other legal instrument containing stronger commitments for developed countries and those in transition.

The cornerstone of the climate change action was the adoption in Japan in December 1997 of the Kyoto Protocol (KP) to the UNFCCC, the most influential climate change action so far taken. It aimed to reduce the industrialized countries' overall emissions of carbon dioxide and other GHGs by at least 5% below the 1990 levels in the commitment period of 2008–2012. The Protocol, which opened for signature in March 1998, came into force on February 16, 2005, 7 years after it was negotiated by more than 160 nations" [3a].

As discussed in the following material, the UN has coordinated several seminal meetings on issues of climate change. Five of the meetings resonate in importance as global efforts to mitigate the consequences of climate change. First, the Montreal Convention in 1987 was convened due to the discovery and global concern that the Earth's ozone layer was at risk of lessening its protective shield of planet Earth. Second, in 1988 the IPCC was established under UN auspices. Third, in 1992 the UNFCCC was adopted by the UN's Member States. Fourth, the KP of the UNFCCC was adopted in 1997. Fifth, the culmination of these several meetings and conventions occurred in the 2015 United Nations Climate Change Conference, COP 21, convened in Paris. The Paris Accord was achieved, following years of global diplomacy and national policymaking on climate control. This accord was the first global agreement on the vital need to commit to mitigation of climate change. Specific climate targets were set in place and interim goals were developed with global targets on temperature rise and carbon emissions. The meetings and conventions that forged the actions resulting in the Paris Accord are summarized in more detail in the succeeding sections.

Perspective: The foregoing history of global policymaking on climate change is important as a lesson of the struggle to gain international cooperation on a matter of vital importance to life on Earth. Leadership by the UN on the matter of environmental health policymaking was essential, given the global impact of changes beginning to occur in the global environment. Simply put, climate change is a global problem; therefore a global policymaking political resource was required. An examination of the UN's numerous attempts at consensus building on mitigation of climate change shows gradual success in gaining global acceptance of responsibility by national governments. The key meetings in the journey to build global consensus and action are described herein.

6.3.1 Montreal Protocol on Substances That Deplete the Ozone Layer, 1987

In 1987 UNEP organized a meeting of the UN Member States to develop a policy on how to protect the Earth's ozone layer. The meeting was precipitated by satellite images showing a large hole had developed in the ozone layer above Antarctica. The ensuing meeting, The Montreal Protocol on Substances that Deplete the Ozone Layer, was designed to reduce the production and consumption of ozone-depleting substances in order to reduce their abundance in the atmosphere, and thereby protect the earth's fragile ozone layer. The ozone layer is what saves the Earth and its living organisms from the harmful radiations from the Sun. Ozone depletion occurs when CFCs—formerly found in aerosol spray cans and refrigerants—are released into the atmosphere. These gases, through several chemical reactions, cause the ozone molecules to break down, reducing ozone's ultraviolet radiation-absorbing capacity. The original Montreal Protocol, an international treaty, was agreed to on September 16, 1987 and entered into force on January 1, 1989. The parties to the protocol agreed to global phasing out of CFS and other ozone-depleting substances.

The Montreal Protocol includes a unique adjustment provision that enables the parties to the Protocol to respond quickly to new scientific information and agree to accelerate the reductions required on chemicals already covered by the Protocol. These adjustments are then automatically applicable to all countries that ratified the Protocol. Since its initial adoption, the Montreal Protocol has been adjusted six times. The adjustments include certain revisions and reductions of production and consumption of the controlled substances listed in the Annexes of the Protocol. In addition to adjustments, the parties to the Montreal Protocol have amended the Protocol to enable, for example, the control of new chemicals and the creation of a financial mechanism to enable developing countries to comply. Unlike adjustments to the Protocol, amendments must be ratified by countries before their requirements are applicable to those countries.

Recent data released by UNEP indicate that global measures to protect the Earth's ozone layer are succeeding. The Earth's protective ozone layer is well on track to recovery in mid-twenty first century due concerted international action against ozone depleting substances, according to a new assessment by 300 scientists [4].

6.3.2 Establishment of the Intergovernmental Panel on Climate Change, 1988

As summarized by UNEP, the IPCC was created in 1988 [5]. It was organized by the WMO and UNEP to prepare, based on available scientific information, assessments on all aspects of climate change and its impacts, with a view of formulating realistic response strategies. The initial task for the IPCC was outlined in UN General Assembly Resolution 43/53 of December 6, 1988. The task was to prepare a comprehensive review and recommendations with respect to the state of knowledge of the science of climate change; the social and economic impact of climate change, and possible response strategies and elements. The review was to be prepared for inclusion in a possible future international convention on climate.

The IPCC's role, as defined in Principles Governing IPCC Work, is: "[…] to assess on a comprehensive, objective, open and transparent basis the scientific, technical and socio-economic information relevant to understanding the scientific basis of risk of human-induced climate change, its potential impacts and options for adaptation and mitigation. IPCC reports should be neutral with respect to policy, although they may need to deal objectively with scientific, technical and socio-economic factors relevant to the application of particular policies" [5].

The Intergovernmental Panel on Climate Change (IPCC) was created in 1988. It was organized by the World Meteorological Organization and UNEP to prepare assessments on all aspects of climate change and its impacts.

The scientific evidence brought forth by the first IPCC Assessment Report of 1990 underlined the importance of climate change as a challenge requiring international cooperation in order to tackle its consequences. This report played a decisive role in the creation of the (UNFCCC), the key international treaty to reduce global warming and cope with the consequences of climate change, as described in the succeeding section.

Following establishment of the Framework Convention, the IPCC has delivered comprehensive scientific reports about climate change produced worldwide. The IPCC Second Assessment Report of 1995 provided important material drawn on by negotiators preparatory to adoption of the KP in 1997. The Third Assessment Report was released in 2001 and the Fourth in 2007. The latter report gave greater attention to the integration of climate change with sustainable development policies and relationships between mitigation and adaptation. At the end of 2007 the IPCC was awarded the Nobel Peace Prize.

The Fifth Assessment Report was released in four parts between September 2013 and November 2014. It provided a contemporary view of the current state of scientific knowledge relevant to climate change. This report provided key data and recommendations useful for policymaking of the Paris Accord of 2015.

6.3.3 United Nations Framework Convention on Climate Change, 1992

In 1992, the social and economic consequences of global warming scenarios, buttressed by measured increases in global temperature and ocean levels over the past century, motivated the UN to organize what has become the Framework Convention on Climate Change (FCCC). The text of the Convention was signed in 1992 at the Earth Summit in Rio de Janeiro [6]. The FCCC adopts as a general objective the "[s]tabilization of greenhouse gas concentrations in the atmosphere at a level that would prevent dangerous anthropogenic interference with the climate system. Such a level should be achieved within a time frame sufficient to allow ecosystems to adapt naturally to climate change, to ensure that food production is not threatened, and to enable economic development to proceed in a sustainable manner" [6].

The Convention on Climate Change sets an overall framework for intergovernmental efforts to tackle the challenge posed by climate change. It recognizes that the climate system is a shared resource whose stability can be affected by industrial and other emissions of carbon dioxide and other GHGs. Under the Convention, governments

- Gather and share information on GHG emissions, national policies, and best practices.
- Launch national strategies for addressing GHG emissions and adapting to expected impacts, including the provision of financial and technological support to developing countries.
- Cooperate in preparing for adaptation to the impacts of climate change.

As a treaty, the Framework Convention went into force for signatories on March 21, 1994. There are now 197 Parties to the Convention.

Perspective: The Framework Convention was what its name implies—a structure upon which to build specific action plans and set environmental goals for emissions of GHGs. The Framework Convention provided the foundation upon which future policymaking could be constructed.

6.3.4 Kyoto Protocol of the UNFCCC, 1987

The KP is an international agreement linked to the UNFCCC; The KP was adopted in Kyoto, Japan, on December 11, 1997 and entered into force on February 16, 2005. The Protocol commits its Parties to set internationally-binding emission reduction targets. The KP recognized that developed countries are primarily responsible for the high levels of GHG emissions into the atmosphere as a result of industrial activity, commencing with the Industrial Revolution, Accordingly, the Protocol placed a heavier burden on developed nations under the principle of "common but differentiated responsibilities" [7].

Parties to the Framework Convention agreed that it had to be augmented by an agreement with stricter demands for reducing GHG emissions. The Framework Convention had taken effect in 1994, and by 1995 governments had begun negotiations on a protocol—an international agreement linked to the existing Framework treaty, but standing on its own. The text of the KP was adopted unanimously in 1997; it entered into force on February 16, 2005 [8].

The KP's major feature is that it has mandatory targets on GHG emissions for the world's leading economies that have accepted it. The targets range from −8% to +10% of the countries' individual 1990 emissions levels "with a view to reducing their overall emissions of such gases by at least 5% below existing 1990 levels in the commitment period 2008 to 2012." In almost all cases—even those set at +10% of 1990 levels—the limits call for significant reductions in currently projected emissions. Future mandatory targets are expected to be established for "commitment periods" after 2012, but remain in 2017 to be established. These are to be negotiated well in advance of the periods concerned.

The KP builds upon the terms and agreements in the Framework Convention (UNFCCC) as follows:

An overall framework: The UNFCCC sets an overall framework for international efforts to tackle the challenge of climate change. The Framework's ultimate objective is to stabilize atmospheric concentrations of GHGs at a level that would prevent harm to the climate system. The Framework Convention enjoys near universal membership; as of June, 2007, 191 countries have ratified it. These countries are referred to as Parties to the Convention.

Reporting on emissions: Parties to the Convention agreed to a number of commitments to address climate change. All Parties must develop and periodically submit special reports called national communications. These national communications must contain information on the GHG emissions of that Party and describe the steps it has taken and plans to take to implement the Convention. The KP stipulates that the net change in carbon stocks and GHG emissions by sources and removals by sinks resulting from direct direct human land use, land-use change and forestry (LULUCF) activities. Specifically, under the KP, Parties shall annually report emissions by sources and removals by sinks of CO_2 and other GHGs resulting from: LULUCF activities under Article 3.3 of the Convention, namely afforestation, reforestation and deforestation that occurred since 1990.

National programs: The Convention requires all Parties to implement national programs and measures to control GHG emissions and to adapt to the impacts of climate change. Parties also agree to promote the development and use of climate-friendly technologies; education and public awareness of climate change and its impacts; sustainable management of forests and other ecosystems that can remove GHG from the atmosphere, and to cooperate with other Parties in these matters. The KP commits developed countries (i.e., those with fully developed national economies) to reduce their collective emissions by more than 5% below 1990 levels of six key GHGs by the period 2008–2012, with different targets negotiated for individual countries.

Commitments under the KP vary from nation to nation. The overall 5% target for developed countries is to be met through cuts (from 1990 levels) of 8% in the EU, Switzerland, and most Central and East European states; 6% in Canada; 7% in the U.S. (although the U.S. has since withdrawn its support for the Protocol); and 6% in Hungary, Japan, and Poland. New Zealand, Russia, and Ukraine are to stabilize their emissions, while Norway may increase emissions by up to 1%, Australia by up to 8% (although Australia has subsequently withdrawn its support for the Protocol), and Iceland by 10% [9]. The EU has made its own internal agreement to meet its 8% target by distributing different rates to its member states. These targets range from a 28% reduction by Luxembourg and 21% cuts by Denmark and Germany to a 25% increase by Greece and a 27% increase by Portugal.

To compensate for the sting of "binding targets," as they are called, the agreement offers flexibility in how countries may meet their targets. For example, they may partially compensate for their emissions by increasing "sinks": or forests, which remove carbon dioxide from the atmosphere. That may be accomplished either on their own territories or in other countries. Or they may pay for foreign projects that result in GHG cuts. Several mechanisms have been set up for this purpose.

Industrialized country commitments: Industrialized countries, which are called Annex I Parties under the Convention, have additional commitments.

These Parties initially agreed to undertake policies and measures with the specific aim of returning their GHG emissions to 1990 levels by 2000. Annex I Parties must also provide more frequent national communications and must separately provide yearly reports on their national GHG emissions.

Sharing technologies: Wealthier developed countries (called Annex II Parties) must also promote and facilitate the transfer of climate friendly technologies to developing countries and to countries with economies in transition. They must also provide financial resources to help developing countries implement their commitments through the Global Environment Facility, which serves as the Convention's financial mechanism, and through bilateral or other multilateral channels.

Stabilizing GHGs: The KP shares the Convention's ultimate objective to stabilize atmospheric concentrations of GHGs at a level that will prevent dangerous interference with the climate system. In pursuit of this objective, the KP builds upon and enhances many of the commitments already in place under the Convention. Only Parties to the Convention can become Parties to the Protocol.

Binding targets for developed countries: Although all Parties have agreed to further advance the implementation of their existing commitments under the Convention, only Annex I Parties took on new targets under the Protocol. Specifically, these Parties have agreed to binding emission targets over the 2008–2012 timeframe. The Clinton Administration agreed to an overall reduction of 7% in U.S. gas emissions; however treaties require ratification by the U.S. Senate, which never occurred.

New tools to reduce emissions: To assist industrialized countries in meeting their binding targets, and to promote sustainable development in developing countries, the KP adopted three innovative mechanisms—the clean development mechanism (CDM), joint implementation, and emissions trading.

Monitoring compliance: To support the implementation of these mechanisms, and promote compliance of Annex I Parties with their emission targets, the KP strengthened the Convention's reporting and review procedures and created a system of electronic databases—called national registries—to monitor transactions under the Kyoto mechanism. It also established a compliance committee, which has the authority to determine and apply consequences for noncompliance.

In 2000, the George W. Bush administration announced that the U.S. would not honor the KP and that the U.S. would withdraw from its ratification, thereby reversing the Clinton administration's position. The Bush's administration's basis for opting out of the Protocol was its stated concern that lower U.S. emissions of GHGs would have dire consequences on the U.S. national economy, an economy strongly reliant on carbon-based sources of energy, such as petroleum.

In October 2004, Russia endorsed the KP, which had already been ratified by 120 countries. Russia's approval of the Protocol pushed the treaty past the 55% emissions reduction required for global adoption. Countries that have not ratified the Protocol are not bound to its terms and conditions. Nevertheless, global adoption of the KP represents a significant step toward reducing the potentially cataclysmic consequences of global climate change.

Perspective: If one accepts the science and ominous signs of climate change, failure of the U.S. government to implement the KP placed the U.S. population and regions of the world at risk of suffering the consequences of global warming. Moreover, this failure violates at least three key public policies: precautionary approach, sustainable development, and the public's right-to-know.

As discussed in Chapter 2, the precautionary approach to environmental hazards states, "[W]here there are threats of serious or irreversible damage, lack of all scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." It is clear that global warming is already causing serious damage to the environment and human health (glacial melting, CO_2 increases, acidification of the oceans, regional increases in health-related deaths) and measures are warranted to prevent further environmental degradation. The KP is one such measure. Adoption by the U.S. and other governments of a policy to forego the use of fossil fuels would be a key prescription to mitigating global warming. In the long run, such a policy would have great economic consequence to those countries that develop the technologies to replace fossil fuels. The historical precedent is the development and commercialization of pollution reduction equipment, which found a ready market in countries lacking such technologies.

Second, the policy of sustainable development is also violated by lack of adherence to the KP. As noted in Chapter 2, sustainable development is "[D]evelopment which meets the needs of the present without compromising the ability of future generations to meet their own needs." Failure to adopt the KP surely puts in question the well-being of future generations, which will face higher ambient air temperatures, wider spread of vector-borne diseases, and diminished food supplies. Future generations will suffer the consequences of current inactions on prevention of global warming. They will not suffer their plight gently.

Third, failure to act aggressively to prevent global warming also violates one of the U.S. public's key policy expectations, right-to-know. As discussed in Chapter 1, the U.S. public expects to be informed about hazards and risks that they may confront. In the U.S. little effort has been expended by federal government to actively communicate the serious consequences of global warming. Both Congress and the Executive Branch have been silent on communicating the effects of global warming. Environmental groups have developed health warnings about temperature rises and heat-related illness, but a national communication strategy is not yet evident. On the other hand, those opposed to actions to

prevent global warming, presumably on the basis of alleged economic impact, have developed media campaigns to discredit global warming. In particular, some radio talk show commentators argue that global warming is nothing more than a naturally occurring cycle, and therefore, costly actions should not be taken to address a problem that doesn't exist. As previously stated, consideration of the precautionary approach and sustainable development argue to the contrary.

6.3.5 The Marrakesh, Morocco, Accord, 2001

The Parties to the KP met as OP 7 in Marrakesh, Morocco, during October/November 2001. The primary purpose was to decide on the KP's requirements for reporting of Land Use, Land Use Change Forestry (LULUCF) activities and related issues. LULUCF is defined by the United Nations Climate Change Secretariat as "A greenhouse gas inventory sector that covers emissions and removals of greenhouse gases resulting from direct human-induced land use, land-use change and forestry activities." As stipulated in the KP the net change in carbon stocks and GHG emissions by sources and removals by sinks resulting from direct human-induced LULCF activities shall be used to meet the commitments referred to in Article 3, paragraph 1, of the KP by each Party included in Annex I. The rules for LULUCF activities, agreed as part of the Marrakesh Accords, include three main elements [10]:

- A set of principles to govern LULUCF activities
- Definitions for Article 3.3 (Kyoto Protocol) activities and agreed activities under Article 3.4
- A four-tier capping system limiting the use of LULUCF activities to meet emission targets

The principles in the Marrakesh Accords were developed in response to concerns that the use of LULUCF activities should not undermine the environmental integrity of the KP. These principles underscore, for example, the need for sound science and consistent methodologies, as well as the importance of conserving biodiversity.

"In order to ensure consistency and comparability among Parties to the KP, a common definition was established for the term "forest." Some flexibility is allowed to take account of national circumstances, so that a Party may choose, for example, to select a minimum tree height of between 2 and 5 m for its definition of a forest. Once the values are chosen, however, they remain fixed" [10]. The Marrakesh Accords also provided definitions for four additional LULUCF activities, these being: Forest Management, Cropland Management, Grazing Land Management, and Revegetation. Parties may choose to include any of these activities to help meet their emission targets, and the choice is then fixed for the first commitment period.

Parties to the Marrakesh Accord also agreed that net removals of GHGs from eligible LULUCF activities generate so-called removal units that Annex I Parties to the KP can use to help meet their emission targets. They are deemed valid only when the removals have been verified by expert review teams under the Protocol's reporting and review procedures, and they cannot be banked (i.e., credits cannot be carried over to future commitment periods). In the case where such LULUCF activities result in a net source of GHG emissions, there would be a cancellation of assigned amount units and/or units issued from Articles 6, 12 and 17 for the Party concerned.

The extent, to which Parties can account for emissions and removals from specific LULUCF activities, for the first commitment period, was limited by the following four-tier capping system:

> *"Tier 1*: If a Party's afforestation, reforestation, and deforestation activities result in more emissions than removals, then the Party may offset these emissions through forest management activities, up to a total level of 9 Mt of carbon per year for the 5-year commitment period.
> *Tier 2*: The extent to which forest management activities can be accounted for to help meet emission targets beyond 9 Mt of carbon per year is subject to an individual cap for each Party, specified in an appendix to the decision on LULUCF. This cap includes joint implementation projects involving forest management.
> *Tier 3*: Emissions and removals from cropland management, grazing land management, and revegetation can be accounted for to help meet emission targets on a net basis (e.g., changes in carbon stocks during 1990, times 5, will be subtracted from the changes in carbon stocks during the first commitment period, in the lands where these activities will take place).
> *Tier 4*: Only afforestation and reforestation projects are eligible under the CDM. GHG removals from such projects may only be used to help meet emission targets up to 1% of a Party's base year emissions for each year of the commitment period " [10].

Perspective: The Marrakesh Accord added further specificity to the terms and agreements in the KP. In particular, specificity about LULUCF activities was a focus and product of this accord.

6.3.6 The Bali Action Plan, Bali, Indonesia, 2007

The 13th session of the Conference of the Parties to the UNFCCC and the 3rd session of the Conference of the Parties serving as the Meeting of the Parties to the KP occurred in Bali, Indonesia, December 3–14, 2007.

Governments adopted the Bali Road Map, a set of decisions that represented the various tracks that were seen as key to reaching a global climate deal. "The Bali Road Map includes the Bali Action Plan, which launched a 'new, comprehensive process to enable the full, effective and sustained implementation of the Convention through long-term

cooperative action, now, up to and beyond 2012, with the aim of reaching an agreed outcome and adopting a decision at COP15 in Copenhagen. Governments divided the plan into five main categories: shared vision, mitigation, adaptation, technology and financing" [11]. Other elements in the Bali Road Map included

- A decision on deforestation and forest management.
- A decision on technology for developing countries.
- The establishment of the Adaptation Fund Board.
- The review of the financial mechanism, going beyond the existing Global Environmental Facility.

Perspective: The Bali Road Map provided the Parties to the KP with opportunities to further define the Protocol's terms and served also to prepare negotiators for climate change issues projected for debate at the forthcoming Paris meeting in 2015.

6.3.7 The Cancún, Mexico, Agreements, 2010

The sixteenth session of the Conference of the Parties to the UNFCCC and the sixth session of the Conference of the Parties serving as the Meeting of the Parties to the KP took place in Cancún, Mexico, from November 29 through December 10, 2010, ending with the adoption of a package of decisions that set all governments more firmly on the path toward a low-emissions future and support enhanced action on climate change in the developing world.

The meeting produced a comprehensive and far-reaching international response to climate change for reduction of carbon emissions and to build a system that made all countries accountable to each other for those reductions. Following is an overview of the Cancun Agreements and the key outcomes. In particular, Parties agreed [12]:

- "To commit to a maximum temperature rise of 2°C above pre-industrial levels, and to consider lowering that maximum to 1.5 degrees in the near future.
- To make fully operational by 2012 a technology mechanism to boost the innovation, development and spread of new climate-friendly technologies.
- To establish a Green Climate Fund to provide financing to projects, programmes, policies and other activities in developing countries via thematic funding windows; on the Cancún Adaptation Framework, which included setting up an Adaptation Committee to promote the implementation of stronger, cohesive action on adaptation."

On the mitigation front, developed countries submitted economy-wide emission reduction targets and agreed on strengthened reporting frequency and standards and to develop low-carbon national plans and strategies. Developing countries submitted nationally appropriate mitigation actions (NAMAs), to be implemented subject to financial and technical support. Work continued on shaping the form and functions of a registry for NAMAs to enable the matching of such actions with finance and technology. Developing countries were also encouraged to develop low-carbon national plans and strategies.

Work also progressed on reducing emissions from deforestation and forest degradation, boosting capacity-building in developing countries, and how to deal with any consequences of response measures to action on climate change. Governments also agreed to include carbon capture and storage (CCS) in the projects under the CDM, subject to technical and safety standards.

Perspective: The Cancún Agreements metaphorically kicked the KP ball further down the path toward global agreement on mitigation of climate change. The Parties to the KP agreed on a target goal of 2°C maximum of rise in global temperature, which was an important agreement. A concrete goal had been set. Additionally, the Cancún parties made progress in how to involve developing countries in the global effort to reduce climate change.

6.3.8 UN Climate Change Conference, Doha, Qatar, 2012

At the 2012 UN Climate Change Conference in Doha, Qatar (COP18/CMP8), governments consolidated the gains of the previous 3 years of international climate change negotiations and opened a gateway to greater ambition and action on all levels. In many ways, the Doha conference was about preparations for the 2015 conference in Paris. Among the many decisions taken, governments [13]

- Strengthened their resolve and set out a timetable to adopt a universal climate agreement by 2015, which will go into effect in 2020.
- Streamlined the negotiations, completing the work under the Bali Action Plan to concentrate on the new work toward a 2015 agreement under a single negotiating stream in the Ad Hoc Working Group on the Durban Platform for Enhanced Action.
- Emphasized the need to increase their ambition to cut GHGs and to help vulnerable countries to adapt.
- Launched a new commitment period under the KP, thereby ensuring that this treaty's important legal and accounting models remain in place and underlining the principle that developed countries lead mandated action to cut GHG emissions.
- Made further progress toward establishing the financial and technology support and new institutions to enable clean energy investments and sustainable growth in developing countries.

Perspective: The Doha meeting was useful for making further preparations for the 2015 Paris meeting. Of note is the agreement to set a timetable for adopting a global climate change agreement, which would take effect in 2020.

6.3.9 UN Climate Change Conference, Paris, France, 2015

The COP 21 convened in Paris, France, from November 30 to December 11, 2015. The strong momentum toward an agreement that built over the preceding months was dramatically underscored on the opening day of the summit by the presence of 150 presidents and prime ministers, the largest ever single-day gathering of heads of state. President Barack Obama represented the U.S. Parties to the UNFCCC reached a historic agreement to combat climate change and to accelerate and intensify the actions and investments needed for a sustainable low carbon future [14].

The Paris Agreement's central aim was to strengthen the global response to the threat of climate change by keeping a global temperature rise this century well below 2°C above pre-industrial levels and to pursue efforts to limit the temperature increase even further to 1.5°C. Additionally, the agreement aimed to strengthen the ability of countries to deal with the impacts of climate change. To reach these ambitious goals, appropriate financial flows, a new technology framework, and an enhanced capacity building framework will be put in place, thus supporting action by developing countries and the most vulnerable countries, in line with their own national objectives. The Agreement also provides for enhanced transparency of action and support through a more robust transparency framework.

The Paris Agreement's central aim was to keep a global temperature in the twenty first century well below 2°C above pre-industrial levels and to pursue efforts to limit the temperature increase even further to 1.5°C.

The Paris Agreement requires all Parties to put forward their best efforts through "nationally determined contributions" (NDCs) and to strengthen these efforts in the years ahead. There will also be a global accounting every 5 years to assess the collective progress toward achieving the purpose of the agreement and to inform further individual actions by Parties.

Of note, the new treaty ends the strict differentiation between developed and developing countries that characterized earlier Framework Convention efforts, replacing it with a common framework that commits all countries to put forward their best efforts and to strengthen them in the years ahead. This includes, for the first time, requirements that all parties regularly report on their emissions and implementation efforts, and undergo international review [14].

"The agreement and a companion decision by parties were the key outcomes of the Paris Conference. Together, the Paris Agreement and the accompanying Conference of Parties to the Framework Convention (COP) decisions:

- Reaffirm the goal of limiting global temperature increase well below 2 degrees Celsius, while urging efforts to limit the increase to 1.5°C;
- Establish binding commitments by all parties to make 'nationally determined contributions' (NDCs), and to pursue domestic measures aimed at achieving them;
- Commit all countries to report regularly on their emissions and 'progress made in implementing and achieving' their NDCs, and to undergo international review;
- Commit all countries to submit new NDCs every five years, with the clear expectation that they will 'represent a progression' beyond previous ones;
- Reaffirm the binding obligations of developed countries under the UNFCCC to support the efforts of developing countries, while for the first time encouraging voluntary contributions by developing countries too;
- Extend the current goal of mobilizing $100 billion a year in support by 2020 through 2025, with a new, higher goal to be set for the period after 2025;
- Extend a mechanism to address 'loss and damage' resulting from climate change, which explicitly will not 'involve or provide a basis for any liability or compensation;'
- Require parties engaging in international emissions trading to avoid 'double counting;' and
- Call for a new mechanism, similar to the Clean Development Mechanism under the Kyoto Protocol, enabling emission reductions in one country to be counted toward another country's NDC" [14].

As outcome, 195 countries adopted at the conference the first-ever universal, legally binding global climate deal at the Paris conference. Among these counties were all the major contributors to carbon dioxide levels released into the atmosphere: China, U.S., India, Russia, and Japan, (Figure 6.4). Collectively, these five countries' emissions approximate 60% of all CO_2 emissions released into the atmosphere. The Paris Agreement also achieved a level of harmony between nations, regardless of their level of

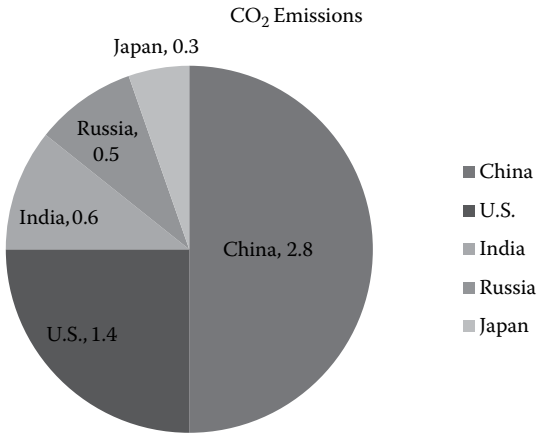

FIGURE 6.4 Distribution of top five countries' CO_2 emissions in 2013. (From Boden and Andres, Fossil-fuel CO_2 emissions, Carbon Dioxide Information Analysis Center, Oak Ridge National Laboratory, Oak Ridge, TN, 2016.)

national economies. Further, procedures for monitoring each country's progress toward meeting its emission goal were achieved. However, as with preceding meetings held to implement the Framework Convention on Climate Change, key steps remain from the Paris Accord. Many operational details of the new framework were left to be decided by future COPs. And the agreement will take effect only once enough countries have formally ratified it.

Perspective: It is not an exaggeration to call the Paris Agreement a historic global achievement. Legal and binding agreements on nations' commitments to reduce their CO_2 emissions were achieved, with the important proviso of monitoring each nation's progress toward its goal of reduction. This meeting also achieved international acceptance of climate change as a vital global policy. However, the success of the Paris Agreement will be tempered if nations do not fulfill their commitments. Debate has begun on whether the Paris climate agreement will be a legally binding treaty. There is confusion in the U.S. because the term "treaty" means different things under international and U.S. law. As observed by one source, the bottom line is that the Paris agreement will very likely be a treaty under international law, but probably not a treaty as that term is generally understood in the U.S. context [15]. Whether the U.S.'s signatory to the Paris Agreement can be considered as an acceptable "executive agreement" (i.e., an action by a U.S. President) or should be considered an international treaty—which would require approval by the U.S. Senate under Article II of the Constitution—is a question that awaits an answer. Further uncertainty about the U.S. commitment to the Paris Agreement arose from the Trump administration, which in on August 4, 2017 notified the UN of U.S. exit from the Paris Agreement [14a].

6.4 PORTENT OF CLIMATE CHANGE ON AGRICULTURE AND SPECIES ENDANGERMENT

Climate change will have significant global impacts on agriculture and the species that populate the planet. In recognition of these impacts, international, regional, and some national governments have developed statements and proffered advice specific to agriculture. For example, the UN Food and Agriculture Organization (FAO) considers climate change to be a fundamental threat to global food security, sustainable development, and poverty eradication. Agriculture, including the forestry and fisheries sectors, must adapt to the impacts of climate change and improve the resilience of food production systems in order to feed a growing population [16]. While the FAO and some regional groups offer some technical and financial assistance, by and large, regional and individual national governments must assume the primary responsibility for implementing policies for application to agriculture operations.

Similar to the FAO's concerns about the impacts of climate change on agriculture, the EU has expressed both concerns and advice [17]. In particular, they note that agriculture is highly exposed to climate change, as farming activities directly depend on climatic conditions. Change in rainfall will be a serious problem in many EU regions, as well as rising temperatures; variability and seasonality as well as extreme events, heat waves, droughts, storms, and floods across the EU. But agriculture also contributes to the release of GHGs to the atmosphere. However, agriculture can also help to provide solutions to the overall climate change problem by reducing emissions and by sequestering carbon while not threatening viable food production.

Climate change across the EU will require adaptive measures (both at farm and at sectorial level) in agriculture, ranging from technological solutions to adjustments in farm management or structures, and to political changes, such as adaptation plans. Concerning farm-level adaptation, possible short- to medium-term adaptive solutions may include the following:

- "Adjusting the timing of farm operations, such as planting or sowing dates and treatments
- Technical solutions, such as protecting orchards from frost damage or improving ventilation and cooling systems in animal shelters
- Choosing crops and varieties better adapted to the expected length of the growing season and water availability, and more resistant to new conditions of temperature and humidity
- Adapting crops with the help of existing genetic diversity and new possibilities offered by biotechnology
- Improving the effectiveness of pest and disease control, for instance, through better monitoring, diversified crop rotations, or integrated pest management methods
- Using water more efficiently by reducing water losses, improving irrigation practices, and recycling or storing water
- Improving soil management by increasing water retention to conserve soil moisture, and landscape management, such as maintaining landscape features providing shelter to livestock
- Introducing more heat-tolerant livestock" [17].

In the U.S., a major producer of food for domestic and global distribution—the U.S. Department of Agriculture expects, increases in atmospheric CO_2, rising temperatures, and altered precipitation patterns to affect agricultural productivity [18]. Increases in temperature coupled with more variable precipitation will reduce productivity of crops. Effects will vary among annual and perennial crops, and regions of the U.S.; however, all production systems will be affected to some degree by climate change. Agricultural systems depend upon reliable water sources, and the pattern and potential magnitude of precipitation changes is not well understood, thus adding considerable uncertainty to assessment efforts. More specifically,

- "Livestock production systems are vulnerable to temperature stresses. An animal's ability to adjust its metabolic rate to cope with temperature extremes can lead to reduced productivity and in extreme cases death.
- Projections for crops and livestock production systems reveal that climate change effects over the next 25 years will be mixed. The continued degree of change in the climate by mid-century and beyond is expected to have overall detrimental effects on most crops and livestock.
- Climate change will exacerbate current biotic stresses on agricultural plants and animals. Changing pressures associated with weeds, diseases, and insect pests, together with potential changes in timing and coincidence of pollinator lifecycles, will affect growth and yields.
- Agriculture is dependent on a wide range of ecosystem processes that support productivity including maintenance of soil quality and regulation of water quality and quantity. Multiple stressors, including climate change, increasingly compromise the ability of ecosystems to provide these services" [18].

The predicted higher incidence of extreme weather events will have an increasing influence on agricultural productivity. Extremes matter because agricultural productivity is largely driven by environmental conditions during critical threshold periods of crop and livestock development. The vulnerability of agriculture to climatic change is strongly dependent on the responses taken by humans to moderate the effects of climate change [18]. Climate change will necessitate adaptation procedures and access to contemporary, reliable sources of advice and data. Food security produced by agricultural operations will require no less.

* * *

The health of the world's soils hinges on the abundance and diversity of the microbes and fungi they contain. According to a study that examined microbial diversity in 78 drylands on all inhabited continents and 179 sites in Scotland, environmental changes, including from global warming, will undermine their ability to support humans and other species. The investigators found that the loss of varieties—such as from climate change increasing arid zones—undermined the services the soils provided. The authors commented, "As the aridity of soils goes up, the microbial diversity and abundance is reduced, as the soils' multi-functions are reduced, so there are social and economic consequences" [19].

A different study investigated the adaptability of soil microbes under changing climate conditions. A 17-year study into the effect of global warming on microbes—the tiny bacteria, fungi and other micro-organisms that determine soil health—reveals them to be far less adaptable to changing conditions than expected [20]. The study involved swapping soil samples between two sites on a mountainside in 1994—the higher location had a warmer, drier climate than the one 500 m below. Seventeen years later they went back to check on the microbes' activities, focusing on their rate of respiration—how quickly they convert carbon in the soil to carbon dioxide as they break down the organic matter—to get a broader sense of their ability to adapt to the changing conditions. But they found very little change. The microbes that had been native to the higher site naturally respired at a faster rate because they were used to greater levels of rainfall and vegetation, or carbon. They continued to respire at a faster rate at their lower elevation—even 17 years later. And the microbes taken from lower down the mountain demonstrated very little change when they were moved uphill, suggesting them to be far less adaptable to changing conditions than expected. The study's findings raise concerns the microbes will not be able to carry out essential functions that plants need to grow, such as breaking down leaves and other organic matter in a process which converts them into nitrogen and other nutrients.

USDA projections for crops and livestock production reveal that the continued degree of change in the climate by mid-century and beyond is expected to have an overall detrimental effect on most crops and livestock in the U.S.

In addition to concerns about how soil microbes are responding to climate change is a companion issue of how plants themselves are responding. A report by UNEP says that crops such as wheat and maize are generating more potential toxins as a reaction to protect themselves from extreme weather [21]. But these chemical compounds are harmful to people and animals if consumed for a prolonged period of time. According to the UNEP report, under normal conditions, for instance, plants convert nitrates they absorb into nutritious amino acids and proteins. But the report said that prolonged drought slows or prevents this conversion, leading to more potentially problematic nitrate accumulating in the plant. If people consume too much nitrate in their diets, it can interfere with the ability of red blood cells to transport oxygen in the body. According to UNEP, crops susceptible to accumulating too much nitrate in times of stress include maize, wheat, barley, soybeans, millet, and sorghum. Some drought-stressed crops, when then exposed to sudden large amounts of rain that lead to rapid growth, in turn accumulate hydrogen cyanide, more commonly known as prussic acid, UNEP reported. Prussic acid can interfere with oxygen flow in humans. Plants such as cassava, flax, maize, and sorghum are most vulnerable to dangerous prussic acid accumulation, the report said.

Aflatoxins, molds that can affect plant crops and raise the risk of liver damage, cancer, and blindness, as well as stunting fetuses and infants, are also spreading to more areas as a result of shifting weather patterns as a result of climate change, scientists said. UNEP observed that about 4.5 billion people in developing countries are exposed to aflatoxins annually. Europe will be at growing risk from aflatoxins in locally grown crops if global temperatures rise by at least 2°C [21].

Perspective: Global climate change portends significant impacts on agriculture and correspondingly food security.

Droughts and other extreme weather events will severely impact agricultural methods and crop yields if adaptation practices are not implemented. Further, the impacts of climate change on soil and plant quality will exacerbate the overall impact on agriculture and food production.

* * *

The projected effects of climate change will present serious consequences to species globally. In a study by the International Union for Conservation of Nature, which updated their list of endangered species, about 12% of the animals on the list are either endangered or critically endangered because of climate change. This equates to approximately 1400 species. A sample of the threatened species includes; seahorses, the Kaputar pink slug, wombats and wallabies, whooping cranes and ibises, akikikas, sea otter, seals, and sea lions [22]. Rising sea temperatures is a significant factor in causing this species endangerment.

In a separate study, climate change could drive up to a sixth of animals and plants on Earth to extinction unless climate change mitigation occurs. Overall, it found that one in six species could be driven to extinction if GHG emissions are unchecked and temperatures rise above pre-industrial times by 4.3°C by 2100, which is in line with one scenario from the IPCC. The study averaged 131 previous studies of climate change, whose projections of the number of species that could be lost to climate change ranged from 0% to 54% of species. Species in South America, Australia and New Zealand are most at risk, since many live in small areas or cannot easily move away to adapt to heatwaves, droughts, floods, or rising seas [23].

According to a new report by Australian scientists, climate change has claimed its first mammalian species. Researchers from Australia's University of Queensland and Queensland Government say a rodent known as the Bramble Cay melomys, which lived on Bramble Cay, a small sandy island in the Great Barrier Reef, has died due to "rising sea levels and an increased incidence of extreme weather events," the first mammal on record to be declared extinct "due solely (or primarily) to anthropogenic climate change." While the researchers were certain the animals were washed away from their only known home, they did observe the "possibility that the species occurs elsewhere on islands in the Torres Strait," an area between Australia and Papua New Guinea comprised of more than 200 islands [24].

6.5 PORTENT OF CLIMATE CHANGE ON HUMAN HEALTH

Climate change has been cast here as the current single greatest environmental hazard to planet Earth and its inhabitants. This hazard has drawn considerable attention and action by national and international governments and private sector organizations. Left unabated, climate change has been forecast as exerting a terrible toll on human life. One might assert that the foregoing words are mere hyperbole, but that rebuttal would be disarmed by the collection of global environmental science and current ominous signs of adverse consequences of a hotter atmosphere, more acidic oceans, migration of pests into warmer, previously uninhabited geographic regions, and increased numbers and severity of droughts, storms, and other weather events.

The consequences of these projected changes in global and regional environments will cause serious impacts on public health, national economies, and environmental quality. Public health impacts have been categorized by the IPCC as follows:

- Increased frequency of heat waves. Heat waves bring heat-related mortalities and morbidities, together with loss of economic productivity.
- Regional variations in precipitation patterns would cause problems with fresh water supplies, producing an increase in waterborne diseases as human populations use impure water supplies in lieu of freshwater.
- Food production would be compromised in regions with lesser precipitation and increased ambient temperature.
- Rising ocean levels would cause coastal flooding, placing human populations at risk.
- Vector-borne diseases would increase as vectors such as mosquitoes expand their region of activity.

The severity of these health risks will depend on the ability of public health and safety systems to address or prepare for these changing threats, as well as factors such as an individual's behavior, age, sex, and economic status. Impacts will vary based on where a person resides, their sensitivity to health threats, their level of exposure to climate change impacts, and how well they and their community are prepared to adapt to climate change. WHO has forecast an estimation of the human health impacts of climate change as follows [25]:

- It is estimated that approximately 150,000 deaths in year 2000 were attributable to changes in global climate experienced over the preceding decade.
- The public health impacts of global warming will be hardest on regions and countries that have the least resources to defend themselves against the consequences of global warming. For example, lack of a public health infrastructure in some of the world's poorest countries will lead to inabilities to prevent heat-related illness and consumption of impure drinking water. In the long term, the primary prevention of global warming health effects must be through marked reductions in the generation and release into the atmosphere of GHGs.
- Between 2030 and 2050, climate change is expected to cause approximately 250,000 additional deaths per year from malnutrition, malaria, diarrhea, and heat stress.
- The direct damage costs to health (i.e., excluding costs in health-determining sectors such as agriculture and water and sanitation), is estimated to be between US$ 2 and 4 billion/year by 2030.

- Areas with weak health infrastructure—mostly in developing countries—will be the least able to cope without assistance to prepare and respond.
- Reducing emissions of GHGs through better transport, food and energy-use choices can result in improved health, particularly through reduced air pollution.

Of note, because children are at elevated health risk associated with climate change, the American Academy of Pediatricians released a policy statement in 2015 as follows [26]:

- "There is wide consensus among scientific organizations and climatologists that the broad effects known commonly as 'climate change' are the result of contemporary human activities.
- According to WHO, more than 88% of the existing burden of disease attributable to climate change occurs in children younger than 5 years old.
- Climate change poses a threat to human health and safety, but children are uniquely vulnerable.
- Failure to take prompt, substantive action would be an act of injustice to all children" [26].

* * *

Several attempts have been made to estimate the risk to human well-being of climate change. A study by the World Bank focused on the impact of disasters on human life and economic consequences [27]. The report notes that a rapid increase in climate change-related natural disasters occurring by 2050 will put 1.3 billion people at risk, and damages totaling $158 trillion—double the total current annual output of the global economy. The global community is badly prepared for a rapid increase in climate change-related natural disasters. Densely populated coastal cities are at particularly high risk, according to the report. In a companion report, the World Bank opines that without the right policies to keep the global poor safe from extreme weather and rising seas, climate change could drive more than 100 million more people into poverty by 2030. The bank's estimate of 100 million more poor by 2030 is on top of 900 million expected to be living in extreme poverty if development progresses slowly. In 2015, the bank puts the number of poor at 702 million people [28].

WHO estimates that between 2030 and 2050, climate change is expected to cause approximately 250,000 additional deaths per year, from malnutrition, malaria, diarrhea, and heat stress.

Projections of the number of premature deaths in the U.S. associated with climate change vary. A study by a Duke University team examined the health and economic benefits of U.S. climate change polices that would reduce global temperature by 2°C by 2013 [29]. Their work estimates that by 2030 proposed U.S. clean energy policies would reduce premature deaths by approximately 175,000, with another 120,000 premature deaths saved by U.S. clean transportation polices.

In a separate study, investigators at Syracuse and Harvard universities examined the public health benefits of implementation of the Obama administration's Clean Power Plan [30]. Their study concludes that reductions in national carbon emissions (CO_2, fine particulate, others) from U.S. power plants could prevent more than 3000 premature deaths per year in the U.S. Coal plants not only produce carbon dioxide (CO_2), but also air pollutants including particulate matter (PM) and precursors to tropospheric (ground-level) ozone. Both PM and ozone have been linked with many health problems including asthma and lung disease.

Perspective: The estimates by WHO and by U.S. sources of the potential toll on global human health are sobering. Particularly sobering are the predictions that vulnerable populations disproportionately will suffer due simply to geographic location, income level, age, and local sociopolitical status. Preparing for and responding to this human health portent will strain public health resources in affected areas when responding to these kinds of vulnerabilities.

6.6 PORTENT OF CLIMATE CHANGE ON ECOSYSTEM HEALTH

As reminder, an ecosystem is an interdependent system of plants, animals, and microorganisms interacting with one another and with their physical environment. An ecosystem can be as large as the Mojave Desert or as small as a local pond. Ecosystems provide people with food, goods, medicines, and many other products. They also play a vital role in nutrient cycling, water purification, and climate moderation [31]. Climate is an important environmental influence on ecosystems. Climate changes and the impacts of climate change affect ecosystems in a variety of ways. For instance, warming could force species to migrate to higher latitudes or higher elevations where temperatures are more conducive to their survival. The EPA has grouped some of the more important effects of climate change on ecosystems as follows [31]:

Changes in the timing of seasonal life-cycle events: For many species, the climate where they live or spend part of the year influences key stages of their annual life cycle, such as migration, blooming, and breeding. Because the climate has warmed in recent decades, the timing of these events has changed in some parts of the U.S. Changes like these can lead to mismatches in the timing of migration, breeding, and food availability. Growth and survival are reduced when migrants arrive at a location before or after food sources are present.

Range shifts: As temperatures rise, the habitat ranges of many North American species are moving northward in latitude and upward in elevation. While this means a range expansion for some species, for others it means a range reduction or a movement into less hospitable habitat or increased competition for

food and shelter. Some species have nowhere to go because they are already at the northern or upper limit of their habitat.

Food web disruptions: Energy from the Sun and CO_2 are used for photosynthesis by phytoplankton which are either consumed by zooplankton or create sedimentation. The sedimentation turns into organic deposits that are consumed by seafloor creatures. Fish eat the seafloor creatures and zooplankton and are subsequently consumed by larger animals like seals, which are then consumed by animals at the top of the food chain, like polar bears. Ultimately the energy from the sun and CO_2 create the food source for all species within the food web, including humans.

Threshold effects: In some cases, ecosystem change occurs rapidly and irreversibly because a threshold, or "tipping point," is passed. One area of concern for thresholds is the Prairie Pothole Region in the north-central part of the U.S. This ecosystem is a vast area of small, shallow lakes, known as "prairie potholes" or "playa lakes." These wetlands provide essential breeding habitat for most North American waterfowl species. The pothole region has experienced temporary droughts in the past. Similarly, when coral reefs become stressed, they expel microorganisms that live within their tissues and are essential to their health. This is known as coral bleaching. As ocean temperatures warm and the acidity of the ocean increases, bleaching and coral die-offs are likely to become more frequent. Chronically stressed coral reefs are less likely to recover.

Pathogens, parasites, and disease: Climate change and shifts in ecological conditions could support the spread of pathogens, parasites, and diseases, with potentially serious effects on human health, agriculture, and fisheries (Chapter 13). For example, the oyster parasite, Perkinsus marinus, is capable of causing large oyster die-offs. This parasite has extended its range northward from Chesapeake Bay to Maine, a 310-mile expansion tied to above average winter temperatures.

Extinction risks: Climate change, along with habitat destruction and environmental pollution, is one of the important stressors that can contribute to species extinction (Chapter 16). The IPCC estimates that 20%–30% of the plant and animal species evaluated so far in climate change studies are at risk of extinction if temperatures reach levels projected to occur by the end of this century [31]. Projected rates of species extinctions are 10 times greater than recently observed global average rates and 10,000 times greater than rates observed in the distant past (as recorded in fossils).

Also noted as consequences of the effects of climate change on ecosystem health are reports of species in decline, ocean acidification, and spikes in air pollution. As examples:

- Frog populations are decreasing in several areas of the world due to global warming. Warmer temperatures have been associated with outbreaks of a skin fungus that is fatal to frogs. The fungus proliferates with warmer temperatures [31a].
- Acidification of oceans is occurring according to the British Royal Society, which observes that ocean water is now 8.1 pH, a decrease of 0.1 over that of 200 years ago, which translates to a 30% increase in hydrogen ions in the water. The Society predicts that the pH of ocean water near the surface will decrease to 7.7–7.9 by year 2100. The increased acidity could reduce populations of plankton, disrupting the ocean food chain and harming fisheries [31b].
- Spikes in U.S. air pollution were linked by the American Lung Association (ALA) with warmer temperatures due to climate change. In particular, the ALA analysis suggests global warming is causing short-term spikes in air pollution. The spikes result from droughts and wildfires that temporarily increase particulate levels from dust and smoke. Wildfires occur more frequently and with greater severity in drier, hotter climates affected by global warming [32].

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Several investigations of the observed impact of climate change on ecosystem health are available. For example, according to the National Oceanic and Atmospheric Administration (NOAA) there is strong evidence that global sea level is now rising at an increased rate and will continue to rise during the twenty first century. While studies show that sea levels changed little from AD 0 until 1900, sea levels began to climb in the twentieth century.

The two major causes of global sea-level rise are thermal expansion caused by the warming of the oceans (since water expands as it warms) and the loss of land-based ice (such as glaciers) due to increased melting. Records and research show that sea level has been steadily rising at a rate of 0.04 to 0.1 inches per year since 1900. Since 1992, new methods of satellite altimetry (the measurement of elevation or altitude) indicate a rate of rise of 0.12 inches per year. This is a significantly larger rate than the sea-level rise averaged over the last several thousand years [33].

In addition to rise in sea levels, the Earth's temperatures have continued to rise. NOAA data indicate that the combined average temperature over global land and ocean surfaces for July 2015 was the highest for July in the 136-year period of record, at 0.81°C (1.46°F) above the twentieth century average of 15.8°C (60.4°F), surpassing the previous record set

in 1998 by 0.08°C (0.14°F). As July is climatologically the warmest month of the year globally, this monthly global temperature of 16.61°C (61.86°F) was also the highest among all 1627 months in the record that began in January 1880. The July temperature is currently increasing at an average rate of 0.65°C (1.17°F) per century [34].

The effect of climate change on ocean acidity has also been documented. According to one source, every day, 22 million tons of CO_2 are absorbed by the world's oceans [35]. This equates to approximately 1 ton of CO_2 per person on Earth annually. The oceans have become 30% more acidic because of the carbon pollution pumped into the atmosphere. This absorption makes seawater more acidic, spelling disaster for many marine animals, from plankton and coral up the food chain to sea stars, salmon, sea otters, whales—and ultimately people, who rely on oceans for food.

Perspective: For persons focused on human health in general and health effects of climate change specifically, these aforementioned effects of climate change on ecosystems may seem irrelevant or uninteresting. That would be an unfortunate myopic attitude. Humans occupy a niche in global and local ecosystems; which sustain us in many ways. Loss of healthy ecosystems will portend difficulties for human health and well-being. Warmer air and ocean temperatures, more acidic oceans, and rising sea levels are consequences of climate change and as such portend global challenges to human well-being.

6.7. POLICY ISSUES

There are many policy issues presented by actions intended for mitigation of climate change. The challenges to climate change policymaking are for the purpose of this book grouped into issues of science, technology, economics, legal, and public perspective. The following narrative begins with a description of U.S. issues and experience in climate change policymaking. This is followed by descriptions of climate change polices in the EU and those in China. Because climate change is a global problem and challenge, knowledge of climate change policies in the major generators of GHGs, namely, China, the U.S., and the EU, is important.

6.7.1 Overview of U.S. Climate Change Policymaking

The science of climate assessment, its analysis, and propagation of results is at the core of any consideration of policymaking on climate change. This is because the economic, political, and social consequences are so great in import that the science which supports mitigation of climate change must be well grounded and adhere to the standards expected of scientific investigation and reporting. Mere suspicion of climate change's portent cannot sustain and justify the extraordinary global revisions of national practices of energy development and use, food security, and sociopolitical stability. The science of climate change must be the foundation for policymaking on climate change. The efforts in the U.S. to develop environmental health policies for mitigation of climate change has involved both legal issues and executive branch efforts, primarily by the Obama administration. Both factors are described in the subsequent sections.

6.7.2 Obama Administration's Policymaking on Climate Change

How to deal within the U.S. federal government with the political, economic, and health issues arising from climate change became itself a matter of environmental policy as the science of climate change began to amass. The EPA was the logical and perhaps only choice, in which to entrust U.S. policy leadership on climate change. This choice was dictated by both matters of practicality as well as legality. The EPA, since its establishment by the Nixon administration, had become the U.S.'s central federal resource on environmental policy and implementation of environmental statutes enacted by Congress. Moreover, the EPA was the lead federal agency for air pollution policies, principally the Clean Air Act (CAAct) (Chapter 8), and had thereby accrued more than 40 years of practical experience in working on issues of contaminants in air, the environmental medium of greatest relevance to climate change.

Early in the twenty-first century, the EPA made a policy decision to consider using the existing CAAct as its basis for regulating the emissions of GHGs. This represented a new extension of the act and was quickly met with resistance by some industrial groups that opposed any attempt by the U.S. federal government to develop climate change policies. As the EPA proceeded with its plans to develop regulations to control GHGs, the policymaking arena moved from EPA to U.S. federal courts. Without discussing the litany of court cases, three decisions by the U.S. Supreme Court were a key to shaping the U.S. policies on climate change. These decisions are discussed in the following section.

6.7.2.1 U.S. Supreme Court Decisions

The first of three seminal U.S. Supreme Court decisions that helped shape U.S. policy on climate change dealt with the central issue of whether the EPA could regulate GHGs under the provisions of the CAAct (Chapter 8). In 2003 the EPA had decided that it lacked authority under the CAAct to regulate GHGs, principally carbon dioxide emissions into the atmosphere. Further, the agency had some uncertainty on whether the science base on climate change was sufficiently robust so as to consider using the CAAct in relation to climate change. The EPA's policy position of 2003 was challenged in litigation [36].

Massachusetts and several other states petitioned the EPA asking EPA to regulate emissions of carbon dioxide and other gases that contribute to global warming from new motor vehicles. Massachusetts argued that EPA was required to regulate these "greenhouse gases" by the CAAct—which states that Congress must regulate "any air pollutant" that can "reasonably be anticipated to endanger public health or welfare" [36].

EPA denied the petition, claiming that the CAAct does not authorize it to regulate greenhouse gas emissions. Even if it did, EPA argued, the Agency had discretion to defer a decision until more research could be done on 'the causes, extent and significance of climate change and the potential options for addressing it.' Massachusetts appealed the denial of the petition to the Court of Appeals for the D.C. Circuit, and a divided panel ruled in favor of EPA [36]. The petitioners appealed the appellate court's decision to the U.S. Supreme Court, with the following two questions forming the central questions put before the court:

1. May the EPA decline to issue emission standards for motor vehicles based on policy considerations not enumerated in the CAAct?
2. Does the CAAct give the EPA authority to regulate carbon dioxide and other GHGs?

By a 5-4 vote the Court reversed the D.C. Circuit and ruled in favor of Massachusetts. "The opinion by Justice John Paul Stevens held that Massachusetts, due to its 'stake in protecting its quasi-sovereign interests' as a state, had standing to sue EPA over potential damage caused to its territory by global warming. The Court rejected EPA's argument that the CAAct was not meant to refer to carbon emissions in the section giving EPA authority to regulate 'air pollution agent[s]'. The Act's definition of air pollutant was written with 'sweeping,' 'capacious' language so that it would not become obsolete. Finally, the majority ruled that EPA was unjustified in delaying its decision on the basis of prudential and policy considerations. The Court held that if EPA wishes to continue its inaction on carbon regulation, it is required by the act to base the decision on a consideration of 'whether greenhouse gas emissions contribute to climate change.' Chief Justice Roberts's dissenting opinion argued that Massachusetts should not have had standing to sue, because the potential injuries from global warming were not concrete or particularized (individual and personal). Justice Scalia's dissent argued that the CAAct was intended to combat conventional lower-atmosphere pollutants and not global climate change" [36].

The court's decision was decided in April 2007.

Perspective: This was a pivotal decision for U.S. climate change policy, since the court decided that existing law, the CAAct, could be interpreted as applying to GHGs. However, the court only opened the door to EPA's potential use of the CAAct for regulating GHGs. How the EPA chose to pursue that use was up to the agency. The EPA's use of its new authority viz. GHGs led to the second of the three major Supreme Court decisions.

Given the path that the EPA chose, i.e., use of the CAAct for extension to cover GHGs, one might ask why not amend the CAAct and make explicit its coverage of GHGs? Presumably such a course might obviate the need for subsequent litigation. However, legislative experience has shown that an attempt to amend an act such as the CAAct might lead to unpredictable and undesirable outcomes. The CAAct is a complex law, with four decades of judicial decisions and executive branch policies, and attempts to amend the law by Congress would likely open a stampede of parties interested in various changes to current law. In other words, opening the legislative door to amend current laws is a risky proposition, given the vicissitudes of legislative processes.

* * *

The second of the three key Supreme Court decisions on climate change followed the 2007 Court decision in Massachusetts v. EPA, as previously described. Following that decision from the Court, the EPA developed a series of standards governing GHG emissions. "One of these benchmarks set emission standards for vehicles, while another one required stationary sources of greenhouse gases to obtain constructing and operating permits from EPA. The petitioners, who include various state and industry groups, challenged these rules on the grounds that they were based on an improper construction of the CAAct and were arbitrary and capricious because they were based on an inadequate scientific record. The U.S. Court of Appeals for the Federal Circuit dismissed the challenges" [37]. The petitioners appealed the appellate court's decision to the U.S. Supreme Court.

The gist of the case was the question: "Did the EPA permissibly determine that its regulation of greenhouse gas emissions from new motor vehicles under the CAAct also triggered permit requirements for stationary sources of greenhouse gas emissions? [37].

The Court decided No. Justice Antonin Scalia delivered the opinion for the 9-0 member majority. The Court held that, while the Massachusetts decision found that the CAAct's general definition of 'air pollutant' included greenhouse gas emissions, it does not *require* [emphasis added] the EPA to include greenhouse gas emissions every time the act uses the term 'air pollutant'. Instead, EPA retains its ability to interpret the term in a context-appropriate way depending on where the term was being used. Because the inclusion of greenhouse gases as an 'air pollutant' under the permitting scheme would compel EPA to regulate tens of thousands of additional pollution emitters, it would not be reasonable for EPA to interpret this specific instance of 'air pollution' to include greenhouse gas emissions. Furthermore, even if EPA were able to interpret this instance of 'air pollution' to include greenhouse gases, EPA lacks the authority to modify the threshold limits Congress dictated. Though EPA overstepped its authority in trying to regulate greenhouse gases under this section of the CAAct, the Court held that EPA's decision was within the boundaries of EPA's discretion" [37].

An independent assessment of the Court's decision stated, "The Supreme Court on Monday mostly validated the EPA's plans to regulate major sources of greenhouse gas emissions such as power plants and factories but said the agency had gone too far in interpreting its power. The court's bifurcated opinion on one hand criticized the agency for trying to rewrite provisions of the CAAct. But it nevertheless granted the Obama administration and environmentalists a big victory by agreeing that there are other ways for EPA to reach its goal of regulating the gases that contribute to global warming.

It bears mention that EPA is getting almost everything it wanted in this case," Justice Antonin Scalia said in announcing his opinion from the bench. "It sought to regulate sources that it said were responsible for 86% of all the greenhouse gases emitted from stationary sources nationwide. Under our holdings, EPA will be able to regulate sources responsible for 83% of those emissions" [38].

Perspective: This second decision by the Supreme Court essentially validated EPA's plan to regulate GHG emissions from stationary sources, e.g., electrical power plants. This plan was built on the EPA's regulatory framework for mobile sources of air pollution emissions, e.g., vehicles. Although the Court's opinion in both the cited cases split along ideological lines, few decisions arrive from this court with a common voice and opinion. One might interpret this diversity of legal opinion as a desirable product of democratic processes.

The Supreme Court's third decision on climate change was less supportive of an EPA climate change policy, its Clean Power Plan. The Court's decision will be discussed subsequent to a description of the Clean Power Plan.

6.7.2.2 GHG Reporting Program, 2008

In response to the FY2008 Consolidated Appropriations Act (H.R. 2764; Public Law 110-161), the EPA issued the Mandatory Reporting of Greenhouse Gases Rule (74 FR 56260), which requires reporting of GHG data and other relevant information from large sources and suppliers in the U.S. The purpose of the rule is to collect accurate and timely GHG data to inform future policy decisions. In general, the Rule is referred to as 40 CFR Part 98 (Part 98). Implementation of Part 98 is referred to as the Greenhouse Gas Reporting Program (GHGRP).

Suppliers of certain products that would result in GHG emissions if released, combusted, or oxidized; direct emitting source categories; and facilities that inject CO_2 underground for geologic sequestration or any purpose other than geologic sequestration, are covered in Part 98. Facilities that emit 25,000 Mt or more per year of GHGs are required to submit annual reports to the EPA. Part 98 was published in the *Federal Register* (www.regulations.gov) on October 30, 2009.

Categories subject to Part 98 began reporting their yearly emissions with the 2010 reporting year. Additional sources began reporting yearly emissions in September 2012, bringing the total to 41 source categories reporting. In January 2012, the EPA made the first year of GHGRP reporting data available to the public through its interactive Data Publication Tool, called Facility Level Information on Green House gases Tool (FLIGHT) [38a].

6.7.2.3 Climate Action Plan, 2013

For several reasons, including accrued climate change science, global political pressure, and urging from domestic environmental organizations, the Obama administration became the first U.S. presidential administration to adopt policies on climate change. On June 25, 2013 the Obama administration announced its Climate Action Plan. The Plan states, "While no single step can reverse the effects of climate change, we have a moral obligation to act on behalf of future generations. Climate change represents one of the major challenges of the twenty first century, but as a nation of innovators, we can and will meet this challenge in a way that advances our economy, our environment, and public health all at the same time. That is why the President's comprehensive plan takes action to:

Cuts Carbon Pollution in America: In 2012, U.S. carbon pollution from the energy sector fell to the lowest level in two decades even as the economy continued to grow. To build on this progress, the Obama administration is putting in place tough new rules to cut carbon pollution—just like we have for other toxins like mercury and arsenic—so we protect the health of our children and move our economy toward American-made clean energy sources that will create good jobs and lower home energy bills. For example, the plan:

- Directs EPA to work closely with states, industry and other stakeholder to establish carbon pollution standards for both new and existing power plants;
- Makes up to $8 billion in loan guarantee authority available for a wide array of advanced fossil energy and efficiency projects to support investments in innovative technologies;
- Directs DOI to permit enough renewables project—like wind and solar – on public lands by 2020 to power more than 6 million homes; designates the first-ever hydropower project for priority permitting; and sets a new goal to install 100 megawatts of renewables on federally assisted housing by 2020; while maintaining the commitment to deploy renewables on military installations;
- Expands the President's Better Building Challenge, focusing on helping commercial, industrial, and multi-family buildings cut waste and become at least 20% more energy efficient by 2020;
- Sets a goal to reduce carbon pollution by at least 3 billion metric tons cumulatively by 2030 – more than half of the annual carbon pollution from the U.S. energy sector – through efficiency standards set over the course of the Obama administration for appliances and federal buildings;
- Commits to partnering with industry and stakeholders to develop fuel economy standards for heavy-duty vehicles to save families money at the pump and further reduce reliance on foreign oil and fuel consumption post-2018; and
- Leverages new opportunities to reduce pollution of highly-potent greenhouse gases known as hydrofluorocarbons; directs agencies to develop a comprehensive methane strategy; and commits to protect our forests and critical landscapes.

Prepares the United States for the Impacts of Climate Change: Even as we take new steps to cut carbon pollution, we must also prepare for the impacts of a changing climate that are already being felt across the country. Building on progress over the last four years, the plan:

- Directs agencies to support local climate-resilient investment by removing barriers or counterproductive policies and modernizing programs; and establishes a short-term task force of state, local, and tribal officials to advise on key actions the Federal government can take to help strengthen communities on the ground;
- Pilots innovative strategies in the Hurricane Sandy-affected region to strengthen communities against future extreme weather and other climate impacts; and building on a new, consistent flood risk reduction standard established for the Sandy-affected region, agencies will update flood-risk reduction standards for all federally funded projects;
- Launches an effort to create sustainable and resilient hospitals in the face of climate change through a public-private partnership with the healthcare industry;
- Maintains agricultural productivity by delivering tailored, science-based knowledge to farmers, ranchers, and landowners; and helps communities prepare for drought and wildfire by launching a National Drought Resilience Partnership and by expanding and prioritizing forest- and rangeland- restoration efforts to make areas less vulnerable to catastrophic fire; and
- Provides climate preparedness tools and information needed by state, local, and private-sector leaders through a centralized "toolkit" and a new Climate Data Initiative.

Lead International Efforts to Address Global Climate Change: Just as no country is immune from the impacts of climate change, no country can meet this challenge alone. That is why it is imperative for the U.S. to couple action at home with leadership internationally. America must help forge a truly global solution to this global challenge by galvanizing international action to significantly reduce emissions, prepare for climate impacts, and drive progress through the international negotiations. For example, the plan:

- Commits to expand major new and existing international initiatives, including bilateral initiatives with China, India, and other major emitting countries;
- Leads global sector public financing towards cleaner energy by calling for the end of U.S. government support for public financing of new coal-fired powers plants overseas, except for the most efficient coal technology available in the world's poorest countries, or facilities deploying carbon capture and sequestration technologies; and
- Strengthens global resilience to climate change by expanding government and local community planning and response capacities" [39].

It remains to be seen whether the implementation of the Climate Action Plan will extend beyond President Obama's term in office, which ended in 2016. One of the key elements of the Plan is the Clean Power Plan. In 2017 the Trump administration announced its disavowal of the Clean Power Plan.

6.7.2.4 Clean Power Plan, 2015

On August 3, 2015, the Obama administration announced its Clean Power Plan, the administration's linchpin policy on reducing U.S. carbon emissions that contribute to climate change. The Plan targets electricity power generation plants, with the goal of reducing carbon dioxide emissions by forcing plants to use alternative, less polluting fuels and cleaner technology for power generation. The Clean Power Plan establishes through EPA regulations carbon emission standards for power plants, and customized goals for U.S. states to cut the carbon pollution generated within their borders. The Clean Power Plan was the culmination of the EPA's efforts to generate an environmental policy that would result in lower carbon emissions. The Plan also served as the Obama administration's principal contribution to global negotiations on climate change. The administration promoted the Plan as an example of one industrialized nation's commitment to mitigating the effects of climate change. A summary provided by the EPA of the Clean Power Plan's key provisions follows [40].

- The CAAct—under § 111(d)—creates a partnership between the EPA, states, tribes, and U.S. territories—with the EPA setting a goal and states, territories, and tribes choosing how they will meet it.
- The final Clean Power Plan follows that approach. EPA is establishing interim and final carbon dioxide (CO_2) emission performance rates for two subcategories of fossil fuel-fired electric generating units:
- Fossil fuel-fired electric steam generating units (generally, coal- and oil-fired power plants); and
- Natural gas-fired combined cycle generating units.
- To maximize the range of choices available to states in implementing the standards and to

The Clean Power Plan establishes EPA regulations on carbon emission standards for power plants and mandates states to develop customized plans to enforce standards for power plants within their borders.

utilities in meeting them, the EPA is establishing interim and final statewide goals in three forms:
  - A rate-based state goal measured in pounds per megawatt hour (lb/MWh)
  - A mass-based state goal measured in total short tons of CO_2
  - A mass-based state goal with a new source complement measured in total short tons of CO_2
- States then develop and implement plans that ensure that the power plants in their state—either individually, together, or in combination with other measures—achieve both the interim CO_2 emissions performance rates over the period of 2022–2029 and the final CO_2 emission performance rate-based or mass-based goals by 2030.
- These final guidelines are consistent with the law and align with the approach that Congress and the EPA have always taken to regulate emissions from this and all other industrial sectors—setting source-level, source category-wide standards that sources can be met through a variety of technologies and measures.

Perspective: The Clean Power Plan is the Obama administration's centerpiece policy on mitigating the effects of climate change. Moreover, the Plan was the primary offering of U.S. diplomacy at the Paris Accords. The Plan's supporters promoted it as a statement of U.S. intent to lead global efforts in climate change policies. But because the Plan transacts into substantive economic and sociopolitical changes in the U.S., the Plan was quickly challenged in federal courts. The litigation once again reached the docket of the U.S. Supreme Court, as described in the following paragraph. However, the Trump administration issued an executive order on March 28, 2017 entitled "Energy Independence," which is targeted at revoking the Obama administration's Clean Power Plan. The Obama plan would have discouraged U.S. coal production in order to reduce the emission of GHGs emitted when fossil fuels are combusted. Whether electric utilities will increase their use of coal, however, is uncertain, given the alternative of less expensive natural gas supplies [41].

* * *

The third key Supreme Court decision on climate change resulted from litigation brought by some U.S. states and the energy industry, both preceding and following the EPAs' issuance of the Clean Power Plan. Some states did not want the responsibility of preparing plans on how they would implement the Plan. Energy industries argued that the Plan would force costly changes in technology and result in high energy costs for customers. On February 9, 2016, the Supreme Court stayed (i.e., set aside) by 5-4 vote the EPA's implementation of the Clean Power Plan pending judicial review by a lower federal court. The Court's decision was not on the merits of the rule. The EPA asserts that the Clean Power Plan will be upheld when the merits are considered because the rule rests on strong scientific and legal foundations. The EPA further asserts that for the states that chose to continue working on cutting carbon pollution, the EPA will continue to provide tools and support [42].

Comment: The Obama administration's Clean Power Plan can be characterized as a policy comprising one part technology and one part politics. The Plan is one part technology because it will force major changes in how the U.S. generates much of its energy supply. More specifically, the use of carbonaceous fuels will cease for combustion in electricity generating plants, replaced by sources of renewable energy, e.g., solar and wind, and fuels for combustion that yield a smaller carbon footprint, e.g., natural gas. Some technologists have forecast that fuel cells may become a significant factor in the U.S. energy calculus. Some of these changes in the technology of energy generation are already in place, e.g., reduced use of coal for power generation. These contemporary changes are occurring even in the absence of a final imposition of the Clean Power Plan, whose ultimate disposition of legal authority awaits further passage through legal gauntlets.

As to the political part of the Clean Power Plan, the U.S. and other countries with strong national economies had been criticized by countries with low- to mid-level economies for attempting to impose unpopular climate control actions on them. As previously discussed, this divide between the "haves" and "still developing" economies had led to stalemates at climate control meetings previous to the Paris conference, yielding little agreement on how to proceed in developing global policies on mitigation of climate change. Because the U.S. historically had been the largest emitter of carbon into the atmosphere, the U.S. found itself in an awkward political stance in global meetings on climate change. This stance changed at the Paris meeting. The Clean Power Plan became the U.S. centerpiece as a political action for demonstrating to other nations of U.S. intention to seriously reduce its national carbon footprint on the global environment. However, the Plan's ultimate fate will remain somewhat uncertain, awaiting review by President Obama's successor as U.S. president. As previously commented, the Trump administration has disavowed support for the Clean Power Plan.

6.7.3 Global Policies on Climate Change

Climate change is a global hazard, with global awareness of its consequences, albeit not without continuing sociopolitical debate as to causes and longevity. Given the global import of the warming of the oceans and ambient outdoor air, many nations have adopted policies that are intended to mitigate the effects of climate change. The climate change policies of the EU and of China are particularly important, given their contributions to GHG emissions.

6.7.3.1 EU Climate Change Policies

The European Commission began its climate related initiatives in 1991, when it issued the first EU community strategy to limit CO_2 emissions and improve energy efficiency [43]. From these first efforts has evolved a comprehensive EU

climate change program. The climate change legislation in the EU consists of the following directives and programs in support of its commitment to three targets for 2020. The first is to reduce emissions by 20% of 1990 levels. The second is to provide 20% of its total energy from renewables. The third is to increase energy efficiency by 20% from 2007 levels. EU leaders have also endorsed an 80%–95% reduction in emissions by 2050. A low carbon roadmap has been produced to show how this target could be achieved. The EU initiatives to reduce GHG emissions include the following [44]:

- *EU Emissions Trading System (EU ETS)*: The EU ETS works by capping overall emissions from high-emitting industry sectors and power stations, with a yearly decrease in the level of the cap. Within this cap, companies can buy and sell emission allowances as needed. This cap-and-trade approach gives companies the flexibility they need to cut their emissions in the most cost-effective way. The cap will lead to a 21% decrease in emissions by 2020.
- *Renewable Energy Directive (RED)*: This was put in place to help the EU meet its renewables target. Renewables include biomass, wind power, solar power, hydropower, and geothermal energy. In addition at least 10% of final energy consumption in the transport sector must come from renewables by 2020. Each Member State has an individual target within RED. The UK's target is for 15%.
- *Energy Efficiency Directive (2012)*: This sets the framework for measures to promote energy efficiency across the EU and help the EU reduce its energy consumption by 20%.
- *New car and van CO_2 targets*: The EU has binding targets on the level of emissions allowed from new cars and vans to decrease emissions from road transport.
- *Carbon Capture and Storage (CCS)*: The EU is supporting the development of CCS technology to trap and store CO_2 emitted from power stations and other major industrial installations.
- *2030 Climate Framework*: The EU began plans in 2015 to prepare a framework for reducing greenhouse gases in the period until 2030 to continue the trajectory toward a low-carbon economy in the period beyond 2020.

The EU ETS caps overall emissions from high-emitting industry sectors and power stations, with a yearly decrease in the level of the cap. Within this cap, companies can buy and sell emission allowances as needed.

In order to prepare for climate change in the EU, in April 2013 the EU adopted an adaptation strategy that encourages Members States and cities to produce comprehensive adaptation strategies. The framework also ensures that EU action is consistent with its climate adaptation objectives, particularly on agriculture, fisheries and cohesion policy. The European Environment Agency is developing an adaptation preparedness scoreboard, identifying key indicators for measuring levels of readiness of Member States [44].

6.7.3.2 China's Climate Change Policies

China has been the world's largest GHG emitter since 2006. As summarized by the Center for Climate and Energy Solutions, under the 2009 Copenhagen Accord, China pledged to reduce its emissions intensity by 40%–45% from 2005 levels by 2020. In a joint announcement with the U.S. in Beijing in November 2014, China announced two new goals: peaking GHG emissions by around 2030, and increasing nonfossil sources to 20% of total energy by 2030. China later included these two goals in its contribution to the climate agreement concluded in Paris in December 2015, along with a goal of reducing carbon intensity 60%–65% below 2005 levels by 2030 [45].

- *"Guiding Policy Framework*: China's 13th 5-year plan (FYP), was released in March 2016 and covers the period up to 2020. The headline targets are to reduce energy intensity by 15% and carbon intensity by 18% compared to 2015 levels. In addition, energy consumption will be capped at 5 billion tons of coal equivalent, and the share of primary energy consumption from non-renewable sources will increase to 15%. The increased carbon intensity goal means that China would reach, or potentially exceed, its Copenhagen pledge to reduce carbon intensity 40%–45% below 2005 levels.
- *Cap and Trade Programs*: In October 2011, China announced its intention to establish seven pilot carbon trading systems in five municipalities and two provinces across the country. On June 19, 2014, the seventh of these pilots was launched in the city of Chongqing. The pilot systems cover between 35% and 60% of emissions within their respective jurisdictions. Each operates under its own rules tailored to regional or local circumstances. The sub-national pilots reflect China's growing interest in the use of market-based instruments—and emissions trading in particular—to reduce GHG emissions. The experience gained through these pilot programs is developing familiarity with emissions trading among companies and regulators in large portions of China. On September 25, 2015, China's President Xi Jinping announced a plan to launch a nationwide cap-and-trade program in 2017, covering the power generation, iron and steel, chemicals, building materials including cement, paper making and nonferrous metals sectors.
- *Renewable Energy*: The 12th FYP set a target of increasing nonfossil energy to 11.4% of total energy use by 2015. Hydroelectric power is the main nonfossil energy source in China, generating 14.7% of electricity in 2011. Indeed, China is the largest hydroelectric producer in the world. The government

wishes to increase installed hydroelectric capacity from 230 GW in 2011, to 330 GW in 2017. Solar and wind energy deployment has increased at rapid pace—for instance, China installed 12.9 GW of solar photovoltaic in 2013 to reach a total capacity to 20 GW. The Chinese government announced targets to increase solar and wind capacity to 70–150 GW, respectively, by 2017.

- *Coal*: After many years of rapid increases, the government is now taking steps to reduce China's coal consumption. In 2013, 67.5% of energy consumption was from coal. In September that year, following rising concerned about air pollution, the government issued the Air Pollution Prevention and Control Action plan with the headline target of reducing coal consumption to 65% of total primary energy by 2017. Bans on new coal power plants are now in place in three industrial regions: Beijing-Tianjin-Hebei, Yangtze River Delta and the Pearl River Delta. More recently, the Ministry of Industry and Information Technology announced plans to reduce coal consumption by 80 million tons by 2017, and 160 million tons by 2020—China's total coal consumption in 2014 was approximately 2.8 billion tons. Furthermore, the State Council has announced plans to cap national coal consumption at 4.2 billion tons from 2020 onwards.
- *Nuclear*: Nuclear power will play an increasing role in China's energy mix in coming years. Capacity will increase from 14 GW in 2013 to 48 GW by 2017. In total, there are 26 reactors currently in operation, and 28 under construction. The government has set a target of 58 GW of nuclear capacity by 2020.
- *Energy Efficiency*: Improving energy efficiency is critical to achieving China's carbon intensity targets. In 2008, China passed the Energy Conservation Law to boost energy efficiency throughout the Chinese economy. In 2010, the China National Development and Reform Commission implemented demand-side management regulations that require utilities to achieve electricity savings of 0.3% per year, and reduce peak demand by the same percentage. China also has sector-specific energy efficiency standards—for instance, new commercial buildings must comply with building codes on energy use. There are also energy efficiency standards for household appliances that become more stringent over time.
- *Transportation*: In 2012 the China State Council approved a development plan for energy saving from the automobile industry up to 2020. The objective is to speed the development and roll out of more fuel-efficient cars and new energy sources. For manufacturers, China set target fuel economy standards for new cars of 5 L/100 km, approximately 47 miles per gallon (mpg), by 2020. Consumers were offered a reduction in the vehicle tax paid on energy saving vehicles by half, and eliminating vehicle tax altogether on electric cars" [45].

Perspective: As related in this section, both the EU and China have developed and committed to comprehensive climate change policies that involve both policies to reduce emissions of GHGs as well as policies on energy development and use. The U.S. has not developed a similar set of climate and energy related policies, although some progress has been achieved in the U.S. through implementation of air pollution regulations that incorporate control of GHG emissions.

6.7.4 Policy Frameworks for Mitigating Climate Change

There are polices other than the U.S. federal government's Clean Power Plan that have been proposed or actually implement as means to reduce the emission of GHGs into the atmosphere. Two of these policies are a tax on carbon and system of cap and trade of carbon emissions. Both policies have been adopted by certain policymakers, but not at the U.S. federal level. The passage of time may advance both kinds of policies to a wider congress of policymakers.

6.7.4.1 Carbon Taxes and Emissions Trading Systems

A carbon tax is a form of explicit carbon pricing; it refers to a tax directly linked to the level of CO_2 emissions, often expressed as a value per tonne CO_2 equivalent (per tCO_2e). "Carbon taxes provide certainty in regard to the marginal cost faced by emitters per tCO_2e, but do not guarantee a maximum level of emission reductions, unlike an emissions trading scheme. However, this economic instrument can be used to achieve a cost-effective reduction in emissions. Since a carbon tax puts a price on each tonne of GHG emitted, it sends a price signal that gradually causes a market response across an entire economy, creating incentives for emitters to shift to less greenhouse-gas intensive ways of production and ultimately resulting in reduced emissions" [46].

Carbon taxes can be introduced as an independent instrument or they can exist alongside other carbon pricing instrument, such as an energy tax. While the experience with direct carbon tax implementation is relatively new, such instruments are being increasingly introduced at a fast pace.

Currently 14 countries and 1 Canadian province have adopted somewhat different forms of carbon taxes, according to what form of carbon or energy source is subject to taxation. Shown in Table 6.1 is an overview of existing national jurisdictions that have introduced a direct carbon tax [46]. As an example, the Danish carbon tax covers all consumption of fossil fuels (natural gas, oil, and coal), with partial exemption and refund provisions for sectors covered by the EU ETS, (described in Section 6.7.3.1) energy-intensive processes, exported goods, fuels in refineries, and many transport-related activities. Fuels used for electricity production are also not taxed by the Danish carbon tax, but instead a tax on electricity production applies. As a second example, the carbon tax in British Columbia applies to the purchase or use of fuels within the province. The carbon tax there is revenue neutral; all funds generated by the tax are returned there to citizens through reductions in other taxes [46].

TABLE 6.1
Countries with Taxes on Carbon

Country	Year of Adoption	Cost
Canada/British Columbia	2008	CAD30 per tCO_2e (2012)
Chile	2014	USD5 per tCO_2e (2018)
Costa Rica	1997	3.5% tax on hydrocarbon fossil fuels
Denmark	1992	USD31 per tCO_2e (2014)
Finland	1990	EUR35 per tCO_2e (2013)
France	2014	EUR7 per tCO_2e (2014)
Iceland	2010	USD10 per tCO_2e (2014)
Ireland	2010	EUR 20 per tCO_2e (2013)
Japan	2012	USD2 per tCO_2e (2014)
Mexico	2012	Mex$ 10-50 per tCO_2e (2014) (Depending on fuel type)
Norway	1991	USD 4-69 per tCO_2e (2014) (Depending on fossil fuel type and usage)
South Africa	2016	R120/tCO_2 (Proposed tax rate for 2016) (Tax is proposed to increase by 10% per year until end-2019)
Sweden	1991	USD168 per tCO_2e (2014)
Switzerland	2008	USD 68 per tCO_2e (2014)

Source: World Bank, Putting a price on carbon with a tax, http://www.worldbank.org/content/dam/Worldbank/document/SDN/background-note_carbon-tax.pdf, 2015.

A carbon tax can be a regressive tax, depending on a country's economic structure. Recall that regressive tax is a tax that takes a larger percentage from low-income persons than from those with high-income. Because, in general, persons at or below poverty levels tend to be more energy dependent in the context of income spent on essential resources and services, income spend on energy supply is disproportionally spent by persons of low income. Therefore, a carbon tax can be a regressive tax for the poor or low income populations. Governments can make a carbon tax less regressive or neutral by utilizing policies of tax rebates or lump sum payments to persons adversely impacted by carbon taxes.

Fourteen countries and one Canadian province have adopted forms of carbon taxes, according to what form of carbon or energy source is subject to taxation.

Perspective: A carbon tax has the following advantages: Predictable carbon prices, easier to understand, and revenue can be returned via tax cuts and/or used for public good. Disadvantages include: Most politicians are hesitate to advocate for any tax, the public distrusts government programs, CO_2 tax revenues may end up being wasted in special interest spending, or priorities that are only peripheral to climate or sustainability [47].

6.7.4.2 Cap and Trade of GHGs

A second form of non-regulatory policy purposed for reduction of GHGs is a cap-and-trade system. As will be discussed in Chapter 8, cap and trade has been used successfully as a means to reduce the release of certain air pollutants; for example, the elimination of "acid rain" in the eastern U.S. was a consequence of a cap-and-trade system for reducing emissions of sulfur compounds. As will become evident, cap and trade is a policy different from a tax on carbon emissions because sources of GHG emissions play a more active and direct role in the policy's implementation.

6.7.4.2.1 European Union's Emissions Trading System

The EU launched the EU ETS in 2005 as the cornerstone of its strategy for reducing emissions of CO_2 and other GHGs at the least cost. In contrast to traditional "command and control" regulation, emissions trading harnesses market forces to find the cheapest ways to reduce emissions. The EU ETS is a cap-and-trade system. It caps the total volume of GHG emissions from installations and aircraft operators responsible for around 45% of EU GHG emissions. The system allows trading of emission allowances so that the total emissions of the installations and aircraft operators stays within the cap and the least cost measures can be taken up to reduce emissions [48].

The system works by putting a limit on overall emissions from high-emitting industry sectors, a limit that is reduced each year. Within this limit, companies can buy and sell emission allowances as needed. This cap-and-trade approach gives companies the flexibility they need to cut their emissions in the most cost-effective way. The EU ETS covers more than 11,000 power stations and manufacturing plants in the 28 EU Member States as well as Iceland, Liechtenstein, and Norway. Aviation operators flying within and between most of these countries are also covered. In total, around 45% of total EU CO_2 emissions are limited by the EU ETS.

The EU ETS is the world's first and largest major carbon market. As the first international emissions trading system to address GHG emissions from companies, the European system accounts for more than three-quarters of the trading volume of the international carbon market and functions as its engine. By putting a price on carbon and thereby giving a financial value to each ton of emissions saved, the EU ETS has placed climate change policy on the agenda of company boards across Europe. A sufficiently high carbon price also promotes investment in clean, low-carbon technologies. By allowing companies to buy credits from emission-saving projects around the world, the EU ETS also acts as a major driver of investment in clean technologies and low-carbon solutions, particularly in developing countries.

6.7.4.2.2 Regional Greenhouse Gas Initiative

The Regional Greenhouse Gas Initiative (RGGI) was the first mandatory cap-and-trade program in the U.S. to limit CO_2 from the power sector [49]. It consists of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont. Following discussions initiated by the Governor of New York in 2003, the RGGI was established in 2005, and administered its first auction of CO_2 emissions allowances in 2008. By 2020, the RGGI CO_2 cap is projected to contribute to a 45% reduction in the region's annual power-sector CO_2 emissions from 2005 levels, or between 80 and 90 million short tons of CO_2. The RGGI requires fossil fuel power plants over 25 MW in participating states to obtain an allowance for each ton of CO_2 emitted annually. Power plants within the region may comply with the cap by purchasing allowances from quarterly auctions, other generators within the region, or offset projects.

The Regional Greenhouse Gas Initiative, Inc. (RGGI, Inc.) is a 501(c)(3) nonprofit corporation created in the U.S. to support development and implementation of the RGGI. The organization's "exclusive purpose is to provide administrative and technical services to support the development and implementation of each RGGI State's CO_2 Budget Trading Program" [49]. RGGI, Inc.'s activities include

- "Development and maintenance of a system to report data from emissions sources subject to RGGI, and to track CO_2 allowances
- Implementation of a platform to auction CO_2 allowances
- Monitoring the market related to the auction and trading of CO_2 allowances
- Providing technical assistance to the participating states in reviewing applications for emissions offset projects
- Providing technical assistance to the participating states to evaluate proposed changes to the States' RGGI programs" [49].

Following a comprehensive 2012 Program Review, the RGGI states implemented a new 2014 RGGI cap of 91 million short tons. The RGGI CO_2 cap then declines 2.5% annually from 2015 to 2020. The RGGI CO_2 cap represents a regional budget for CO_2 emissions from the power sector.

RGGI states sell nearly all emission allowances through auctions and invest proceeds in energy efficiency, renewable energy, and other consumer benefit programs. These programs are spurring innovation in the clean energy economy and creating green jobs in the RGGI states [49]. RGGI, Inc. has no regulatory or enforcement authority. All such sovereign authority is reserved within the Member States.

6.7.4.2.3 California Cap and Trade of GHGs

California has often been the trendsetter in U.S. sociopolitical affairs. The state ranks first in population (38.8 million in 2013) and third in total area. In 2014, if California had been a separate country, it would have had the eighth largest economy in the world, ahead of Italy, India, and Russia [50]. As a state rich in economic, natural, and culture, policies established by California often are emulated in whole or part by other entities. This is certainly true of the state's leadership in environmental health policymaking. For instance, as observed in Chapter 8, California was the first U.S. state to investigate and respond to emerging problems of air pollution, actions that predated those of the U.S. federal government. The state's response to climate change has correspondingly preceded policies of other U.S. states and the U.S. federal government. In particular, California's cap-and-trade policy for the purpose of lowering emissions of GHGs is noteworthy and described in the following paragraphs.

In 2013 California launched its cap-and-trade program, which uses a market-based mechanism to lower the state's GHG emissions. The state's cap-and-trade rules went into effect on January 1, 2013 and applied at that time to large electric power plants and large industrial plants. In 2015, the cap-and-trade rules were extended to fuel distributors (including distributors of heating and transportation fuels). At that stage, the program will encompass around 360 businesses throughout California and nearly 85% of the state's total GHG emissions. The state forecasts that its emissions trading system will reduce GHG emissions from regulated entities by more than 16% between 2013 and 2020. It is a central component of the state's broader strategy to reduce total GHG emissions to 1990 levels by 2020 [51].

Under a cap-and-trade system, companies must hold enough emission allowances to cover their emissions, and are free to buy and sell allowances on the open market. California held its first auction of GHG allowances on November 14, 2012. California's program is second in size only to the EU ETS, based on the amount of emissions covered. California's program will provide salient experience in how an economy-wide cap-and-trade system can function in the U.S.

Perspective: Cap and trade can have the following advantages: Predictable carbon emissions, fewer political obstacles than a tax on emissions, revenue can be returned via rebates and/or used for public good, and revenue rises as emissions decline. Some of the disadvantages include: Total emissions are capped, but the dollar price is unknown and dependent on many market variables; depending on the scope, method

of allocation, and other design elements, too many permits may be issued, and other market imperfections may arise [47].

6.7.5 Policies on Climate Change Adaptation

As the signs of climate change became more evident, some national governments have begun the development of policies that are purposed for adapting to the changes. The U.S. Government Accountability Office (GAO) undertook a study of how selected governments have approached enhancing resilience through climate change adaptation, finding that some nations have aligned adaptation with broader resilience efforts [52]. "All five selected governments have enacted laws and developed long-term plans as a part of their approaches to climate change adaptation. These plans established frameworks for addressing climate risks. For example, the EU and The Netherlands made long-term funding commitments for enhancing resilience, and the United Kingdom developed a system for monitoring and evaluating its climate change strategy. These laws and strategies have helped governments identify priority actions, facilitate consensus among stakeholders, provide reliable resources, and identify areas for improvement. The Philippines and the UK have also aligned their adaptation strategies with broader resilience strategies that address other risks, such as terrorism and health pandemics. This alignment may provide co-benefits, such as infrastructure investments that protect against climate change impacts; enhance resilience to all disasters; and create economic opportunities."

The U.S. has initiated some nascent steps to enhance resilience through climate change adaptation and aligning climate change adaptation with broader resilience efforts. Legislation has been introduced in Congress to enhance resilience to weather-related events. Specifically, in 2014 and 2015, a bill to enhance the federal government's planning and preparation for extreme weather was introduced in Congress but not enacted. Additionally, President Obama issued an executive order directing federal government agencies to develop or update adaptation plans and establishing the Council on Climate Change Preparedness and Resilience. Further, the President's Climate Action Plan sets strategic climate change adaptation priorities. The GAO also notes that the Executive Office of the President also collaborates with the Mitigation Framework Leadership Group, an intergovernmental coordinating body created to integrate federal efforts and incorporate risk management and hazard mitigation in all planning, decision-making, and development [52].

6.7.6 The Public's Role in Climate Change Policymaking

The public has an important role, indeed responsibility, in addressing the issues attending policymaking actions on climate change. Put simply, influencing the responsible policymakers is the course of action to be taken. The currency to be used is education, communication, and persistence. Whether as an individual or member of a like-minded group, one must be educated on the issues at hand (e.g., portent of climate change on human health) and be prepared to communicate one's knowledge and concerns to policymakers, no matter whether they are in the public or private sector. Persistence in advocacy for a particular policy is usually a prerequisite for a successful outright to policymakers. Grassroots advocacy can be a highly effective impactful resource for making or changing environmental health policies. As but one of many examples of grassroots advocacy are the local campaigns by anti-smoking groups. Their currency of education, communication, and persistence was used throughout the U.S. and other countries to achieve policies of no smoking in public buildings and recreation areas.

6.8 HAZARD INTERVENTIONS

Assuming that the projections of the dire portent of climate change are true, interventions to mitigate climate change go beyond necessary to the level of vital. Some persons might argue that interventions would be extraordinarily costly, burdensome to global societies, and a misuse of resources needed for use by an increasing global human population. But upon reflection of what can already be observed and attributable to climate change (e.g., rising sea levels, melting polar ice, shrinking glaciers), the question must be put, "Can humankind afford to be wrong about mitigating climate change?" Given this question, interventions must be implemented. Some of the interventions to lessen the hazard posed by climate change are the following:

- On a global scale, support through sociopolitical means those policies that are based on consensus science, presented in transparent reports, and implemented through diplomatic dialog and resolution.
- On a national scale, support through sociopolitical means those policies and policymakers that advocate for the development and promulgation of policies for climate change mitigation.
- On a personal scale, use objective, transparent sources of climate change information as the basis for personal decisions and policies. This could include choosing consumer products manufactured by sources that have a neutral carbon impact on the environment. Other individual policies might include selecting energy sources that are not carbon-based, e.g., solar power, wind, and geothermal.
- Industrial entities should understand their role in mitigating climate change and redesign or replace carbon-dependent manufacturing processes and products.

6.9 SUMMARY

This chapter presents Earth's climate change as the single greatest current environmental threat to life on the planet.

This assertion is based on both the science of climate change together with observable changes already occurring in global temperature, acidification of seas, impacted ecosystems, and human health morbidity and mortality. While the science of GHG accumulation and its contribution to global warming is not incontrovertible, nevertheless, it is compelling and leads to a conclusion that global interventions to mitigate further climate change cannot wait. Fortunately, as described in some detail in this chapter, international efforts through the auspices of the UN have produced global agreements on actions to reduce the greenhouse effect of heat-trapping gases emitted into the atmosphere, as well as reducing the carbon footprint of national economies. The passage of time will yield an answer to the degree of success of these and subsequent climate control policies.

6.10 POLICY QUESTIONS

1. This chapter has presented climate change as a global hazard to humankind. Do you agree? If not, why? Discuss in detail, including any limitations in your knowledge of the position you have taken in responding to this question.
2. The relationship between technology and climate change was discussed in this chapter. Discuss what current technology should be abandoned as a contribution to mitigating climate change. Be specific and describe in detail the pros and cons of your recommendation.
3. In your opinion are elected representatives of the people moving too slowly or outright ignoring the urgency of action for mitigating climate change? If so, what can you personally do about your concern?
4. Taxing a product or process can have both positive and negative effects. For example, taxing tobacco products has shown to reduce tobacco use by youth persons. Should the U.S. place a tax on the release of carbon dioxide into the atmosphere? Discuss the political implications of a carbon tax?
5. When discussing climate change with you grandmother, she replies, "Nothing new about hot weather! Whew! I remember all the hot summers on the farm. This climate thing is just what I remember as a young girl working in the corn fields. Tell all your friends not to worry about that climate whatsathing." What do you say and do in reply?
6. Oops, we failed to mention that your grandmother is a Member of the U.S. Congress. What do you say and do in reply to her comment in Question 5?
7. The International Committee on Climate Change is an organization created by the UN. Do you agree that the UN is the appropriate body to coordinate global actions to mitigate climate change? Do you have trust in the UN? Is there a more appropriate body to lead the efforts to mitigate climate change? If so, why is this body more appropriate? If not, why and what body would be better? Detail your reasons for your answers.
8. The Clean Power Plan is summarized in this chapter. As discussed the plan has engendered both considerable political support and opposition. Discuss your personal assessment of the core goal of the Clean Power Plan and state why you support or oppose the plan.
9. If the dire predictions of food shortages become reality due to climate change, what is your plan to prevent human famine in those geographic areas of persistent or permanent drought? Be specific about the elements of your plan.
10. It is proffered in this chapter that reducing the impact of climate change will require global effort. In this sense, describe three actions that you can execute in a global context that will contribute to mitigation of climate change. Be specific and be detailed.
11. Assume that due to reduction in the use of coal as a source of energy, coal mining has ended in the U.S. Does the federal government have an obligation to subsidize coal companies and coal miners due to government's greenhouse policies that ended the use of coal? Present your answer with arguments both pro and con in regard to government subsidies.
12. List, detail, and discuss three actions that you can perform as your responsibility for mitigating climate change. Be specific and real.
13. In the previous question, the word *responsibility* was used. Would the word *duty* have been a better choice? Explant the difference in meaning between the two words. Which word was best for the purpose of the previous question? Discuss you choice of word and relate your choice to your course of academic study.
14. Congratulations! Your research team has discovered and patented a novel method for manufacturing fuel cells in ways that produce no waste in manufacture and yields a sustainable fuel cell that will revolutionize transportation and home energy supply. Your research team has two offers to commercialize your invention: (1) sell the patent to a large energy corporation or (2) donate the patent to an international NGO for their global distribution of fuel cells at cost of manufacture. Which choice do you make and why? Discuss the ethics of your choice.
15. The year is 2050. Sadly, global efforts to mitigate climate change failed. The planet has fallen victim to the predictions of global disaster and uncompromising effects of disasters to many forms of life on the planet. Explain to your descendants why the dire predictions of what went wrong in efforts to mitigate climate change. Be as specific as possible. Your response to this question should be composed as an apology to your descendants.
16. On Earth Day, 2016, the presidents of China and the U.S. met and jointly signed their nations'

responsibilities under the Paris Accord. Was this a significant event? Why? Was there a common denominator that brought together the world's two largest emitters of carbon into the environment? Discuss the sociopolitical implications of this event.

17. Much of the U.S. policymaking on climate change was ultimately shaped by judicial decisions, particularly the U.S. federal courts. As a newly-appointed member of the U.S. Supreme Court, but a person who has a background both in law and environmental science, do you believe the latter credential might be a hindrance to your consideration of environmental cases brought before the court? Be specific in your reply.
18. After several years of reliable, but polluting service, the family car needs to be replaced. You have been active in protecting your neighborhood's nature preserve and parks. Recently announced was the marketing of a fuel cell vehicle and also a solar-powered electric car. And still on the market are fuel-efficient hybrid vehicles, powered by internal combustion engines and batteries. Assuming fuel cell and solar vehicles are each 1.5 times the cost of a hybrid vehicle, which vehicle do you purchase? Why? List the pros and cons of your decision.
19. Decades have passed since the global community of the first-half of the twenty first century attempted to mitigate climate change. Some success was achieved, and global ambient air temperatures cooled, but insufficiently to fully mitigate the effects of climate change. Your planet's food supply has dramatically changed, in part due to climate change, and partly due to the increase in the global population. Speculate in some detail what your daily food consumption might comprise. How is your diet different from that of your twentieth century ancestors?
20. After lumbering, stumbling, or slumbering, through this chapter, discusses the three most important lessons you learned. Was your personal environmental health behavior changed by the content of this chapter? If so, how? If not, why?

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7 Tobacco Products

7.1 INTRODUCTION

In stark contrast to the other physical hazards described in this book, tobacco products stand alone as an environmental health hazard. This is because the hazard is one that is self-administered; moreover, it is a hazard that is accepted with knowledge of its health consequence. This is because there is now global knowledge of the public health consequences of cigarette smoking, in particular, and companion knowledge about the health implications of other tobacco products as well. Further, in distinction to the other environmental hazards described herein, the adverse effects of tobacco use are relatively amenable to traditional public health methods of prevention and policymaking. The prevention paradigm is rather simple: don't use tobacco products and avoid contact with persons who do. That dictum is, of course, easily expressed but difficult to practice.

This chapter presents the public health impacts and attendant policies of the uses of tobacco products. As illustrated in Figure 7.1, tobacco is an agricultural crop, most commonly used to make cigarettes and other consumer products. It is widely cultivated in warm regions, especially in the U.S. and China. In the U.S., tobacco is principally grown in the border states of Kentucky, Maryland, North Carolina, and Virginia. Tobacco plants comprise a vertical stalk, with leaves growing outward from the stalk, much like limbs on a tree trunk. At harvest, leaves are removed from the stalk, dried, and made into various tobacco products. The tobacco products are smoked, chewed, or snorted.

The psychoactive ingredient of tobacco is nicotine. It is likely that over time nicotine evolved in tobacco as a defense mechanism, akin to how many other plants and animals evolved poisons for defensive measures. The tobacco plant should therefore be considered poisonous. It is interesting that a recent new class of insecticides, neonicotinoids, is chemically related to nicotine. Nicotine is a stimulant. In small doses, nicotine can increase heart rate and blood pressure. When inhaled as a component of tobacco smoke, nicotine rapidly reaches the brain, crossing the blood-brain barrier within 8–20 s. Tobacco products that are chewed, placed inside the mouth, or snorted tend to release considerably larger amounts of nicotine into the body than smoking. Nicotine is a highly addictive stimulant drug, one that makes cessation of tobacco smoking and other uses of tobacco a challenging proposition.

Covered in this chapter are several forms of tobacco products. Cigarettes are the most prevalent form of tobacco products, consisting of various tobacco blends encased in a paper cylinder. Cigarette smoking consists of placing one end of the cigarette into one's mouth and using a flame or other source of heat to ignite the tobacco at the other end of the cigarette. Another tobacco product is the cigar, which is a tightly-rolled bundle of dried and fermented tobacco leaves, rolled in a series of types and sizes. As with cigarettes, one end of a cigar is placed into one's mouth, with the distal end set afire. Pipes are a third form of tobacco delivery system, where a mixture of ground tobacco leaves and additives are tamped into the bowl of the pipe and ignited. A third general product is smokeless tobacco, defined as tobacco that is chewed or snuffed rather than smoked by the user. Each of these tobacco delivery systems exposes the user to serious health consequences, which are elaborated subsequently in this chapter, accompanied by details of public health policies and actions to reduce the health toll of tobacco use.

7.2 PRÉCIS HISTORY OF TOBACCO USE

Tobacco has been with humankind for several millennia. According to one source, tobacco, a native plant of the Americas, was first discovered thousands of years ago. However, growing tobacco as a crop was pioneered by communities in the Andes at a much later time. Most estimates put this occurrence between 5000 and 3000 BCE [1]. In addition to chewing or smoking tobacco leaves, tobacco's history reveals many other lesser-known uses. For instance, some South American natives used it as an insect repellent, and many early civilizations incorporated its use into sacred rites. Multiple sources are available of the plant's history. Some of the history brings a smile, perhaps even a soft chuckle, as the global spread of tobacco is depicted in various compilations of the history of tobacco [2–4]. However, the humorous moments are quickly sobered with the knowledge of the human misery caused by the use of tobacco products.

A history of tobacco in important in a policy context as a premier example of how difficult it is for policymakers to formulate protective health policies in light of a common personal choice made by millions of people over many centuries. Table 7.1 shows a short summary that was synthesized across several sources with an emphasis on actions that portended public health consequences.

A review of these salient dates in the history of tobacco shows the gradual global spread of tobacco use. A plant that seems likely to have originated in the Americas gradually made its way around the planet. Although many societies have banned or elsewise controlled the distribution of tobacco products, principally cigarettes, tobacco products are still available around the globe. A further reflection on the key dates in tobacco's history reveals the emergence of health concerns, as expressed by medical doctors

FIGURE 7.1 Tobacco plants growing on a Kentucky farm. (With permission of University of Kentucky College of Agriculture, Food, and Environment, Lexington, KY.)

in China, Germany, England, and the U.S. In response to health concerns, policymakers in Europe and the U.S. have enacted laws, ordinances, and directives to control the use of tobacco products. Especially noteworthy is WHO's Framework Convention on Tobacco Control (WHO FCTC), the first international treaty negotiated under the auspices of WHO. It was adopted by the World Health Assembly on May 21, 2003 and entered into force on February 27, 2005. In a policy context, a treaty is a most important statement of intent, since a treaty is an official agreement that is made between two or more countries or groups. Perhaps a future WHO hallmark date will be the elimination of tobacco as a hazard to humankind, thereby emulating WHO's announcement in 1980 that smallpox had been eradicated as a scourge to humankind.

TABLE 7.1
Précis Summary of the History of Tobacco

Date	Country	Event
5000–3000 BCE	Americas	First cultivation of the tobacco plant
About 1 BCE	Native Americans	Begin occasional smoking and using tobacco enemas
600–900 A.D.	Mexico	Mayans drew carved stone images depicting tobacco use
Early 1500s	Middle East	Tobacco first introduced when the Turks took it to Egypt
1492	Cuba	Columbus discovers tobacco smoking and takes the behavior to Europe
1531	Santo Domingo	European settlers begin tobacco cultivation
1530–1600	China	Tobacco introduced via Japan or the Philippines
1558	Europe	Tobacco plants brought to Europe. Attempts at cultivation fail
1600s	China	China philosopher Fang Yizhi points out years of smoking "scorches" one's lung
1612	Jamestown	First American settlers, Jamestown, Virginia, grew tobacco as cash crop
1614	England	Seven thousand tobacco shops open with first sale of Virginia tobacco
1633	Turkey	Death penalty imposed for smoking
1660	Africa	Portuguese and Spaniards ship tobacco to East Africa, spreading to Central and West Africa
1761	England	First study of effects of tobacco (John Hill); snuff users warned they risk nasal cancers
1769	New Zealand	Capt. James Cook arrives, smoking a pipe, and was doused in case he was a demon
1788	Australia	Tobacco arrives with the first fleet
1795	Germany	Sammuel Thomas von Soemmering reports cancers of the lip in pipe smokers
1865	U.S.	First commercial cigarettes were made by Washington Duke, Raleigh, North Carolina
1881	U.S.	James Bonsack invents first cigarette-making machine, Raleigh, North Carolina
1950s	China	State monopoly took control of the tobacco business
1962	UK	First report of the British Royal College of Physicians on Smoking and Disease
1964	U.S.	Surgeon General Luther Terry reports that smoking causes lung cancer in men
1965	U.S.	Federal Cigarette Labeling and Advertising Act of 1965
1969	U.S.	Public Health Smoking Act of 1969
1984	U.S.	Comprehensive Smokeless Tobacco Health Education Act of 1984
1987	Australia—Victoria	First to use a tobacco tax to establish a health foundation to counter tobacco use
2001	Belgium	EU adopts its first Tobacco Products Directive
2003	China	Electronic cigarette invented by Chinese pharmacist Hon Lik as anti-smoking aid
2003	Switzerland	WHO Framework Convention on Tobacco Control adopted as a global treaty
2009	U.S.	Family Smoking Prevention and Tobacco Control Act
2014	Belgium	EU amends and tightens its Tobacco Products Directive
2015	Switzerland	WHO estimates tobacco kills around 6 million people annually
2016	U.S.	FDA issues regulations on sales and use of e-cigarettes

Source: Jacobs, M., *From the First to the Last Ash: The History, Economics,* and *Hazards of Tobacco*. Cambridge: Cambridge Department of Human Service Programs, Cambridge Tobacco Education Program, 1997; WHO (World Health Organization), The history of tobacco. Atlas 2. http://www.who.int/tobacco/en/atlas2.pdf, 2000; Randall, V.R., *History of Tobacco*. Dayton, OH: The University of Dayton School of Law, 1999.

7.3 PREVALENCE OF TOBACCO PRODUCTS AND USERS IN THE U.S.

As evident in the history of tobacco, use of tobacco products in the Americas has a long history. The cultivation of tobacco for commercial purposes began in what later became the U.S., as was the invention of cigarette manufacturing equipment. In the U.S., as elsewhere, cigarette smoking is the most prevalent form of tobacco use, with other tobacco products rising and falling in use over the centuries. A considerable volume of tobacco use data is available from public health and business sources. This section will summarize the data on the prevalence in the U.S. of tobacco products and where data are available, the numbers of users of various tobacco products. Use of tobacco products by middle and high school students in the U.S. is an especially important public health concern, given the fact that many long-term tobacco users began as youth.

In 2015, the CDC and the Food and Drug Administration (FDA) reported their analysis of data from the 2011–2014 National Youth Tobacco Surveys [5]. In 2014, a total of 24.6% of high school students reported current use of a tobacco product, including 12.7% who reported current use of ≥2 tobacco products. Among all high school students, e-cigarettes (13.4%) were the most common tobacco products used, followed by hookahs (9.4%), cigarettes (9.2%), cigars (8.2%), smokeless tobacco (5.5%), snus (1.9%), pipes (1.5%), bidis (0.9%), and dissolvables (0.6%). Current use of any tobacco and ≥2 tobacco products among middle school students was 7.7% and 3.1%, respectively. E-cigarettes (3.9%) were the tobacco product used most commonly by middle school students, followed by hookahs (2.5%), cigarettes (2.5%), cigars (1.9%), smokeless tobacco (1.6%), pipes (0.6%), bidis (0.5%), snus (0.5%), and dissolvables (0.3%).

In response to health concerns, policymakers in Europe and the U.S. have enacted laws, ordinances, and directive to control the use of tobacco products. Especially noteworthy is WHO's Framework Convention on Tobacco Control, the first international treaty negotiated under the auspices of WHO.

From 2011 to 2014, statistically significant increases were observed among high school students for current e-cigarette (1.5% to 13.4%) and hookah (4.1% to 9.4%) use. Statistically significant decreases were observed for current cigarette (15.8% to 9.2%) and snus (2.9% to 1.9%) use. Statistically significant decreases were observed for current cigar (11.6% to 8.2%), pipe (4.0% to 1.5%), and bidi (2.0% to 0.9%) use. Current use of any tobacco product (24.2% to 24.6%) and use of ≥2 tobacco products (12.5% to 12.7%) did not change significantly from 2011 to 2014. Among middle school students, similar trends were observed during 2011–2014. A statistically significant decrease was observed only in middle school students currently using ≥2 tobacco products (3.8% to 3.1%) [5]. These kinds of prevalence data of tobacco use by youth provide essential material for targeting tobacco use prevention programs and for policymaking.

7.3.1 Cigarettes: Adults and Youth

The CDC has assessed national estimates of smoking prevalence among adults aged ≥18 years using data from the 2015 National Health Interview Survey. The percentage of U.S. adults who smoke cigarettes declined from 20.9% in 2005 to 15.0% in 2015. Higher tobacco taxes, tough anti-smoking messages and smoke-free laws that ban smoking from indoor and outdoor areas appear to be factors in reductions in the prevalence of U.S. adults who smoke [6]. Similarly, the CDC reported that from 2011 to 2015, current cigarette smoking declined among American middle and high school students. About 2 of every 100 middle school students (2.3%) reported in 2015 that they smoked cigarettes in the past 30 days—a decrease from 4.3% in 2011. About 9 of every 100 high school students (9.3%) reported in 2015 that they smoked cigarettes in the past 30 days—a decrease from 15.8% in 2011 [7].

7.3.2 Other Tobacco Products

There are several products in addition to cigarettes that contain tobacco and are used for smoking, chewing, or snuffing. These include cigars, pipes, chewing tobacco, and snuff. These products have less commercial appeal than cigarettes and therefore will be described in lesser detail than cigarettes. Further, as will be subsequently related, policies on the use of these products vary according to federal, state, and local laws or ordinances and policies enforced by private sector groups, such as business operations.

- *Cigars:* A cigar is defined as a roll of tobacco wrapped in leaf tobacco or in a substance that contains tobacco. Cigars differ from cigarettes in that cigarettes are a roll of tobacco wrapped in paper or in a substance that does not contain tobacco. The three major types of cigars sold in the U.S. are large cigars, cigarillos, and little cigars. The use of flavorings in some cigar brands has raised concerns that these products may be especially appealing to youth. Prevalence data from the CDC provide cigar smoking rates and distribution data for the U.S. population [8]. In 2013, an estimated 12.4 million people in the U.S. aged 12 years or older (or 5.2%) were current cigar smokers. Percentages of U.S. adults who were current cigar smokers† in 2013: 5.0% of all adults, with 8.2% of adult males and 2.0% of adult females, and for which White males (5%) and Hispanic adults (4%) are the population groups with the greatest cigar smoking rates.
- The percentages of U.S. high school and middle schools students who reported cigar smoking were as follows: U.S. high school students who were current smokers in 2014 were 8.2% of all students in grades 9–12. This aggregate figure represented 5.5% of female students and 10.8% of male students in grades

9–12. For middle school students, the percentage of U.S. students who were current cigar smokers in 2014 was1.9% of all U.S. students in grades 6–8. This figure represented 1.4% of female students and 2.4% of male students in grades 6–8. The percentage of U.S. school students who smoke cigars is rather striking, indicating a need for further public health interventions targeted at school-age children and adolescents [8].

- *Pipes:* Conventional tobacco pipes are basically a configuration consisting of a bowl attached to a tapered stem, which ends in a mouthpiece. Pipe bowls can be constructed of various woods, metal, clay, or corncobs. Mixtures of different varieties of tobacco leaves are shredded into flakes or crumbled by hand, often with some kind of flavoring added for the sake of aroma. The tobacco mix is tamped into the pipe's bowl and ignited, with smoke being drawn through the stem and mouthpiece into the smoker's mouth. One special form of tobacco pipe is a water pipe, which typically consists of a head that is connected to a water jar, with an attached hose and mouthpiece, as illustrated in Figure 7.2. Tobacco and a moist fruit preparation are placed below burning charcoal in the head of the device and the resulting smoke is inhaled through the hose into one's mouth [9]. A special form of water pipe is called a hookah, a water pipe that used to smoke specially-made tobacco that comes in different flavors [9].

FIGURE 7.2 Image of a hookah water pipe. (From FDA (Food and Drug Administration). 2016. Press release: FDA takes significant steps to protect Americans from dangers of tobacco through new regulation, May 5. Silver Spring: Office of Public Affairs.)

- Prevalence data on conventional pipe smokers in the U.S. is relatively sparse, because their numbers have dwindled from the 18th and mid-19th centuries. While pipe smoking was fairly common in 1965 among men age 20 or older, the prevalence of pipe smoking over the following three decades has "declined drastically" across all races, regions, and education levels, as reported in the 1996 Preventive Medicine study. Current pipe smokers are typically men 45 years or older [10].
- In a report from investigators with the American Cancer Society [11], "The prevalence of conventional pipe smoking among adult men in the U.S. has decreased from 14.1% in 1965 to 2.0% in 1991, and pipe smoking remains rare among U.S. women (<0.1% in 1991). The prevalence of pipe smoking is highest among men aged 45 or older and in the Midwest. Pipes are commonly used by some populations, including American Indians (male prevalence 6.9% in 1991) and by both men and women in parts of China (20% prevalence in 1996). The National Youth Tobacco Survey has measured prevalence of pipe smoking among U.S. youth since 1999. The prevalence of current pipe smoking has increased from 2.4% to 3.5% of middle school students and from 2.8% to 3.2% of high school students from 1999 to 2002; prevalence was higher among boys than girls and varied by state and ethnicity" [11].
- Water pipes are another area of health concern. These kinds of pipes are a form of tobacco pipe smoking that differs from conventional pipe smoking. This is a traditional smoking method going back centuries, known across various cultures as hookah, shisha, sheesha, and hubbledubble, among other names. "Hookah" is chosen for use in this chapter, since that is the name most often used by U.S. health agencies in their investigations. These pipes typically consist of a head that is connected to a water jar, with an attached hose and mouthpiece (e.g., Figure 7.2). Tobacco and a moist fruit preparation are placed below burning charcoal in the head of the device. When a smoker inhales through the mouthpiece, the air from the burning charcoal is pulled through the layer of tobacco and then through the water where it is cooled as bubbles, before being breathed in through the hose and mouthpiece [9]. Similar to cigarettes, hookah smoking delivers the addictive drug nicotine and hookah smoke is at least as toxic as cigarette smoke.
- The prevalence of hookah smoking is unknown but the CDC reported "In recent years, there has been an increase in hookah use around the world, most notably among youth and college students. The Monitoring the Future survey found that in 2014, about 23% of 12th grade students in the U.S. had used hookahs in the past year, up from 17% in 2010. In 2014, this

rate was slightly higher among boys (25%) than girls (21%). CDC's National Youth Tobacco Survey found that from 2013 to 2014, hookah smoking roughly doubled for middle and high school students in the U.S. Current hookah use among high school students rose from 5.2% (770,000) to 9.4% (1.3 million) and for middle school students from 1.1% (120,000) to 2.5% (280,000) over this period" [12].

- A consideration of these prevalence data again reveals a concern that young persons are at particular risk of adverse health effects.
- *Smokeless tobacco:* There are several kinds of tobacco products that are not smoked, but rather are placed into the user's mouth or nose. The latter method of using smokeless tobacco was popular in past centuries, a behavior called "snuffing." Currently, some of the more common smokeless tobacco products listed by the American Lung Association include [13]:
  - *Chewing, oral, or spit tobacco:* This tobacco comes as "wads" of loose leaves, plugs, or twists of dried tobacco leaves that may be flavored. A wad is chewed or placed between the cheek and gum or teeth. The nicotine in the tobacco is absorbed through the mouth tissues. The user spits out (or swallows) the brown saliva that has soaked through the tobacco. In centuries past, up through the first half of the twentieth century, containers called spittoons were a common fixture in many public places, including public buildings. Tobacco chewers were expected to spit their wads of tobacco-laden saliva into the spittoons. In some rural areas, tobacco spitting competitions were held as entertainment. This disgusting practice led to unhygienic areas in locales that permitted tobacco spitting.
  - *Snuff or dipping tobacco:* Snuff is finely ground tobacco packaged in cans or pouches. Snuff is sold as dry or moist and may have flavorings added. Snuff is used in "pinches," between the thumb and forefinger. Moist snuff is used by putting a pinch between the lower lip or cheek and gum. The nicotine in the snuff is absorbed through the tissues of the mouth. Moist snuff also comes in small, teabag-like pouches or sachets that can be placed between the cheek and gum. These are designed to be both "smoke-free" and "spit-free" and are marketed as a discreet way to use tobacco. Dry snuff is sold in a powdered form and is used by "snuffing the powder" up one or both nostrils of the user's nose.
  - *Snus:* Snus are a type of moist snuff first used in Sweden and Norway. The tobacco is often flavored with spices or fruit, and is packaged like small tea bags. An American version of snus is similar in content to the Scandinavian variety, but with less moisture in the tobacco. Snus are held between the gum and mouth tissues and the nicotine-laden juice is swallowed. Prevalence of use data are scarce, with the principal use of snus occurring in Sweden and Norway. One report from Norway found that among young male adults, the prevalence of smoking (daily + occasional) was reduced from 50% in 1985 to 21% in 2013. Over the same period, use of snus increased from 9% to 33%. The investigators suggested that use of snus was a possible contributor to reduced use of cigarettes [14]. In Sweden, the prevalence in 2011 of daily snus use among 16–84 year-old males and females was 19% and 4%, respectively. Occasional use of snus (less than daily use) was reported by 6% of Swedish males and 4% of Swedish females [15].
  - *Tobacco sticks:* The tobacco industry test-marketed what were called "tobacco sticks" in Kansas during 2011 [16]. The sticks were sold in matchbook-like packs. According to the manufacturer, tobacco stocks were targeted at adult smokers and snuff users who were seeking a smokeless, spit-free alternative. The sticks were coated with finely milled tobacco and came in different flavors such as "cool mint." The product was later withdrawn from production, in part due to health concerns from public health advocates.

Smokeless tobacco sales in the U.S. are a $5–$6 billion annual business, with sales rising [17]. Convenience stores are the most common place to purchase these products within the U.S. In 2014, U.S. convenience stores generated approximately $5.31 billion from chewing tobacco and snuff products; which amounted to about 1.26 billion units sold [18]. Smokeless tobacco products are highly addictive, owing to their higher content of nicotine [19]. Some users of smokeless tobacco mistakenly consider the products to be a safe or safer alternative to smoking tobacco products, particularly cigarettes. As will be described in the health effects section, there are no tobacco products without adverse health implications.

7.3.3 Electronic Cigarettes (e-Cigarettes)

Strictly speaking, electronic cigarettes (e-cigarettes) are not a tobacco product, although some public health specialists have advocated the classification. However, the product is closely associated with tobacco-based cigarettes and therefore

included in this chapter. The association is due to the fact that both e-cigarettes and tobacco cigarettes contain nicotine. Vapor from both products can be inhaled into a smoker's lungs, thereby delivering a dose of nicotine and other substances [20]. While tobacco cigarettes have been a commercial product in the U.S. since 1865, by comparison, e-cigarettes are rather recent on the nicotine scene. E-cigarettes are marketed as an alternative, safer product than tobacco cigarettes, and can therefore be an aid for smoking reduction or cessation. In agreement, one medical group has opined that use of e-cigarettes can be an aid to reduced or ceased tobacco smoking. The British Royal College of Physicians advised, "Among smokers, e-cigarette use is likely to lead to quit attempts that would not otherwise have happened, and in a proportion of these to successful cessation. In this way, e-cigarettes can act as a gateway from smoking" [21]. The efficacy of vaping as a method for smoking cessation is a subject of current public health research by the CDC and others.

E-cigarettes are one of a class of electronic nicotine delivery systems (ENDS), of which electronic cigarettes are the most common prototype. E-cigarettes are devices that do not burn or use tobacco leaves but instead vaporize a solution the user then inhales. E-cigarettes are designed to simulate the act of tobacco smoking by producing an appealingly flavored aerosol that looks and feels like tobacco smoke and deliver nicotine, but with less of the toxic chemicals produced by burning tobacco leaves [22]. E-cigarettes consist of three components: a cartridge that contains a liquid solution with various levels of nicotine, flavoring, and other chemicals; a heating element (vaporizer); and a power source (usually a battery). Shown in Figure 7.3 are examples of typical forms of e-cigarettes. The main constituents of the solution, in addition to nicotine when nicotine is present, are propylene glycol, with or without glycerol and flavoring agents. ENDS solutions and emissions contain other chemicals, some of which are considered to be toxicants [23].

To address the matter of prevalence, the FDA reports than 3 million middle and high school students were current users of e-cigarettes in 2015, up from an estimated 2.46 million in 2014. Sixteen percent of high school and 5.3% of middle school students were current users of e-cigarettes in 2015, making e-cigarettes the most commonly used tobacco product among youth for the second consecutive year. During 2011–2015, e-cigarette use rose from 1.5% to 16.0% among high school students and from 0.6% to 5.3% among middle school students. In 2013–2014, 81% of current youth e-cigarette users cited the availability of appealing flavors as the primary reason for use. In 2014, 12.6% of U.S. adults had tried an e-cigarette, and about 3.7% of adults used e-cigarettes daily or some days, a figure that represents about 9 million users [24].

7.4 GLOBAL PREVALENCE OF TOBACCO PRODUCTS AND USERS

As evident in the history of tobacco, use of tobacco products is global. Cigarette smoking is the most prevalent form of tobacco use, with other tobacco products rising and falling in use over the centuries. The following excerpt from WHO [3] provides data on the global prevalence of tobacco users: "In 2012, 21% of the global population aged 15 and older smoked tobacco. Men smoked at five times the rate of women; the average rates were 36% and 7%, respectively. Smoking among men was highest in WHO's Western Pacific Region, with 48% of men smoking some form of tobacco. Smoking among women was highest in WHO's European Region at 19%. The rates for which data were available on which adolescent girls aged 13–15 use tobacco average around 8% globally. Among WHO regions, the highest prevalence among girls are seen in WHO's Region of the Americas, where an average of almost 14% of young adolescent girls is already tobacco users. This reflects aggressive tobacco industry marketing to girls in countries with minimal laws against tobacco advertising,

FIGURE 7.3 Examples of e-cigarettes. (From FDA (Food and Drug Administration). 2016. Press release: FDA takes significant steps to protect Americans from dangers of tobacco through new regulation, May 5. Silver Spring: Office of Public Affairs.)

promotion, and sponsorship. Boys aged 13–15 in WHO South-East Asia Region and WHO Eastern Mediterranean Region use tobacco at higher rates than their counterparts in other regions, at over 20% in both regions."

FDA reports than 3 million middle and high school students were current users of e-cigarettes in 2015. Sixteen percent of high school and 5.3% of middle school students were current users of e-cigarettes in 2015.

Perspective: A consideration of the prevalence data on the use of tobacco products leads to substantial health and economic global concerns. Of the greatest gravity are data on use of tobacco products by young people. Children in middle school and in higher grades of school are often introduced to tobacco products via peer pressure. Education of youth on the morbidity and mortality consequences of tobacco products must be an integral part of youth education programs. Policies on controlling tobacco products will be introduced in subsequent sections, but, sadly, young smokers today will be many of tomorrow's adult victims of disease and premature death.

7.5 ASSOCIATIONS BETWEEN USE OF TOBACCO PRODUCTS AND HUMAN HEALTH

Each tobacco product must be considered a potential hazard to human health, including some persons who are not even using a product due to secondhand smoke or similar condition. This section will present effects using tobacco products on an individual's and public health.

7.5.1 Cigarettes

As noted in the history of tobacco, concerns about the health consequence of tobacco products began in several countries where tobacco had come into common use. Included in the medical history of tobacco were studies by medical doctors in China, England, Germany, and the U.S. While other public and individual health studies followed, it remained for two leaders in public health, one British, one American, to lead the elucidation of the association between cigarette smoking and adverse health effects in smokers. Both men were medical doctors and well versed in medical epidemiology. Both held distinguished academic appointments in schools of medicine. Interestingly, both doctors were cigarette smokers until they independently began researching the adverse effects of cigarette smoking on human health and the consequent public health impacts. One can assert with confidence that both men's work has resulted in millions of lives spared of premature death due to cigarette smoking. The following is a précis of each doctor's public health contributions toward cigarette smoking [25].

Sir Richard Doll—Richard Doll was the foremost medical epidemiologist of the twentieth century, credited with turning epidemiology into a rigorous science. He was a leader in conducting research that associated cigarette smoking with lung cancer and heart disease. Richard Doll also did pioneering work on the relationship between radiation and leukemia as well as that between asbestos and lung cancer and alcohol consumption and breast cancer. His findings were further noteworthy because they have led to measures to prevent disease in at-risk populations [26].

William Richard Shaboe Doll studied medicine at St Thomas's Hospital Medical School, King's College, London, from where he graduated in 1937. He joined the Royal College of Physicians after the outbreak of World War II and served for much of the war as a member of the Royal Army Medical Corps as a medical specialist on a hospital ship. After his war service, Doll returned to St Thomas' to research asthma.

In 1950, Richard Doll and Austin Bradford Hill undertook a study of lung cancer patients in 20 London hospitals. The study had been prompted by hospital records of a 30-year period that showed a rapid, but unexplained, increase in lung cancer in men. The three suspects were inhalation of vehicle exhaust fumes, smuts from coal fires, or tarring of roads. The study involved patients with confirmed lung cancer and those without such diagnosis. Doll and Bradford Hill carefully recorded the lifestyle and personal habits of each person in their study. The investigators soon discovered that cigarette smoking was the only factor that the lung cancer patients had in common. Published in the *British Medical Journal* in 1950, the article stated: "The risk of developing the disease increases in proportion to the amount smoked. It may be 50 times as great among those who smoke 25 or more cigarettes a day as among non-smokers."

Four years later, a longitudinal study of approximately 40,000 British medical doctors followed over 20 years confirmed the Doll and Bradford Hill's report, from which the British government issued advice that smoking and lung cancer rates were related. In 1969, Doll moved to Oxford University as the Regius Professor of Medicine. He continued work into carcinogens while at the Imperial Cancer Research Centre at the John Radcliffe Hospital, Oxford, working as part of the Clinical Trial Service Unit. This work notably included a study undertaken with Sir Richard Peto, in which it was estimated that tobacco, along with infections and diet, caused between them three-quarters of all cancers, which was the basis for much of WHO's conclusions on environmental pollution and cancer. Among numerous honors, Richard Doll was made a Fellow of the Royal Society in 1966 and knighted in 1971.

Surgeon General Luther Terry—As U.S. Surgeon General Luther L. Terry led the first public health campaign in the U.S. that warned of the dangers of cigarette smoking; his work persuaded millions to quit, thereby sparing them of the morbidity and premature mortality that comes with tobacco use. Luther Leonidas Terry received an M.D. degree at Tulane University in 1935. From 1940 to 1942 Dr. Terry served as instructor and assistant professor of preventive medicine and public health at the University of Texas at Galveston. In 1958, Terry became the Assistant Director of the National Heart Institute, Bethesda, Maryland. In 1961, President John F.

Kennedy appointed Dr. Terry as U.S. Surgeon General, serving in that position until 1965 [27].

As Surgeon General, Terry quit cigarette smoking in late 1963 and decided to make it his mission to urge millions of Americans who smoked cigarettes to do the same. Shortly after the release of a British report led by Richard Doll that was the first to warn the public of the health hazard of cigarette smoking, Terry established and chaired the Surgeon General's Advisory Committee on Smoking and Health tasked to produce a similar report for the U.S. On January 11, 1964 he delivered the first Surgeon General's Report on Smoking and Health, which reported that cigarette smoking was an unmitigated health hazard, causing lung cancer and chronic bronchitis. The report also noted that there was suggestive evidence, if not definite proof, for a causative role of smoking in other illnesses such as emphysema, cardiovascular disease, and various types of cancer. Based on more than 7000 peer-reviewed articles, Terry's report concluded that cigarette smoking was a sufficient enough health problem to warrant "appropriate remedial action."

The landmark Surgeon General's report of 1964 on smoking and health stimulated in the American public and government policymakers a greatly increased concern about tobacco and led to a broad-based anti-smoking campaign. It also motivated the tobacco industry to intensify its efforts to question the scientific evidence linking smoking and disease.

In June 1964 the U.S. Federal Trade Commission voted by a margin of 3–1 to require that cigarette manufacturers "clearly and prominently" place a warning on packages of cigarettes effective January 1, 1965, stating that smoking is dangerous to health, a warning in line with the warning issued by the Surgeon General's special committee. The same warning would be required in all cigarettes advertising effective July 1, 1965, as a consequence of the passage of the Cigarette Labeling and Advertising Act of 1965.

On January 11, 1964 the first Surgeon General's Report on Smoking and Health reported that cigarette smoking was an unmitigated health hazard, causing lung cancer and chronic bronchitis.

Surgeon General Terry changed this social value by clearly warning the public of the adverse health consequence of cigarette smoking. His association of smoking with the adverse outcomes of lung cancer and chronic bronchitis and other diseases changed how the American society viewed cigarette smoking. Terry set into motion anti-smoking campaigns that continue today. It is now rare to find public (and some private) buildings in the U.S. where smoking is permitted.

The work that Terry began in 1964 quite literally lives on. The work of Doll and Terry stimulated programs of research on the health effects of tobacco, programs of research performed by investigators in academic and government programs of research. These programs of research have identified serious adverse consequences of tobacco use. The health toll is especially acute in cigarette smokers, given that this tobacco product is the most prevalent tobacco product. A summary by the CDC of the human health effects of cigarette smoking is as follows [28]:

Cigarette Smoking and Death

- "Cigarette smoking is the leading preventable cause of death in the U.S.
- Cigarette smoking causes more than 480,000 deaths annually in the U.S. This is nearly one in five deaths. Smoking causes more deaths each year than the following causes combined: human immunodeficiency virus (HIV), illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents.
- More than 10 times as many U.S. citizens have died prematurely from cigarette smoking than have died in all the wars fought by the U.S. during its history.
- Smoking causes about 90% (or 9 out of 10) of all lung cancer deaths in men and women. More women die from lung cancer annually than from breast cancer.
- About 80% (or 8 out of 10) of all deaths from chronic obstructive pulmonary disease (COPD) are caused by smoking.
- Cigarette smoking increases risk for death from all causes in men and women. The risk of dying from cigarette smoking has increased over the last 50 years in men and women in the U.S.

Cigarette Smoking and Increased Health Risks

- Smokers are more likely than nonsmokers to develop heart disease, stroke, and lung cancer.
- Smoking is estimated to increase the risk: for coronary heart disease by 2–4 times, for stroke by 2–4 times.
- Of men developing lung cancer smoking is estimated to increase the risk by 25 times, of women developing lung cancer by 25.7 times.
- Smoking causes diminished overall health, increased absenteeism from work, and increased health care utilization and cost.

Cigarette Smoking and Cardiovascular Disease

- Smokers are at greater risk for diseases that affect the heart and blood vessels (cardiovascular disease).
- Smoking causes stroke and coronary heart disease, which are among the leading causes of death in the U.S.
- Even people who smoke fewer than five cigarettes a day can have early signs of cardiovascular disease.
- Smoking damages blood vessels and can make them thicken and grow narrower. This makes your heart beat faster and your blood pressure go up. Clots can also form.
- A stroke occurs when a clot blocks the blood flow to part of your brain or when a blood vessel in or around your brain bursts.

- Blockages caused by smoking can also reduce blood flow to your legs and skin.

Cigarette Smoking and Respiratory Disease

- Smoking can cause lung disease by damaging your airways and the small air sacs (alveoli) found in your lungs.
- Lung diseases caused by smoking include COPD, which includes emphysema and chronic bronchitis.
- Cigarette smoking causes most cases of lung cancer.
- If you have asthma, tobacco smoke can trigger an attack or make an attack worse.
- Smokers are 12–13 times more likely to die from COPD than nonsmokers.

Cigarette Smoking and Cancer

- Smoking can cause cancer almost anywhere in one's body: bladder, blood (acute, myeloid leukemia), cervix, colon and rectum (colorectal), esophagus, kidney and ureter, larynx, liver, oropharynx, pancreas, stomach, trachea, bronchus, and lung.
- Smoking also increases the risk of dying from cancer and other diseases in cancer patients and survivors.
- If nobody smoked, one of every three cancer deaths in the U.S. would not occur.

Cigarette Smoking and Other Health Risks

- Smoking harms nearly every organ of the body and affects a person's overall health.
- Smoking can make it harder for a woman to become pregnant and can affect her baby's health before and after birth.
- Smoking increases risks for: preterm (early) delivery, stillbirth (death of the baby before birth), low birth weight, sudden infant death syndrome (SIDS), ectopic pregnancy, orofacial clefts in infants, and possibly, schizophrenia in children of mothers who smoked heavily during pregnancy [29].
- Smoking can also affect men's sperm, which can reduce fertility and also increase risks for birth defects and miscarriage.
- Smoking can affect bone health. Women past childbearing years who smoke have weaker bones than women who never smoked, and are at greater risk for broken bones.
- Smoking affects the health of your teeth and gums and can cause tooth loss.
- Smoking can increase your risk for cataracts (clouding of the eye's lens that makes it hard for you to see) and age-related macular degeneration (damage to a small spot near the center of the retina, the part of the eye needed for central vision).
- Smoking is a cause of type 2 diabetes mellitus and can make it harder to control. The risk of developing diabetes is 30–40% higher for active smokers than nonsmokers.
- Smoking causes general adverse effects on the body, including inflammation and decreased immune function.
- Smoking is a cause of rheumatoid arthritis" [28].

The foregoing demonstrates the sweeping, adverse effects of cigarette smoking on the human body. Of special note is the Surgeon General's estimate that 480,000 Americans die annually from cigarette smoking, while another 31,000 are estimated to die annually from exposure to secondhand smoke [30]. For comparison, the population of Atlanta, Georgia, is 447,841, a 2014 figure from the U.S. Census Bureau. Similarly, Miami's population in 2013 was estimated to be 417,650. Smoking deaths annually in the U.S. reflect the annual loss of either of these two major cities.

7.5.1.1 Secondhand Tobacco Smoke

A particularly insidious public health hazard is called secondhand tobacco smoke. This form of environmental hazard is insidious because it affects persons who are not directly smoking tobacco. Secondhand smoke is a mixture of the smoke given off by the burning of tobacco products, such as cigarettes, cigars or pipes, and the smoke exhaled by smokers. Secondhand smoke is also called environmental tobacco smoke (ETS) and exposure to secondhand smoke is sometimes called involuntary or passive smoking. Secondhand smoke contains more than 7000 substances, several of which are known to cause cancer in humans or animals. The EPA has concluded that exposure to secondhand smoke can cause lung cancer in adults who do not smoke. The EPA estimates that exposure to secondhand smoke causes approximately 3000 lung cancer deaths per year in nonsmokers.

The 1992 EPA Risk Assessment, "Respiratory Health Effects of Passive Smoking" concluded that ETS is causally associated with lung cancer in adults and designated ETS as a Group A (known human) carcinogen. Exposure to secondhand smoke has also been shown in a number of studies to increase the risk of heart disease and stroke [31].

The CDC has provided public health data on the consequences of exposure to secondhand tobacco smoke. They note the following:

- During 2011–2012, about 58 million nonsmokers in the U.S. were exposed to secondhand smoke.
- During 2011–2012, 2 out of every 5 children ages 3 to 11—including 7 out of every 10 Black children—in the U.S. were exposed to secondhand smoke regularly.
- In children, secondhand smoke causes the following: ear infections, more frequent and severe asthma attacks, respiratory symptoms (for example, coughing, sneezing, and shortness of breath), respiratory infections (bronchitis and pneumonia), a greater risk for SIDS.

- Among adult nonsmokers in the U.S., it is estimated that secondhand smoke caused nearly 34,000 heart disease deaths each year during 2005–2009. Secondhand smoke exposure caused more than 7300 lung cancer deaths each year during 2005–2009 among adult nonsmokers in the U.S. [32].

7.5.1.2 Thirdhand Tobacco Smoke

In addition to the health hazard of secondhand smoke, a relatively new concept in environmental health is called thirdhand smoke. According to the Mayo Clinic, "Thirdhand smoke is generally considered to be residual nicotine and other chemicals left on a variety of indoor surfaces by tobacco smoke. This residue is thought to react with common indoor pollutants to create a toxic mix. This toxic mix of thirdhand smoke contains cancer-causing substances, posing a potential health hazard to nonsmokers who are exposed to it, especially children. Studies show that thirdhand smoke clings to hair, skin, clothes, furniture, drapes, walls, bedding, carpets, dust, vehicles and other surfaces, even long after smoking has stopped. Infants, children and nonsmoking adults may be at risk of tobacco-related health problems when they inhale, ingest or touch substances containing thirdhand smoke" [33].

Thirdhand smoke residue can accrue on surfaces and its complex mixture resists normal cleaning. Thirdhand smoke can't be eliminated by airing out rooms, opening windows, using fans or air conditioners, or confining smoking to only certain areas of a home. Although thirdhand smoke is a relatively new public health concept, and researchers are still studying its possible dangers, knowledge of the health hazards presented by tobacco smoke suggests a precautionary approach to thirdhand smoke is warranted. Smoke-free environments are a safe method for protection against thirdhand tobacco smoke.

7.5.2 Other Tobacco Products

7.5.2.1 Cigars

A description of the health risks and effects of smoking cigars must begin with the knowledge that cigars contain the same toxic and carcinogenic compounds found in cigarettes and are not a safe alternative to cigarettes. An early examination of the health effects of smoking cigars was performed by a panel of experts convened by the American Cancer Society [33a]. The "following conclusions were reached by consensus: (1) rates of cigar smoking are rising among both adults and adolescents; (2) smoking cigars instead of cigarettes does not reduce the risk of nicotine addiction; (3) as the number of cigars smoked and the amount of smoke inhaled increases, the risk of death related to cigar smoking approaches that of cigarette smoking; (4) cigar smoke contains higher concentrations of toxic and carcinogenic compounds than cigarettes and is a major source of fine particle and carbon monoxide indoor air pollution; and (5) cigar smoking is known to cause cancers of the lung and upper aerodigestive tract."

A more recent pronouncement from the CDC concludes that the health risks of regular cigar smoking include the following consequences [8]:

- Regular cigar smoking is associated with an increased risk for cancers of the lung, esophagus, larynx (voice box), and oral cavity (lip, tongue, mouth, and throat).
- Cigar smoking is linked to gum disease and tooth loss.
- Heavy cigar smokers and those who inhale deeply may be at increased risk for developing coronary heart disease.
- Heavy cigar smoking increases the risk for lung diseases, such as emphysema and chronic bronchitis.

7.5.2.2 Pipes

Although conventional (i.e., excluding water pipes) pipe smoking is much less prevalent than that for cigarettes and cigars, conventional pipe smoking brings serious health consequences to smokers and those exposed to secondhand pipe smoke. This assertion goes counter to belief by some pipe smokers that this form of tobacco smoking is less hazardous to health than that posed by cigarettes. Research on the health hazards of pipe smoking has been summarized by several sources. The seminal study of the association between pipe smoking and adverse health effects was conducted by American Cancer Society investigators [11]. They examined the association between pipe smoking and mortality from tobacco-related cancers and other diseases in a cohort of U.S. men enrolled in the Cancer Prevention Study II, an American Cancer Society prospective study. The cohort of 138,307 men included those who reported, in their 1982 enrollment questionnaire, exclusive current or former use of pipes ($n = 15{,}263$ men) or never use of any tobacco product ($n = 123{,}044$ men). Analyses were based on 23,589 men who died during 18 years of follow-up. Current pipe smoking, compared with never use of tobacco, was associated with an increased risk of death from cancers of the lung, oropharynx, esophagus, colorectum, pancreas, and larynx, and from coronary heart disease, cerebrovascular disease, and COPD. These risks were generally smaller than those associated with cigarette smoking and similar to or larger than those associated with cigar smoking. Relative risks of lung cancer showed statistically significant increases with the number of pipes smoked per day, years of smoking, and depth of inhalation, and decreases with years since quitting.

Water pipes, while methodologically different from traditional tobacco pipes, present their own set of health concerns for smokers. In particular, while many hookah smokers may consider this practice less harmful than smoking cigarettes, hookah smoking carries many of the same health risks as cigarettes. The CDC has determined the cancer risks of hookah smoking as follows [12]:

- The charcoal used to heat tobacco in the hookah increases the health risks by producing smoke that contains high levels of carbon monoxide, metals, and cancer-causing chemicals.
- A typical 1-hour-long hookah smoking session involves 200 puffs, while an average cigarette is 20 puffs.
- The volume of smoke inhaled during a typical hookah session is about 90,000 mL, compared with 500–600 mL inhaled when smoking a cigarette.
- Using a hookah to smoke tobacco poses a serious potential health hazard to smokers and others exposed to the emitted smoke.

Current pipe smoking, compared with never use of tobacco, was associated with an increased risk of death from cancers of the lung, oropharynx, esophagus, colorectum, pancreas, and larynx, and from coronary heart disease, cerebrovascular disease, and COPD.

A review of the health consequences of pipe smoking, be it traditional pipes or water pipes, reveals that this form of tobacco smoking is akin to other methods of smoking tobacco, that is, adverse health consequences accompany their use.

7.5.2.3 Smokeless Tobacco Products

Smokeless tobacco is one of the most addictive and potent ways of consuming tobacco [19]. Half a can (17 g) of U.S.-style moist snuff contains 236 mg of nicotine; more than twice the daily nicotine consumption of the next potent tobacco product, Snus. In fact, holding an average size dip in the mouth for just 30 min can deliver as much nicotine as smoking three cigarettes. The CDC has summarized the adverse health of smokeless tobacco as follows [19]: "*Smokeless tobacco*_is associated with many health problems. Using smokeless tobacco

- Can lead to nicotine addiction.
- Causes cancer of the mouth, esophagus, and pancreas.
- Is associated with diseases of the mouth.
- Can increase risks for early delivery and stillbirth when used during pregnancy.
- Can cause nicotine poisoning in children.
- May increase the risk for death from heart disease and stroke.

These CDC findings indicate that regular use of smokeless tobacco can result in serious adverse health effects. Specifically, as noted above, there is an association between smokeless tobacco use and cancers of the mouth, esophagus, and pancreas and diseases of the mouth in general. Regrettably, such knowledge about these health effects has been ignored by some users of smokeless tobacco products. As an example, use of smokeless tobacco has been a favorite habit of many professional baseball players. This practice was implemented using chewing tobacco, which was gradually replaced over time with snuff. Both products provided the player with a dose of nicotine, which was a stimulus when performing the various actions required of baseball play. In the late twentieth century, use of smokeless tobacco was discontinued in the minor league baseball system in the U.S. This policy was implemented by owners of the baseball teams, with consent of players' representatives. However, the major league baseball system has eschewed any policy on controlling smokeless tobacco use by major league players, an outcome favored by players' representatives and their labor union. This was an arrangement that left the decision on smokeless tobacco use as a matter of individual preference by players. However, this laisse fare policy has begun to change due to some cities' banning tobacco in municipal parks and arenas. Examples are the cities of San Francisco, Los Angeles, and Boston [34]. Should this trend continue, municipal ordinances ultimately may be the remedy for preventing baseball players' health problems due to use of smokeless tobacco.

Regular use of smokeless tobacco, as with other uses of tobacco, can result in serious adverse health effects. Specifically, there is an association between smokeless tobacco use and cancers of the mouth, esophagus, and pancreas and diseases of the mouth in general [19].

7.5.3 Electronic Cigarettes

As a relatively new product, consensus information regarding e-cigarettes is currently lacking on any potential adverse health effects on individuals and the public health. Research is ongoing in several countries to address the health issues, an important subject given the rapid grown in vaping populations and global distribution of e-cigarettes. However, given the fact that the key constituent of e-cigarette vapor is nicotine—indeed, nicotine delivery is the primary feature of e-cigarettes—the CDC has published some cautionary advice about nicotine in general. As enunciated by that agency, "Nicotine from e-cigarettes is absorbed by users and bystanders. Nicotine is highly addictive; Nicotine is especially a health danger to youth who use e-cigarettes. It may have long-term, negative effects on brain growth; Nicotine is a health danger for pregnant women and their developing babies. Using an e-cigarette and even being around someone else using an e-cigarette can expose pregnant women to nicotine and other chemicals that may be toxic" [35].

7.6 ASSOCIATIONS BETWEEN USE OF TOBACCO PRODUCTS AND ECOSYSTEM HEALTH

The use of tobacco products has an impact on the health of ecosystems, albeit not as direct or evident as the effects on human health. Recall that healthy ecosystems contribute to clean air and water, fertile soil for crop production, pollination,

and flood control, among many other benefits [36]. Bearing this in mind, the impacts of tobacco products on ecosystems are several. Waste from tobacco products is a particular threat to ecosystems as pollutants in bodies of water. Fish and other marine life are exposed to the nicotine and other hazardous substances in tobacco products. Cigarette butts are a special form of water pollutant, given that butts contain the residual of tobacco smoke drawn through the cigarette by the smoker. This results in the tars and other toxicants reaching water sources, exposing aquatic life to chemically-contaminated water. Another impact of tobacco products is the cultivation of tobacco for commercial purposes. Because tobacco is not a food product, its cultivation removes the arable soil from food production. In a world of increasing human population, food security is already an issue of paramount importance due climate change (Chapter 6).

One measured impact of tobacco waste impacting ecosystems is provided by volunteers who remove trash from coastal areas globally. In 2014 the total number of trash items picked up during the 29th year of Ocean Conservancy's International Coastal Cleanup, amounted to 15 million items, which weighed more than 16 million pounds. Cigarette butts were the most common item found, with more than 2 million collected. Ocean trash threatens ocean animals, fisheries, and tourism globally [37]. Another source observes that approximately 4.5 ton of the 6 ton cigarettes consumed- annually are littered across the globe [38].

7.7 U.S. FEDERAL POLICIES ON TOBACCO USE AND CONTROL

There are several U.S. federal laws that pertain to the sales, marketing, and use of tobacco products. The primary laws are directed at cigarette smoking. As will be discussed, fewer legislative actions exist for control of other tobacco products, owing to their lesser prevalence of use in the U.S. A comprehensive description of the federal tobacco laws is beyond the purposes of this book and is available elsewhere [39]. Following is a distillation of the most significant federal actions targeted at public health implications of tobacco use [39].

Federal Trade Commission Act of 1914 (amended in 1938)

- Empowers the Federal Trade Commission (FTC) to "prevent persons, partnerships, or corporations, from using unfair or deceptive acts or practices in commerce."
- On January 3, 1964, the FTC proposed a rule to strictly regulate the imagery and copy of cigarette ads to prohibit explicit or implicit health claims.
- 1985—FTC acts to remove the RJ Reynolds advertisements, "Of Cigarettes and Science," in which the multiple risk factor intervention trail results were misinterpreted.

Federal Hazardous Substances Labeling Act of 1960

- 1960—Authorized the FDA to regulate substances that are hazardous (either toxic, corrosive, irritant, strong sensitizers, flammable, or pressure-generating). Such substances may cause substantial personal injury or illness during or as a result of customary use.
- 1963—the FDA expressed its interpretation that tobacco did not fit the "hazardous" criteria stated previously and withheld recommendations pending the release of the report of the Surgeon General's Advisory Committee on Smoking and Health.

Federal Cigarette Labeling and Advertising Act of 1965

- Required package warning label—"Caution: Cigarette Smoking May Be Hazardous to Your Health" (other health warnings prohibited).
- Required no labels on cigarette advertisements (in fact, implemented a 3-year prohibition of any such labels).
- Required the FTC to report to Congress annually on the effectiveness of cigarette labeling, current cigarette advertising, and promotion practices and to make recommendations for legislation.
- Required Department of Health, Education, and Welfare to report annually to Congress on the health consequences of smoking.

Public Health Cigarette Smoking Act of 1969

- Required package warning label—"Warning: The Surgeon General Has Determined that Cigarette Smoking Is Dangerous to Your Health" (other health warnings prohibited).
- Temporarily preempted FTC requirement of health labels on advertisements.
- Prohibited cigarette advertising on television and radio (authority to Department of Justice [DOJ]).
- Prevents states or localities from regulating or prohibiting cigarette advertising or promotion for health-related reasons.

Consumer Product Safety Act of 1972

- Transferred authority from the FDA to regulate hazardous substances as designated by the Federal Hazardous Substances Labeling Act (FHSAct) to the Consumer Product Safety Commission (CPSC).
- The term "consumer product" does not include tobacco and tobacco products.

Little Cigar Act of 1973

- Bans little cigar advertisements from television and radio (authority to DOJ).

1976 Amendment to the FHSAct of 1960

- The term "hazardous substance" shall not apply to tobacco and tobacco products.

Toxic Substances Control Act of 1976

- To "regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment."
- The term "chemical substance" does not include tobacco or any tobacco products.

Comprehensive Smoking Education Act of 1984

- Requires four rotating health warning labels (all listed as Surgeon General's Warnings) on cigarette packages and advertisements (smoking causes lung cancer, heart disease and may complicate pregnancy; quitting smoking now greatly reduces serious risks to your health; smoking by pregnant women may result in fetal injury, premature birth, and low birth weight; cigarette smoke contains carbon monoxide) (preempted other package warnings).
- Requires Department of Health and Human Services (DHHS) to publish a biennial status report to Congress on smoking and health.
- Creates a Federal Interagency Committee on Smoking and Health.
- Requires the cigarette industry to provide a confidential list of ingredients added to cigarettes manufactured in or imported into the U.S. (brand-specific ingredients and quantities not required).

Comprehensive Smokeless Tobacco Health Education Act of 1986

- Institutes three rotating health warning labels on smokeless tobacco packages and advertisements (this product may cause mouth cancer; this product may cause gum disease and tooth loss; this product is not a safe alternative to cigarettes) (preempts other health warnings on packages or advertisements [except billboards]).
- Prohibits smokeless tobacco advertising on television and radio.
- Requires DHHS to publish a biennial status report to Congress on smokeless tobacco.
- Requires FTC to report to Congress on smokeless tobacco sales, advertising, and marketing.
- Requires smokeless tobacco companies to provide a confidential list of additives and a specification of nicotine content in smokeless tobacco products.
- Requires DHHS to conduct public information campaign on the health hazards of smokeless tobacco.

Appropriations Act: Public Law 100–202 (1987)

- Banned smoking on domestic airline flights scheduled for 2 hours or less.

Public Law 101–164 (1989)

- Bans smoking on domestic airline flights scheduled for 6 hours or less.

Synar Amendment to the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992

- Requires all states to adopt and enforce restrictions on tobacco sales and distribution to minors.

Pro-Children Act of 1994

- Requires all federally funded children's services to become smoke-free. Expands upon 1993 law that banned smoking in Women, Infants, and Children clinics.

Family Smoking Prevention and Tobacco Control Act of 2009

- Grants FDA the authority to regulate tobacco products.

Perspective: A review of this set of legislative actions by the U.S. Congress indicates a political struggle of more than seven decades, commencing in 1938. One can observe the legislative hopscotch of moving about the legislative board the tobacco control responsibilities of various U.S. executive branch agencies. These agencies include the FTC, FDA, DHHS, and CPSC. A further review reveals that most of the aggregate legislation dealt with issues of advertising, labeling, and distribution of tobacco products. Noteworthy is the absence of any federal language that would have denied states their authority to construct tobacco control policies.

* * *

The most recent U.S. tobacco law, the Family Smoking Prevention and Tobacco Control Act of 2009, merits additional description. The law, commonly called the Tobacco Control Act, was enacted by Congress in response to a prior decision from the U.S. Supreme Court. This decision is considered the most significant legal finding in U.S. tobacco litigation. The genesis of the litigation can be put simply, "FDA attempted to regulate tobacco products under its existing authorities to regulate food, drugs, and devices." This attempt prompted the lawsuit, which is described herein [40].

In March 2000, in a 5-4 opinion delivered by Justice Sandra Day O'Connor, the Supreme Court held that

"Congress has not given the FDA the authority to regulate tobacco products as customarily marketed." The ruling was based on the Food, Drug, and Cosmetic Act (FDCAct) as a whole and in conjunction with Congress' subsequent tobacco-specific legislation. "By no means do we question the seriousness of the problem that the FDA has sought to address," Justice O'Connor wrote for the majority. Nonetheless, Justice O'Connor wrote, "Congress, for better or for worse, has created a distinct regulatory scheme for tobacco products, squarely rejected proposals to give the FDA jurisdiction over tobacco, and repeatedly acted to preclude any agency from exercising significant policymaking authority in the area" [40]. Those words from the Court set the agenda for Congress to act, and the bipartisan result was the Tobacco Control Act.

The preface to the act states, "To protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, U.S. Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes" [40]. Of particular note is the Act's definition of "tobacco product," a definition intended to respond to the Supreme Court's decision about FDA's lack of language to control tobacco products. As summarized by the FDA [40], the key provisions of the Tobacco Control Act are as follows:

"Title I—Authority Of The Food And Drug Administration

[*101] SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) Definition of Tobacco Products—§ 201 of the Federal FDCAct (21 U.S.C. 321) is amended by adding at the end the following:

"(rr) (1) The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

(y)(2) The term 'tobacco product' does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in § 503(g)."

The Tobacco Control Act:

- Restricts tobacco marketing and sales to youth,
- Requires smokeless tobacco product warning labels,
- Ensures "modified risk" claims are supported by scientific evidence,
- Requires disclosure of ingredients in tobacco products,
- Preserves state, local, and tribal authority [41].

RESTRICTS TOBACCO MARKETING AND SALES TO YOUTH

The Tobacco Control Act puts in place specific restrictions on marketing tobacco products to children and gives the FDA authority to take further action in the future to protect public health. These provisions ban:

- Sales to minors
- Vending machine sales, except in adult-only facilities
- The sale of packages of fewer than 20 cigarettes
- Tobacco-brand sponsorships of sports and entertainment events or other social or cultural events
- Free giveaways of sample cigarettes and brand-name nontobacco promotional items

REQUIRES SMOKELESS TOBACCO PRODUCT WARNING LABELS

The Tobacco Control Act requires that smokeless tobacco packages and advertisements have larger and more visible warnings. Smokeless tobacco includes tobacco products such as moist snuff, chewing tobacco, and snus. Every smokeless tobacco package and advertisement will include one of the following warning label statements:

- *WARNING*: This product can cause mouth cancer.
- *WARNING*: This product can cause gum disease and tooth loss.
- *WARNING*: This product is not a safe alternative to cigarettes.
- *WARNING*: Smokeless tobacco is addictive.

For smokeless tobacco packaging, the warning label statement must be located on the two principal sides of the package and cover at least 30% of each side. For advertisements, the warning label statements must cover at least 20% of the area of the ad. These changes aim to increase awareness of the health risks associated with smokeless tobacco use and improve the public health.

Ensures "Modified Risk" Claims are Supported by Scientific Evidence: The landmark law prohibits tobacco companies from making reduced harm claims like "light," "low," or "mild," without filing an application for a modified risk tobacco product and obtaining an order to market as such.

Requires Disclosure of Ingredients in Tobacco Products: Tobacco companies must provide FDA with detailed information about the ingredients in their products.

Preserves State, Local, and Tribal Authority: The Tobacco Control Act preserves the authority of state, local, and tribal governments to regulate tobacco products in specific respects.

ADDITIONAL AUTHORITIES

The Tobacco Control Act further gives FDA authorities to

- Require tobacco company owners and operators to register annually and open their manufacturing and processing facilities to be subject to inspection by FDA every 2 years.

- To implement standards for tobacco products to protect public health. For example, the FDA has the authority to regulate nicotine and ingredient levels.
- Ban cigarettes with characterizing flavors, except menthol and tobacco.
- Fund FDA regulation of tobacco products through a user fee on the manufacturers of certain tobacco products sold in the U.S., based on their U.S. market share.

On May 5, 2016 the FDA released its final rule (21 CFR Parts 1100, 1140, and 1143) on regulation of tobacco products under the agency's authorities in the Tobacco Control Act. In announcing its release, FDA stated, "The actions being taken today will help the FDA prevent misleading claims by tobacco product manufacturers, evaluate the ingredients of tobacco products and how they are made, as well as communicate their potential risks" [41]. The FDA's rule also requires manufacturers of all newly regulated products to show that the products meet the applicable public health standard set forth in the law and receive marketing authorization from the FDA, unless the product was on the market as of February 15, 2007. The tobacco product review process for the first time gives the FDA the ability to evaluate important factors such as ingredients, product design, and health risks, as well as their appeal to youth and nonusers. The FDA rule provides tobacco product manufacturers a staggered timetable for compliance with the new rule. Under the new rule, manufacturers can continue selling their products for up to 2 years while they submit—and an additional year while the FDA reviews—a new tobacco product application. The FDA will issue an order granting marketing authorization where appropriate; otherwise, the product will face FDA enforcement. The FDA's actions will subject all manufacturers, importers and/or retailers of newly regulated tobacco products to any applicable provisions, bringing them in line with other tobacco products the FDA has regulated under the TCA since 2009.

The rule's requirements include

- Registering manufacturing establishments and providing product listings to the FDA
- Reporting ingredients, and harmful and potentially harmful constituents
- Requiring premarket review and authorization of new tobacco products by the FDA
- Placing health warnings on product packages and advertisements
- Not selling modified risk tobacco products (including those described as "light," "low," or "mild") unless authorized by the FDA.

The same final rule extends its regulatory authority to cover all tobacco products, including vaporizers, vape pens, hookah pens, electronic cigarettes (e-cigarettes), e-pipes, and all other ENDS. The FDA now regulates the manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of ENDS. This includes components and parts of ENDS but excludes accessories. However, products marketed for therapeutic purposes (for example, marketed as a product to help people quit smoking) are regulated by the FDA through the Center for Drug Evaluation and Research.

These regulations went into effect on August 8, 2016. The FDA will have to approve all e-cigarette products that have been available since February 2007. That means nearly every e-cigarette product on the market must go through an application process to deem whether it can continue to be sold. Manufacturers will be able to keep selling their products for up to 2 years while they submit a new production application, plus an additional year while the FDA reviews it.

Under the new regulations, vape shops cannot give free samples to customers or sell to people younger than 18. Merchants will be required to ask for identification from customers who appear to be under the age of 27. And vending machine sales of e-cigarettes are prohibited unless the machines are in adult-only facilities. Also covered are premium, hand-rolled cigars, as well as hookah and pipe tobacco. Before the new regulations, there was no federal law prohibiting retailers from selling e-cigarettes, hookah tobacco, or cigars to minors, though almost all states had already prohibited such sales.

* * *

In a policy context, the placement of labels on tobacco product has engendered considerable challenges to government authorities, with concomitant litigation in the U.S. Labels on tobacco products have been considered for policy purposes as two kinds: health warnings and product advertisements. Health warning labels on cigarette containers have been required for many years in the U.S., with the 2009 Tobacco Control Act mandating that FDA strengthen such warning labels, including graphic images. FDA's attempts to require graphic images on cigarette packages was met with litigation filed by the tobacco industry, leading to a federal court decision that blocked large graphic health warnings on cigarette packages. A judge ruled that the requirement violated First Amendment free speech protections. An appeals court upheld that ruling, which was not further appealed by the U.S. government, leaving the FDA to develop graphic labels that would muster court review [42]. In contrast to the U.S., some other countries have mandated and implement graphic labels on cigarette packages. For example, shown in Figure 7.4 is a cigarette package from Canada, associating oral disease with cigarette smoking. Whether such graphic labels will appear in the U.S. remains to be determined.

Regarding advertising labels, some governments consider product names placed on cigarette packages to be a form of product advertisement [43]. These governments consider product names to be a kind of inducement to purchase the

FIGURE 7.4 Health-warning cigarette package from Canada. (With permission of copyright holder, Prof. David Hammond, University of Waterloo, Waterloo, ON.)

FIGURE 7.5 Australian cigarette packages with no advertising (right side). (With permission of copyright holder, Prof. David Hammond, University of Waterloo, Waterloo, ON.)

product, and to reduce the appeal of cigarette smoking, no product labels are permitted. Shown in Figure 7.5 is a comparison of cigarette packages bearing product names, with the same product sold in Australia, where product names and advertising are replaced by grim health warnings.

Perspective: Consideration of these federal laws provides an interesting perspective on policymaking directed toward a known health hazard, tobacco products. Of note, the legislative struggle over tobacco has endured for more than seven decades at the federal level, i.e., the U.S. Congress. In fact, tobacco legislation by Congress has been difficult to achieve. This legislative inaction results from the strength of tobacco industry lobbying, as well as other factors such as strong presence of members of Congress from tobacco-growing states in the southern U.S. It

is noteworthy that tobacco has been expressly exempted from some federal laws pertaining to hazardous substance control. In lieu of banning tobacco products, federal laws have aimed at tobacco use reduction via education of the users.

A legislative philosophy of "education, not regulation" has held sway. As a result, federal laws on tobacco have focused on controls on marketing, advertising, and distributing various tobacco products. For example, cigarette packages must by law contain health warning labels, with authority given to the FDA for implementation of content of such. Moreover, one observes that, even with the enactment of laws for control of hazardous substances, no federal law that outright bans tobacco products has been enacted by Congress. The most sweeping of U.S. tobacco control laws is the Tobacco Control Act of 2009. This act gave the FDA several new authorities to regulate tobacco products, including restricting tobacco marketing and sales to youth; requiring smokeless tobacco product warning labels; ensuring "modified risk" claims are supported by scientific evidence; requiring disclosure of ingredients in tobacco products; and preserving state, local, and tribal authority over tobacco control and restrictions. Worthy of note is the act's language that preserves state, local, and tribal authorities. Sometimes an organization will attempt to add language that prevents states, local authorities, and indigenous tribes from enacting unwelcome policies. Federal law would override other levels of government, thereby giving lobbying groups only one target, Congress, rather than multiple targets.

* * *

In addition to the federal tobacco laws previously enumerated, federal regulations on the safe use of e-cigarettes have been promulgated. In particular, the U.S. Department of Transportation (DOT) has proceeded to issue two regulations on e-cigarettes. The first regulation bans the placement of e-cigarettes in passenger non-carry-on luggage. As stated in the DOT announcement, "In its continuing effort to improve transportation safety, the U.S. Department of Transportation Pipeline and Hazardous Materials Safety Administration today issued an interim final rule to prohibit passengers and crewmembers from carrying battery-powered portable electronic smoking devices (e.g., e-cigarettes, e-cigs, e-cigars, e-pipes, personal vaporizers, ENDS) in checked baggage and prohibit passengers and crewmembers from charging the devices and/or batteries on board the aircraft" [44].

This rule was based on data that reported some kinds of batteries used in e-cigs had exploded, causing fire in surrounding materials, such as the clothing of e-cig smokers.

The second DOT regulation bans vaping on commercial aircraft, which encompasses all domestic U.S. carriers, U.S. charter aircraft, and foreign air carriers that provide service to the U.S. As to the intent and purpose of the health-based regulation the DOT stated, "Electronic cigarettes cause concern because studies have shown that e-cigarette aerosol can contain a number of harmful chemicals. While further study is needed to fully understand the risks, the Department believes that a precautionary approach is best. The Department is particularly concerned that vulnerable populations (such as children, the elderly, and passengers with respiratory issues) would be exposed to the aerosol within a confined space, without the opportunity to avoid the chemicals. This rule explicitly bans the use of electronic cigarettes in all forms, including but not limited to electronic cigars, pipes, and devices designed to look like everyday products such as pens. The ban does not include the use of medical devices such as nebulizers" [45].

Perspective: These two DOT policies, released as federal regulations, illustrate two interesting implications. First, the DOT has utilized the precautionary principle (Chapter 2) on which to base its ban of vaping on commercial aircraft. Recall that the Precautionary Principle recommends public health action to mitigate a hazard when data are sufficient, but not necessarily complete, The DOT has acted in a precautionary sense based on the knowledge that vaping produces an aerosol smoke that contains nicotine and possibly other hazardous substances. In a closed environment such as an aircraft cabin, passengers should not be exposed to secondhand smoke that perhaps contains noxious constituents. The second policy-reliant observation is the decision by the DOT to group e-cigarettes in the same category of tobacco cigarettes. Regulating e-cigs in the same manner as tobacco cigarettes is a parity policy statement. As other policies emerge in regard to vaping, the DOT judgment on parity may be replicated in other policies that relate to control of e-cig smoking.

7.8 STATE AND LOCAL TOBACCO POLICIES

The seminal work of Doll and Terry in the 1960s brought forth the association between cigarette smoking and adverse health effects. This led to education campaigns in the U.S. and Britain concerning the health hazard of smoking. But laws, regulations, and ordinances specific to limiting smoking did not follow; smoking was considered a personal choice and as such did not require legislation to limit a "personal" choice. In the 1980s a new body of smoking research began to associate "secondhand smoke" with adverse health effects. This new information gave anti-smoking campaigners the ammunition needed to prod policymakers into action. Secondhand smoke meant there were innocent victims of other persons' harmful behavior. This brought into policymaking play the notion of "victims' rights" and therefore required protective legislative action. In response, states and local governments began to promulgate laws and ordinances that limited tobacco smoking. By 2014 in the U.S., 77.4% of the population was covered by 100% smoke-free restaurant laws and 65.2% of the population was covered by 100% smoke-free bar laws [46].

In the U.S., states, territories, tribes, and local governments assume the primary responsibility for policies on tobacco use, given that federal legislative polices (i.e., federal laws and federal agency regulations) relate only to marketing and advertising of tobacco products. Moreover, the U.S. Constitution delegates to states all authorities not specifically stated as

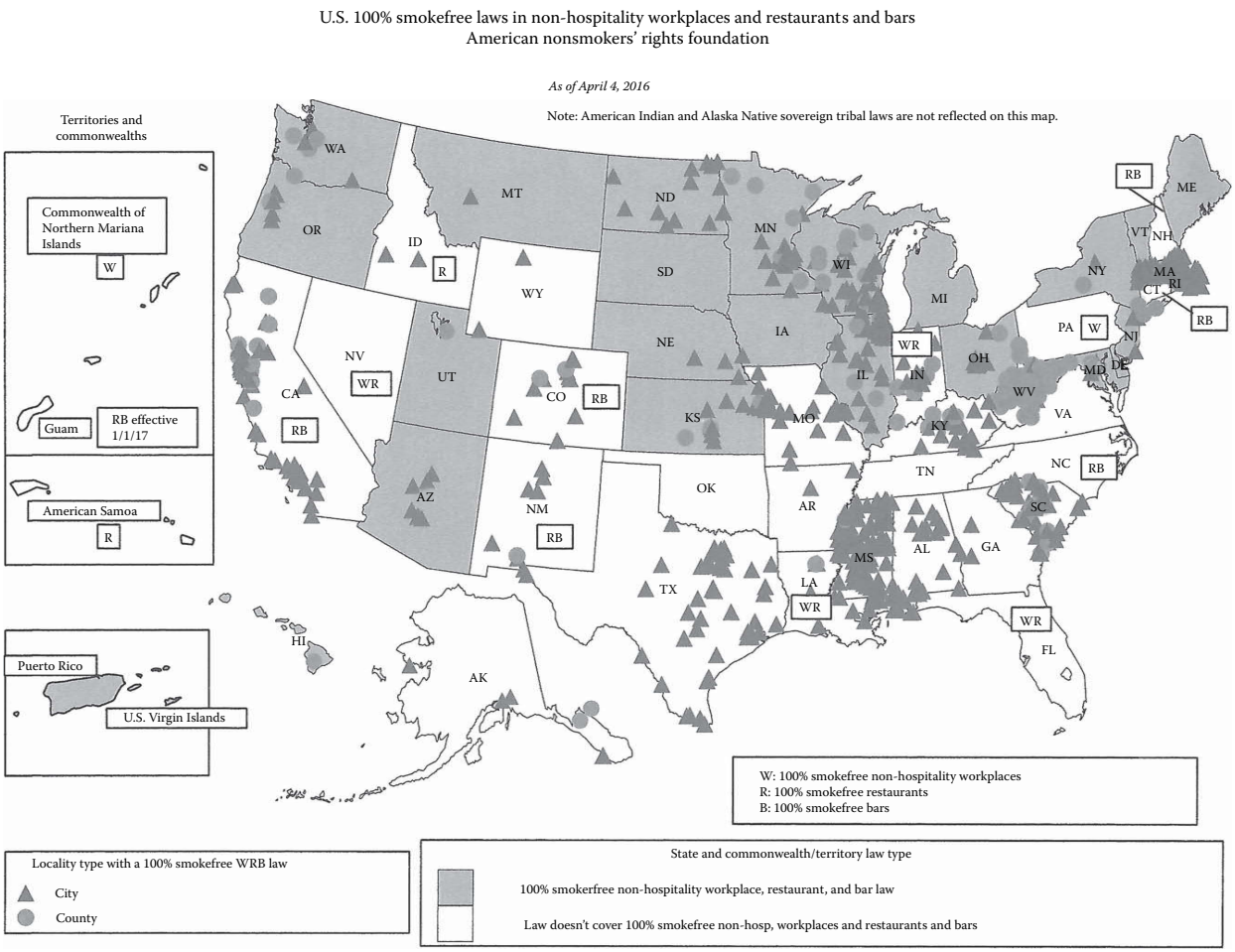

FIGURE 7.6 U.S. states with tobacco smoking policies. (With copyright permission of the American Nonsmokers' Rights Foundation, Berkeley, CA.)

the responsibility of federal government. As a consequence, all 50 states and territories have enacted laws that specify how tobacco products can be used within a state's borders. Although there is considerable variability in tobacco laws across the states, the general intent is to specify under what conditions smoking tobacco can be permitted. As illustrated in Figure 7.6, of the 50 states and territories/commonwealths, 24 states and two territories possess 100% smoke-free laws in all nonhospitality workplaces, restaurants, and bars [47]. An examination of the figure indicates that smoking bans are prevalent in the New England and northern Midwestern states. The remaining states and territories restrict smoking to designated areas. It is instructive to illustrate how one state has chosen to enact tobacco products legislation. Excerpts from the Georgia state law are presented herein.

* * *

The Georgia Smokefree Air Act was signed into law in May 2005. The act prohibits smoking inside most public places and sets guidelines for allowing smoking in and around public establishments. As stated by the Georgia Department of Health, the purpose of the act is to limit secondhand smoke exposure among children, adults, and employees and improve the health and comfort of the people of Georgia [48]. The law contains provisions that permit establishments to allow smoking if any person under the age of 18 is prohibited from entry to or employment in the establishment and if smoking is allowed only in outdoor areas such as patios or in enclosed private rooms with independent air-handling systems [49].

Georgia Smokefree Air Act (Excerpts)

O.C.G.A. §§ 31-12A-1 THROUGH 31-12A-13

Title 31. Health

Chapter 12A. Smokefree Air

O.C.G.A. § 31-12A-1. SHORT TITLE

This chapter shall be known and may be cited as the "Georgia Smokefree Air Act of 2005."

O.C.G.A. § 31-12A-2. Definitions

As used in this chapter, the term:

(1) "Bar" means an establishment that is devoted to the serving of alcoholic beverages for consumption by guests on the premises and in which the serving of food

is only incidental to the consumption of those beverages, including, but not limited to, taverns, nightclubs, cocktail lounges, and cabarets.

[…] (8) "Local governing authority" means a county or municipal corporation of the state. […]

(10) "Public place" means an enclosed area to which the public is invited or in which the public is permitted, including, but not limited to, banks, bars, educational facilities, health care facilities, laundromats, public transportation facilities, reception areas, restaurants, retail food production and marketing establishments, retail service establishments, retail stores, shopping malls, sports arenas, theaters, and waiting rooms. A private residence is not a public place unless it is used as a licensed child care, adult day-care, or health care facility.

(11) "Restaurant" means an eating establishment, including, but not limited to, coffee shops, cafeterias, sandwich stands, and private and public school cafeterias, which gives or offers for sale food to the public, guests, or employees, as well as kitchens and catering facilities in which food is prepared on the premises for serving elsewhere. The term shall include a bar area within any restaurant. (12) "Retail tobacco store" means a retail store utilized primarily for the sale of tobacco products and accessories and in which the sale of other products is merely incidental.

(13) "Secondhand smoke" means smoke emitted from lighted, smoldering, or burning tobacco when the person smoking is not inhaling, smoke emitted at the mouthpiece during puff drawing, and smoke exhaled by the person smoking.[…]

(16) "Smoking" means inhaling, exhaling, burning, or carrying any lighted tobacco product including cigarettes, cigars, and pipe tobacco.

(17) "Smoking area" means a separately designated enclosed room which need not be entered by an employee in order to conduct business that is designated as a smoking area and, when so designated as a smoking area, shall not be construed as to deprive employees of a nonsmoking lounge, waiting area, or break room. […]

O.C.G.A. § 31-12A-3. SMOKING PROHIBITED IN STATE BUILDINGS

Smoking shall be prohibited in all enclosed facilities of, including buildings owned, leased, or operated by, the State of Georgia, its agencies and authorities, and any political subdivision of the state, municipal corporation, or local board or authority created by general, local, or special Act of the General Assembly or by ordinance or resolution of the governing body of a county or municipal corporation individually or jointly with other political subdivisions or municipalities of the state.

O.C.G.A. § 31-12A-4. SMOKING PROHIBITED IN ENCLOSED PUBLIC PLACES

Except as otherwise specifically authorized in Code § 31-12A-6, smoking shall be prohibited in all enclosed public places in this state.

O.C.G.A. § 31-12A-5. SMOKING PROHIBITED IN ENCLOSED AREA WITHIN PLACES OF EMPLOYMENT

(a) Except as otherwise specifically provided in Code § 31-12A-6, smoking shall be prohibited in all enclosed areas within places of employment, including, but not limited to, common work areas, auditoriums, classrooms, conference and meeting rooms, private offices, elevators, hallways, medical facilities, cafeterias, employee lounges, stairs, restrooms, and all other enclosed facilities. (b) Such prohibition on smoking shall be communicated to all current employees by July 1, 2005, and to each prospective employee upon their application for employment.

O.C.G.A. § 31-12A-6. AREAS EXEMPT FROM SMOKING PROHIBITIONS

(a) Notwithstanding any other provision of this chapter, the following areas shall be exempt from the provisions of Code § 31-12A-4 and § 31-12A-5: (1) Private residences, except when used as a licensed child care, adult day-care, or health care facility; (2) Hotel and motel rooms that are rented to guests and are designated as smoking rooms; provided, however, that not more than 20% of rooms rented to guests in a hotel or motel may be so designated; (3) Retail tobacco stores, provided that secondhand smoke from such stores does not infiltrate into areas where smoking is prohibited under the provisions of this chapter; (4) Long-term care facilities as defined in paragraph (3) of Code § 31-8-81; (5) Outdoor areas of places of employment; (6) Smoking areas in international airports, as designated by the airport operator; (7) All workplaces of any manufacturer, importer, or wholesaler of tobacco products, of any tobacco leaf dealer or processor, all tobacco storage facilities, and any other entity set forth in Code § 10-13A-2; (8) Private and semiprivate rooms in health care facilities licensed under this title that are occupied by one or more persons, all of whom have written authorization by their treating physician to smoke; (9) Bars and restaurants, as follows: (A) All bars and restaurants to which access is denied to any person under the age of 18 and that do not employ any individual under the age of 18; or (B) Private rooms in restaurants and bars if such rooms are enclosed and have an air handling system independent from the main air handling system that serves all other areas of the building and all air within the private room is exhausted directly to the outside by an exhaust fan of sufficient size; (10) Convention facility meeting rooms and public and private assembly rooms contained within a convention facility not wholly or partially owned, leased, or operated by the State of Georgia, its agencies and authorities, or any political subdivision of the state, municipal corporation, or local board or authority created by general, local, or special Act of the General Assembly while these places are being used for private functions and where individuals under the age of 18 are prohibited from attending or working as an employee during the function; (11) Smoking areas

designated by an employer which shall meet the following requirements: (A) The smoking area shall be located in a nonwork area where no employee, as part of his or her work responsibilities, shall be required to enter, except such work responsibilities shall not include custodial or maintenance work carried out in the smoking area when it is unoccupied; (B) Air handling systems from the smoking area shall be independent from the main air handling system that serves all other areas of the building and all air within the smoking area shall be exhausted directly to the outside by an exhaust fan of sufficient size and capacity for the smoking area and no air from the smoking area shall be recirculated through or infiltrate other parts of the building; and (C) The smoking area shall be for the use of employees only. The exemption provided for in this paragraph shall not apply to restaurants and bars; (12) Common work areas, conference and meeting rooms, and private offices in private places of employment, other than medical facilities, that are open to the general public by appointment only; except that smoking shall be prohibited in any public reception area of such place of employment; and (13) Private clubs, military officer clubs, and noncommissioned officer clubs.

(b) In order to qualify for exempt status under subsection (a) of this Code section, any area described in subsection (a) of this Code section, except for areas described in paragraph (1) of subsection (a) of this Code section, shall post conspicuously at every entrance a sign indicating that smoking is permitted. [..].

Perspective: As matters of health policy, there are several features of this state's smoking law that merit comment. First, as stated separately by the state's Department of Human Services, "the purpose of the act is to limit secondhand smoke exposure among children, adults, and employees and improve the health and comfort of the people of Georgia." Second, the law commences with an extensive set of definitions. All such policy statements should commence similarly, since health policies, in particular, pertain to serious social subjects, e.g., smoking or operating motor vehicles, and are subject to enforcement. The gravity of such policies requires careful definition of terms and accompanying language, if for no other reason than for legal interpretation.

Third, Georgia's law contains exceptions to the no-smoking rule, e.g., tobacco shops and "open" bars are excluded from enforcement of no-smoking environments. Why are exceptions made to what is supposed to be a public health rule? The answer derives from the fact that policies, such as laws and ordinances, are the products of processes characteristic of democratic societies. And involvement of interested parties and public participation are part of the democratic dialog that occurs in policymaking. In the case of Georgia's smoking law, the state has a large investment in tourism, leading to exempting bars, restaurants, hotels, and tobacco shops—all exempted under specific conditions—from the law's coverage of nonsmoking conditions. In this specific instance, the public health was balanced against the economic benefit of tourism. States that completely ban smoking without exemptions obviously had a different policymaking intent.

Subsequent to enactment of Georgia's law, a study of the law's impact was conducted by one of the state's colleges of public health [49a]. Investigators found that between 2006 and 2012, the percentage of Georgia establishments that permitted smoking without restriction in dining areas did fall by more than half. However, during that same time, the percentage that permitted smoking in designated areas nearly doubled from about 9% in 2006 to almost 18% 6 years later. The investigators commented, "the most effective way to protect people from the dangers of secondhand smoke is to implement and enforce legislation that requires all indoor public places to be 100%" [49a].

* * *

In addition to individual states' tobacco control legislation, such as the aforementioned Georgia law, many of the states and U.S. territories banded together to litigate the tobacco industry for recovery of states' costs associated with tobacco products. After several years of judicial actions and maneuvers by both states and the tobacco industry, a settlement occurred. The Master Settlement Agreement (MSA) is an accord reached in November 1998 between the state attorneys general of forty-six states, five U.S. territories, the District of Columbia, and the five largest U.S. tobacco companies [50]. The settlement addressed the companies' advertising, marketing, and promotion of tobacco products. In addition to requiring the tobacco industry to pay the settling states approximately $10 billion annually for the indefinite future, the MSA also set standards and restrictions on the sale and marketing of cigarettes by participating cigarette manufacturers. Among its many provisions, the MSA

- Forbids participating cigarette manufacturers from directly or indirectly targeting youth.
- Imposes significant prohibitions or restrictions on advertising, marketing and promotional programs or activities.
- Bans or restricts cartoons, transit advertising, most forms of outdoor advertising, including billboards, product placement in media, branded merchandise, free product samples (except in adult-only facilities), and most sponsorships [50].

Over the years, the litigating states and territories have collected record amounts of tobacco revenue from the MSA, but are spending less of it on tobacco prevention programs. "According to the Campaign for Tobacco-Free Kids, which tracks state tobacco prevention spending vs state tobacco revenues, only one state to date—North Dakota—currently funds a tobacco prevention program at even half the level recommended by the Centers for Disease Control and Prevention" [50]. Regrettably, in a public health sense, the states and territories have chosen to merge the tobacco settlement income into their general revenue stream and not for tobacco prevention programs.

* * *

In addition to state laws and regulatory policies, local governments such as counties, townships, and municipalities can also

express tobacco use policies through adoption of ordinances, as long as the ordinances comply with parent state laws. An advantage of local ordinances on tobacco use is that local resources, such as local health and law enforcement, are responsible for enforcement, rather than being solely the state's responsibility. This is an example of the philosophy that civic issues are best resolved at the lowest level of government.

A local smoking policy for DeKalb County, Georgia, is excerpted here. The county is home to Agnes Scott College, CDC, Emory University, Mercer University, Oglethorpe University, and several community and technical colleges. The county has a population of approximately 714,000 residents and has a broad base of commercial enterprises, including health care, manufacturing, financial services, recreation, and schools. Key provisions of DeKalb County's smoking ordinance are excerpted as follows. A complete version of the county's ordinance is available from the county [51].

DeKalb County Smoke-Free Air Ordinance (Excerpted)

SEC. 16-100—TITLE.

This division shall be known, cited, and referred to as the DeKalb County Smoke-Free Air Ordinance. (Ord. No. 41-02, Pt. I, 12-19-02).

SEC. 16-101—FINDINGS AND PURPOSE.

(a) The DeKalb County Board of Commissioners does hereby find that (1) Numerous studies have found that tobacco smoke is a major contributor to indoor air pollution, and that breathing secondhand smoke is a cause of disease in healthy nonsmokers, including heart disease, stroke, respiratory disease, and lung cancer. (2) Secondhand smoke is particularly hazardous to elderly people, individuals with cardiovascular disease, and individuals with impaired respiratory function, including asthmatics and those with obstructive disease. Children exposed to secondhand smoke have an increased risk of asthma, respiratory infections, SIDS, developmental abnormalities, and cancer. (b) Accordingly, the DeKalb County Board of Commissioners finds and declares that the purposes of this division are (1) To protect the public health and welfare by prohibiting smoking in public places and public and private places of employment;(2) To guarantee the right of nonsmokers to breathe smoke-free air; and (3) To recognize that the need to breathe smoke-free air shall have priority over the desire to smoke.

12-19-02)SEC. 16-102—DEFINITIONS.

[..]

Dining area means an interior or exterior (such as porch, patio or courtyard) area containing a counter or tables upon which food is served.

E-cigarette means any electronic oral device, such as one composed of a heating element, battery, and/or electronic circuit, that creates a vapor of nicotine and simulates smoking. This term includes any such device, whether manufactured, distributed, marketed, or sold as an e-cigarette, e-cigar, e-pipe, or under any other product name or descriptive name. […]

Establishment means any business, store, office or other place where goods or services are sold or provided as part of a commercial venture. [..]

Outdoor recreational public place means any outdoor area of a place to which the public is invited or in which the public is permitted that is used, or intended for use, as a recreational area, regardless of any fee or age requirement. […]

Public place means any enclosed area to which the public is invited or in which the public is permitted, including but not limited to, restaurants, stores, waiting rooms, lobbies, reception areas, hallways, concession areas, public transit, restrooms, shopping malls, elevators, service lines, service stations, offices providing professional services, banks and other financial institutions, educational, recreational and health care facilities, childcare facilities, auditoriums, enclosed facilities in outdoor recreational public places, theaters, arenas, meeting rooms, repair shops, automobile dealerships, convention halls, and polling places. Porches, courtyards or decks with a contiguous connection to a public place shall be considered a public place. A private residence is not a public place unless it is used as a childcare facility, an adult daycare facility or a health care facility.

Restaurant means any establishment or area which is primarily devoted to the serving of food to the public or guests and which contains a dining area. […]

Smoking means inhaling, exhaling, burning, or carrying any lighted or heated cigar, cigarette, e-cigarette, oral smoking device, or pipe, or any other lighted or heated tobacco intended for inhalation, in any manner or in any form.

SEC. 16-103—PROHIBITED SMOKING.

Except as allowed in this division, smoking is prohibited in all public places, outdoor recreational public places, common areas, and places of employment.

SEC. 16-104—PROHIBITION OF SMOKING APPLICABLE TO COUNTY PROPERTY

Smoking shall be prohibited in all common areas, public places, places of employment, outdoor recreational public places, parking lots, and vehicles owned, leased, or operated by DeKalb County.

[…]

SEC. 16-106—EXCEPTIONS.

(a) The smoking prohibition shall not apply in the following areas: (1) "Freestanding bar" areas; (2) Retail tobacco stores; (3) Adult entertainment establishments, as defined by this Code; (4) Private residences, including private residences which may serve as an office workplace, except if used as a childcare, an adult day care or a health care

facility; (5) Any property owned or leased by municipalities, the State of Georgia, or the federal government; (6) Designated smoking rooms in hotels and motels rented by guests provided that such designated smoking rooms shall not comprise more than 25% of the total number of rooms available for rent; and (7) Outdoor areas of places of employment, except where an owner or employer declares that the outdoor area is a smoke free environment, as provided in this division. (b) Notwithstanding any other provision of this division, any owner, operator, manager or other person who controls any establishment described in this division may declare that the entire establishment is a nonsmoking establishment.

[…]

SEC. 16-109—ENFORCEMENT.

(a) Any police officer, as defined by Georgia law, may issue a citation for any violation of this division […]

SEC. 16-111—VIOLATIONS AND PENALTIES.

Any person who violates any provision of this division shall be subject to the following penalties: (1) A fine not exceeding fifty dollars ($50.00) for a first violation; (2) A fine not exceeding seventy-five dollars ($75.00) for a second violation of this division within one (1) year; and (3) A fine not exceeding one hundred dollars ($100.00) for each additional violation of this division within one (1) year.

[…]

Perspective: This county's smoking ordinance's framework parallels that of the Georgia state law on smoking. As a matter of policymaking, it is not surprising that the state law and the county ordinance are similar in construction. Federal law supersedes state law and state law supersedes local law. That is one way in which federalism works. But lower levels of government, e.g., county law, can have features not present in the strata above, e.g., state law. This is generally the policy that law or ordinances from lower levels of government can go beyond an overarching law, but only if the lower meets all the conditions of the precedent law. As illustration, DeKalb County's ordinance defines "smoking" so as to include e-cigarettes; whereas, Georgia state law does not.

7.9 PRIVATE SECTOR TOBACCO POLICIES

The private sector is the U.S. and elsewhere in Europe and Asia has been a significant, positive policymaker in terms of control of tobacco use. These policies emerged from the recognition that employees who smoke cost businesses more than nonsmoking employees. These costs were incurred due to additional sick leave taken from work and additional health care costs on health insurance that was paid in part by employers. Simply put, cigarette smokers, in particular, added to the cost of business operations. Companies gradually adopted human resource polices which encouraged tobacco smokers to participate in company-financed programs of smoking cessation. Companion policies consisted of not hiring persons who were smokers. This policy was dramatized by the findings from a longitudinal study by Stanford University researchers of persons seeking re-employment. In a study of 251 San Francisco area job seekers between 2013 and 2015, about half were smokers and half were not. After a year of follow-up, twice as many nonsmokers had found employment. Further, the smokers' jobs paid about 25% less than jobs obtained by the nonsmokers [52].

This policy of not hiring persons who smoked led in the U.S. to occasional complaints of denial of "smokers' rights." These kinds of complaints were generally unsuccessful when taken to litigation, depending on circumstances such as transparency of a company's smoking policies. Other policies restricted areas in business operations where smokers could congregate and smoke. In time, office building became "smoke free" due to policies set by employers or by government ordinance. In some instances employee labor organizations petitioned, on behalf of their membership, for the establishment of smoke-free policies. One example of this kind of action was that taken by the airline flight attendants' union, which worked with airline management to establish no smoking areas on commercial airlines. Later, all airlines became smoke-free, with no smoking allowed while in flight.

7.10 GLOBAL CONTROL OF TOBACCO AND RELATED PRODUCTS

The human health toll of tobacco use is a global problem and therefore a worldwide challenge to policymakers and public health authorities. While many nations have implemented strong policies to reduce or prevent the use of tobacco products, much progress remains to be achieved. The global leader in reducing the use of tobacco products is WHO (Chapter 7), which is an agency of the UN. As an UN agency, WHO has sociopolitical access to the nations of planet Earth, although not with equal impact due to geopolitical differences in national governments. WHO has committed to a global program of action to prevent the health consequences of smoking. This program constitutes the agency's Framework Convention on Tobacco Control.

7.10.1 WHO Framework Convention on Tobacco Control, 2005

The WHO FCTC is the first treaty negotiated under the auspices of WHO. According to WHO, the FCTC represents a paradigm shift in developing a regulatory strategy to address addictive substances; in contrast to previous drug control treaties, the WHO FCTC asserts the importance of demand reduction strategies as well as supply issues [53]. The FCTC went into effect on February 27, 2005. WHO reports that 180 nations have signed the FCTC treaty; the U.S. has not signed, owing to the treaty's expected opposition in the U.S. Senate, which has to ratify all international treaties under the U.S. Constitution.

The WHO FCTC was developed in response to the globalization of the tobacco epidemic. The spread of the tobacco epidemic is facilitated through a variety of complex factors with cross-border effects, including trade liberalization and direct foreign investment. Other factors such as global marketing, transnational tobacco advertising, promotion and sponsorship, and the international movement of contraband and counterfeit cigarettes have also contributed to the explosive increase in tobacco use. The core demand reduction provisions in WHO's FCTC are as follows:

- "Price and tax measures to reduce the demand for tobacco, and
- Nonprice measures to reduce the demand for tobacco, namely:
- Protection from exposure to tobacco smoke;
- Regulation of the contents of tobacco products;
- Regulation of tobacco product disclosures;
- Packaging and labeling of tobacco products;
- Education, communication, training and public awareness;
- Tobacco advertising, promotion and sponsorship; and,
- Demand reduction measures concerning tobacco dependence and cessation" [53].

The core supply reduction provisions in WHO's FCTC are contained in articles 15–17:

- Illicit trade in tobacco products
- Sales to and by minors
- Provision of support for economically viable alternative activities

The treaty has 180 signatories, including the European Community, which makes it one of the most widely embraced treaties in UN history [54]. Implementation of the FCTC by WHO's Member States has led to some criticism. In particular, one study reported "[…] we reviewed every first-cycle national implementation report and reconstructed the WHO database for the provisions most closely related to the six MPOWER priorities […]. As of July 4, 2012, 361 (32.7%) of 1104 countries' responses were misreported: 33 (3.0%) were clear errors, 270 (24.5%) were missing despite countries having submitted responses, and 58 (5.3%) were, in our opinion, misinterpreted by WHO staff" [55]. The authors of this paper imply that budget and staff reductions at WHO contributed to database problems in the FCTC program.

7.10.2 WHO Key Facts on Global Tobacco Control

The WHO FCTC has broadened WHO's access to global databases on tobacco use, and these data provide a troubling image of the human and economic toll caused by tobacco products. The global consequences of tobacco use have been summarized by WHO in the following excerpts [56].

Key Facts

- Tobacco kills up to half of its users.
- Tobacco kills around 6 million people annually. More than 5 million of those deaths are the result of direct tobacco use while more than 600,000 are the result of nonsmokers being exposed to secondhand smoke.
- Nearly 80% of the world's 1 billion smokers live in low and middle-income countries.

[…]

Secondhand Smoke Kills

- Secondhand smoke is the smoke that fills restaurants, offices, or other enclosed spaces when people burn tobacco products such as cigarettes, *bidis,* and water pipes. There are more than 4000 chemicals in tobacco smoke, of which at least 250 are known to be harmful and more than 50 are known to cause cancer. There is no safe level of exposure to secondhand tobacco smoke.
- In adults, secondhand smoke causes serious cardiovascular and respiratory diseases, including coronary heart disease and lung cancer. In infants, it causes sudden death. In pregnant women, it causes low birth weight.
- Almost half of children regularly breathe air polluted by tobacco smoke in public places.
- Secondhand smoke causes more than 600,000 premature deaths per year.
- In 2004, children accounted for 28% of the deaths attributable to secondhand smoke.
- Almost half of children regularly breathe air polluted by tobacco smoke in public places.

WHO: Tobacco kills around 6 million people annually. More than 5 million of those deaths are the result of direct tobacco use while more than 600,000 are the result of nonsmokers being exposed to secondhand smoke.

Picture Warnings Work

Hard hitting anti-tobacco advertisements and graphic pack warnings—especially those that include pictures—reduce the number of children who begin smoking and increase the number of smokers who quit. Graphic warnings can persuade smokers to protect the health of nonsmokers by smoking less inside the home and avoiding smoking near children. Studies carried out after the implementation of pictorial package warnings in Brazil, Canada, Singapore, and Thailand consistently show that pictorial warnings significantly increase people's awareness of the harms of tobacco use [56].

Only 42 countries, representing 19% of the world's population, meet the best practice for pictorial warnings, which

includes the warnings in the local language and cover an average of at least half of the front and back of cigarette packs. Most of these countries are low- or middle-income countries.

Ad Bans Lower Consumption

- Bans on tobacco advertising, promotion, and sponsorship can reduce tobacco consumption.
- A comprehensive ban on all tobacco advertising, promotion, and sponsorship could decrease tobacco consumption by an average of about 7%, with some countries experiencing a decline in consumption of up to 16%.
- Only 29 countries, representing 12% of the world's population, have completely banned all forms of tobacco advertising, promotion, and sponsorship.
- Around one in three countries has minimal or no restrictions at all on tobacco advertising, promotion, and sponsorship.

Taxes Discourage Tobacco Use

Tobacco taxes are the most cost-effective way to reduce tobacco use, especially among the young and poor people. A tax increase that increases tobacco prices by 10% decreases tobacco consumption by about 4% in high-income countries and about 5% in low-and middle-income countries. Even so, high tobacco taxes are a measure that is rarely implemented. Only 33 countries, with 10% of the world's population, have introduced taxes on tobacco products so that more than 75% of the retail price is tax. Tobacco tax revenues are on average 269 times higher than spending on tobacco control, based on available data" [53].

Perspective: These findings from WHO characterize a global environmental health epidemic and corresponding challenge to policymakers. Worthy of repeating are a few salient facts gathered by WHO's FTC: Use of tobacco kills around 6 million people annually. Nearly 80% of the world's 1 billion smokers live in low- and middle-income countries. Almost half of children regularly breathe air polluted by tobacco smoke in public places. These sobering numbers present the calculus for needed national and international actions and policies for control of the tobacco epidemic.

7.10.3 European Union Directive on Tobacco, 2001

In 2001 the Member States of the EU issued its first directive on tobacco use. As a reminder from Chapter 5, a regulation is similar to a national law with the difference that it is applicable in all EU countries. Directives set out general rules to be transferred into national law by each country as they deem appropriate. Excerpts from the EU 2001 directive follow [54]:

Manufacture, Presentation, and Sale of Tobacco Products

This Directive concerns the manufacture. presentation, and sale of tobacco products in the Member States of the EU, in particular the use of warnings on packets, the prohibition of descriptions such as mild or light, the maximum tar, nicotine and carbon monoxide yields, and the prohibition of tobacco for oral use. The specifics of the directive are as follows:

Act

Directive 2001/37/EC of the European Parliament and of the Council of June 5, 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products [See amending act(s)].

Summary

This directive aims to approximate the laws, regulations and administrative provisions of the Member States concerning:

- The maximum tar, nicotine and carbon monoxide yields of cigarettes;
- The warnings about health and other information to appear on unit packets of tobacco products;
- Certain measures concerning the ingredients and the descriptions of tobacco products.

Cigarettes: Maximum Yields

The Directive specifies maximum tar, nicotine, and carbon monoxide yields for cigarettes released for free circulation, marketed, or manufactured in the Member States. These maximum yields are lower than those laid down by Directive 90/239/EEC concerning maximum tar yields and are extended to two other substances (nicotine and carbon monoxide). From January 1, 2004, the maximum yields for cigarettes released for free circulation, marketed or manufactured in the Member States will be as follows: 10 mg per cigarette for tar, 1 mg per cigarette for nicotine 10 mg per cigarette for carbon monoxide.

As regards measurement methods, tests are carried out on the basis of standards specified by approved laboratories designated by the Member States. The information must be submitted on an annual basis to the competent authorities in the Member States, which will forward it to the European Commission. The Member States must also disseminate this information to consumers, taking account of any information which constitutes a trade secret.

Labeling

With regard to labeling, this Directive lays down the following provisions:

- *Maximum yields*: the information on the maximum yields for cigarettes must cover at least 10% of the surface of the packet (12% for a Member State with two official languages and 15% for a Member State with three official languages). The Directive also specifies where this information is to be placed on the packet.
- *Warnings*: there are two types of compulsory warnings for all products (except for tobacco for oral use and other smokeless tobacco products): general

warnings (Smoking kills/can kill or Smoking seriously harms you and those around you) and additional warnings (Smoking causes 90% of lung cancers, Smoking causes mouth and throat cancer, Smoking destroys your lungs, etc.), which vary on packets and whose list was updated in 2012.
- *Tobacco products for oral use and smokeless tobacco products*: there are separate provisions for these two categories of products, i.e., the following warning: This tobacco product can damage your health and is addictive.
- *Product identification and traceability*: the Directive provides for identification of the place and time of manufacture of the product by means of batch numbering or equivalent.

List of Ingredients

Manufacturers and importers are required to submit to the Member States, on a yearly basis a list of all ingredients, and quantities thereof, used in the manufacture of tobacco products, together with toxicological data on their effects on health and any addictive effects. This list must be accompanied by a statement setting out the reasons for their inclusion. It must also be made public and be submitted to the Commission on a yearly basis.

[…]

Tobacco for Oral Use

Member States shall prohibit the placing on the market of tobacco for oral use without prejudice to Article 151 of the Act of Accession of Austria, Finland, and Sweden, which stipulates that the placing on the market in Sweden of tobacco for oral use may continue.

[…]

Lacking in the EU directive is any language that outright bans tobacco smoking in public places. That subject is left to the individual Member States of the EU. In a way, this delegation of responsibility is akin to the U.S. federal and state law arrangement. Most of the Member States have implemented some form of tobacco products control. The most significant of these Member State laws is that of Ireland, which became the first country ever to implement a comprehensive national workplace smoking ban in March 2004 [57]. One remarkable feature of the Irish law is its primary concern for service personnel who worked in establishments that accommodated tobacco smoking customers. In a sense, the Irish smoking ban is an occupational health law, with benefits for customers of the public places that banned smoking.

As observed by an anti-smoking organization, "Ireland became the first country to go smoke-free in all public places and workplaces, including restaurants and pubs, on March 29, 2004. […] Ireland's smoke free workplace law enjoys over 93% public support, including 80% of smokers, a 97% compliance rate, and a 33% reduction in the smoking prevalence rate. In addition, pub and restaurant workers report being 40% healthier since the law went into effect last year" [58]. Two interesting reports have examined the outcomes of the Irish ban on smoking in public places. In a 2013 study, the Tobacco Free Research Institute Ireland estimated that the smoking ban had prevented an estimated 3726 smoking-related deaths; the mortality decreases were attributed primarily to reductions in passive smoking (i.e., secondhand smoke), rather than a reduction in active smoking [57]. A second study, reported by WHO indicated that the number of customers in 38 Dublin smoke-free pubs had increased by 11%, an increased interpreted as an effective indicator of public support for the Irish smoke-free law [59].

Perspective: The EU directive on tobacco products is different from U.S. federal and state tobacco laws in the degree of specificity and detail. For instance, the EU directive contains considerable specificity on the permitted composition of tobacco products; the form, content, and dimensions of labels required for placement on tobacco products; and bans promotional and misleading elements related to tobacco products [54]. The EU directive also requires that the tobacco industry provide Member States with detailed information on the ingredients used in tobacco products and, further, to notify Member States with information about novel products prior to their introduction into commerce. FDA regulations released in 2016 under provisions of the Tobacco Control Act now address these same EU industry reporting requirements. A subsequent amendment to the EU directive strengthened the original directive by focusing on prevention of young persons from using tobacco products [60].

7.10.4 Tobacco Use in China

China is the world's most populous country, with the second largest national economy. Sociopolitical events in China resonate globally. This resonance includes tobacco use and the consequences to China's people and ecosystems. As noted in the history of tobacco (Table 7.1), tobacco has been a part of China's culture since the sixteenth century. In the 1950s China's government took control of the country's tobacco business, assuring control over the manufacture, distribution, and state income from the sale of tobacco products. WHO has assessed and opined on the use of tobacco products in China, providing the following facts [61]:

- "There are more than 300 million smokers in China, nearly one-third of the world's total.
- About one in every 3 cigarettes smoked in the world is smoked in China. Nearly 2.3 trillion cigarettes were consumed in China in 2009—more than in the other top-4 tobacco consuming countries (Indonesia, Japan, the Russian Federation, and the U.S.) combined.
- According to the Global Adult Tobacco Survey (GATS) in China in 2010, nearly one-third (28.1%) of the population smokes, including 52.9% of men and 2.4% of women. More than half (52.7%) of smokers aged 20–34 years started smoking daily before the age of 20.

- Approximately 1 million deaths in china are caused by tobacco every year—around one in six of all such deaths worldwide.
- Approximately 100,000 people die as a result of exposure to second-hand smoke each year.
- In other words, someone in China dies approximately every 30 s because of tobacco use; or around 3000 people every day.
- If the prevalence of tobacco use in China is not reduced, the number of tobacco-related deaths every year in China will increase to 3 million by 2050 […]" [61].

7.10.4.1 Factors Affecting Tobacco Use in China

- "Awareness about the health hazards of smoking is low. Only 25% of Chinese adults have a comprehensive understanding of the specific health hazards of smoking. Less than one-third of adults are aware of the dangers of second hand smoke.
- Health warnings on cigarette packs in China carry only text warnings, not graphic health warnings. […]
- The affordability of tobacco products is an important factor influencing smoking rates.
- In China, in 2010 the retail price of the most sold brand of tobacco was U.S. $0.74 (5 RMB). The average cost of a packet of cigarettes in developed countries is much higher.
- According to academic studies, in 2000, nearly 14% of the average annual per capita income was required to buy 100 packets of the cheapest cigarettes; in 2010, the same number of packets could be purchased for less than 3% of average annual per capita income.
- WHO recommends that at least 70% of the retail price of cigarettes comes from excise taxes.
- The effective rate of taxation as a proportion of the retail price of tobacco in China is around 40% for the most popular brand.

7.10.4.2 Tobacco Control Progress in China

- China signed the Framework Convention on Tobacco Control (FCTC) in November 2003, and ratified the FCTC in January 2005.
- China's 12th 5-Year Plan calls for smoke-free public places as part of the major national goal to increase life expectancy" [61].

These foregoing data from WHO portray a grim image of the impact of cigarette smoking on the population of China. A summary of findings pertaining to smoking patterns in China indicates that more Chinese men were commencing smoking, with more beginning as teenagers. But on a more positive note, more Chinese smokers were quitting by choice, although only 9% were doing so. The findings indicated that smoking prevalence among Chinse women is low, about 10%, but with increases among teenage girls [62].

In 2015 the Chinese government banned smoking in public places in Beijing, the nation's capital. Beijing is home to around 4.2 million of China's 300 million smokers, according to official figures. But under rules that came into effect on June 1, 2015 they are now forbidden from smoking in all public places. Cafes, bars, restaurants, hotels, schools, railway stations and hospitals must now be entirely smoke-free [63]. However, there is a conflict of interest in China. The government agency charged with dissuading people from smoking cigarettes also runs the Chinese National Tobacco Corporation, the company that has a monopoly on making and selling cigarettes in China. Cigarette sales in China produce more than 7% of the central government's revenue [64].

WHO presents the following global picture of tobacco use [56]:

- Tobacco kills up to half of its users;
- Tobacco kills around 6 million people each year. More than 5 million of those deaths are the result of direct tobacco use while more than 600,000 are the result of nonsmokers being exposed to second-hand smoke.

Nearly 80% of the world's 1 billion smokers live in low- and middle-income countries.

Perspective: The WHO characterization of the prevalence of tobacco smoking in China presents a sobering image of a nation in the midst of an epidemic. One statistic alone sends a clarion sign of the toll of tobacco on China's people. WHO estimates that every 30 s one person dies in China from a tobacco-related cause. No other country on the globe has a tobacco toll near parity with China. How China's government engages the country's tobacco epidemic will require time, resolve, and perseverance.

7.11 HAZARD INTERVENTIONS

As detailed in this chapter, use of tobacco products is a hazard to human and ecosystem health. Bearing in mind that one-half of tobacco users will die from use of the product, there are interventions known to reduce the hazard. These interventions include the following:

- The most effective intervention is not to start using any tobacco products—cigarettes, smokeless tobacco, and tobacco-imitation products. Education of potential tobacco users can be an aid to prevention of tobacco use—especially among young persons.
- For persons who have chosen to use tobacco products, there are programs of assistance in quitting tobacco's grip. Contacting one's medical doctor or public health agency for advice is a good first step. Additionally, a tobacco user can obtain assistance from government sources (e.g., CDC.gov) and an Internet search will identify local Quit Smoking organizations.

- Avoid secondhand smoke. This can be facilitated by not patronizing businesses that allow smoking on their premises. Nontobacco users should not reside with those who use tobacco.
- Support government agencies and NGOs that endeavor to restrict tobacco use.
- Do not financially support organizations that invest in tobacco companies.
- Make known to policymakers your concerns about tobacco products and their use.

7.12 SUMMARY

WHO estimates that tobacco kills approximately 6 million people annually. This figure does not include the premature deaths attributable to smokeless tobacco. Put in perspective, this annual toll is equal to the genocide of the Holocaust, or the regional metropolitan populations of Dallas-Ft. Worth, U.S., Madrid, Spain, or Nanjing, China [65]. Of equal gravity, as WHO observes, tobacco kills up to half of its users. This is a health risk level without equal. For the person who decides to smoke tobacco, the risk is the same as playing Russian roulette with half of the weapon's chambers containing live ammunition.

On a more promising note, health research has clearly identified the adverse health effects of tobacco use, and focused policymaking has been generally successful in lowering smoking rates in many countries, although much remains to be achieved. Such intervention strategies, particularly: controls on advertising of tobacco products, limits on smoking in public places, taxes on tobacco products, prosecution of illicit distribution of tobacco products, and youth education programs have been beneficial as policy elements in tobacco control policies. Future generations will ask with incredulity why a poisonous plant, tobacco, was allowed to kill so many of their ancestors.

7.13 POLICY QUESTIONS

1. Various forms of tobacco are still used by many young people. Using your own experience as a current, former, or nontobacco user, discuss (1) The reasons why tobacco use is acceptable to some youth and (2) The best methods to use to prevent smoking or other tobacco use by youth.
2. Do you as an individual have a personal policy about tobacco use? If so, describe your policy. If not, why not?
3. Does your state or province have any laws or other kinds of policies in regard to control of tobacco use? Describe in summary the purposes of the laws or policies that you identified? In your opinion, are these laws effective? If so, how? If not, why not?
4. Using Internet resources, determine which methods, in your opinion, are the most effective way to quit tobacco use? For example, how effective are nicotine patches for smoking cessation?
5. One policy for reducing tobacco use, particularly for cigarette smoking, is to tax tobacco products. Conduct a local survey on the amount of tax placed on typical tobacco products, e.g., what is the tax on cigarettes, pipe tobacco, smokeless tobacco, and cigars? What is the disposition of the taxes collected by vendors of tobacco products? On an annual basis, how much tax money does your state collect?
6. In some countries, e.g., China, the government owns the tobacco manufacturing system. As a result, such countries reap all the revenue from domestic and export sales of tobacco products, thereby yielding income for the state. Discuss the ethics, in your opinion, of state-operated manufacturing and sales of tobacco products, knowing the public health impacts of tobacco use.
7. Water pipes have increased in popularity in some locales, attracting younger smokers in particular. Using the material in this chapter, together with material available on the Internet, describe three or more hazards presented by smoking water pipes. For each hazard, provide a public health method to reduce or mitigate the hazard.
8. Using the material in this chapter, along with any additional materials, provide an analysis of the value or harm of e-cigarettes when used as a cigarette smoking cessation device. Be specific and provide supportive data for your analysis.
9. Assume that cigarettes constitute a major export for a particular country; discuss the pros and cons of a policy expressed in law that would forbid exporting cigarettes. Be specific. Include factors such as economic, sociopolitical, and ethical issues in your analysis.
10. In the U.S. there are federal laws prohibiting advertisements of cigarettes on television and similar media. However, there are no legal bans on showing cigarette-smoking characters in motion pictures and television productions. Using the PACM model for policymaking (Chapter 2), outline how you would lead a campaign targeted at the production of smoking-free movies and TV productions.
11. Some business enterprises in the U.S. and elsewhere have forged a policy of not hiring cigarette smokers, with the justification that nonsmokers are an economic resource to businesses. Describe your support or objection to this kind of policy. Include in your analysis the rights of individuals (i.e., personal freedoms) versus the rights of business entities.
12. Discuss how climate change could affect the prevalence and health consequences of the use of tobacco products, with emphasis on cigarettes. To the extent possible, use material from Chapter 6 as an aid for your evaluation.

13. Using the material in Section 7.5, select a Congressional action that exempted tobacco as a hazardous product and use Internet resources to investigate and report how this exemption came into the selected legislative action.
14. Should tobacco smoking be forbidden in homes in which young children reside? Discuss the pros and cons of action by child protective services (CPS). As a public health specialist, would you support an ordinance or other form of health policy that would authorize CPS to remove children from the homes of parents or guardians who smoke?
15. Assume you are a parent of a child who is of age to be impressionable by peer pressure. Describe in detail what you as a parent would do and say to your child in order to discourage social pressures to smoke or otherwise use a tobacco product?
16. Federal laws require warning labels to be placed on cigarette packages and some other tobacco products. Focusing on cigarette packages, prepare three different warning labels, with images, that you would use for discouraging adolescents from smoking cigarettes.
17. Congratulations! Love has arrived. Your love interest has proposed marriage. To celebrate the forthcoming nuptials, a family dinner has been arranged at a local restaurant. Your state of residence permits smoking in closed areas of restaurants. After seating, you take note that most of your beloved's family are cigarette smokers. Following dinner, you learn from a friend that your fiancée has only recently quit smoking. What would you do? Specify a plan of action; including a plan of no action should that be your choice.
18. Using Internet resources conduct an analysis of the degree of success associated with the WHO FCTC. Be specific and provide details on the program's accomplishments as well as missed opportunities to reduce global use of tobacco products.
19. The U.S. has never ratified WHO's FCTC, an international treaty that requires approval by the U.S. Senate. Conduct an analysis of why this treaty has never been submitted to the Senate for consideration. Further, opine on whether the treaty merits approval by the U.S. and give reasons for your decision.
20. Well, after digesting every jot and tittle of the material in this chapter, discusses the three most important lessons you learned. Was your personal environmental health behavior or policy changed by the content of this chapter? If so, how? If not, why?

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8 Air Quality

8.1 INTRODUCTION

This chapter's subject is air pollution, which is justifiably considered the world's single greatest environmental risk, responsible for one in eight premature deaths globally according to WHO [1]. Air pollution is global; air contaminants released in Asia and elsewhere will appear in North America and Europe and vice versa. Contained in this chapter are descriptions of the major sources of air pollution, one of which is the toxicology of the primary air contaminants, associations between air pollution and human and ecological health, global policies developed for control of air pollution sources, and some interventions for reduction of the hazard presented by polluted ambient (outdoor) (illustrated in Figure 8.1) and indoor air. Along the course of the chapter, some pertinent history that attends the subject of air pollution is provided.

Before proceeding, it is important to define air pollution: "Air pollution is contamination of the indoor or outdoor environment by any chemical, physical, or biological agent that modifies the natural characteristics of the atmosphere" [2]. Noteworthy is the mention of both indoor and outdoor locales where air pollution occurs. Indoor sources are especially consequential as an environmental global hazard, principally a problem of developing countries and economically and culturally poor populations. WHO's assessment points to a huge surge in disease burden and deaths due to air pollution exposure. The latest data show that deaths due to air pollution, which include outdoor as well as indoor pollution, have increased fourfold across the globe over the past decade. The total number of deaths due to air pollution is estimated at eight million every year, which is comparable to the population of New York City. Approximately half of deaths result from exposure to indoor air pollution [1].

Correspondingly, another definition of air pollutant is important: "Any substance in air that could, in high enough concentration, harm animals, humans, vegetation, and/or materials. Such pollutants may be present as solid particles, liquid droplets, or gases. Air pollutants fall into two main groups: (1) those emitted from identifiable sources and, (2) those formed in the air by interaction between other pollutants. Over one hundred air pollutants have been identified, which include halogen compounds, nitrogen compounds, oxygen compounds, radioactive compounds, sulphur (sulfur) compounds, and volatile organic chemicals (VOC)" [3].

With these definitions in hand, a history of air pollution is instructive as concerns its sources, consequences, and public policies. Morrison provides a helpful summary of this history [4]. "Contaminated air has been around in one form or another for thousands of years. First it was wood fires in ancient homes, the effects of which have been found in the blackened lungs of mummified tissue from Egypt, Peru and Great Britain. And the Romans earn the dubious credit of being perhaps the first to spew metallic pollutants into the air, long before the Industrial Revolution. The residents of ancient Rome referred to their city's smoke cloud as gravioris caeli ('heavy heaven') and infamis aer ('infamous air'). Several complaints about its effects can be found in classical writings. Roman courts considered civil claims over smoke pollution 2000 years ago. The empire even tried a very early version of the CAAct. In 535, then Emperor Justinian proclaimed the importance of clean air as a birthright […].

Later, smelting to create lead and copper appeared, fouling medieval air. Analyses of ice cores from the Arctic reveal that extraction and smelting on the Iberian Peninsula, England, Greece, and elsewhere increased lead in the environment by a factor of ten. By 1200, […] London had been deforested and a switch began to 'sea-coal,' coal that washed up on beaches. As early as the 1280s, there were complaints about smoke from burning coal. Attempts to ban burning then and 250 years later during the reign of Queen Elizabeth I failed. […]

Europeans imported air pollution to the New World. Spanish conquistadors mining silver in what is now Bolivia in 1572 used amalgamation, a technique that grinds ore into powder and that shot lead plumes into the air. […] By the 1600s, smoke from burning coal was damaging the architecture in London and other major cities. The invention and eventually widespread use of the steam engine accelerated pollution. Until then, businesses were artisan shops dispersed throughout a city. But centralized factories on a large scale meant even more air pollution.

The shift to fossil fuels eliminated constraints on urban expansion as factories, powered by steam created by burning coal, attracted new workers. Residents of emerging industrial giants—Birmingham, Leeds, Manchester, Chicago, Pittsburgh, and St. Louis, among others—found acrid smoke stung their eyes and hindered their breathing. Thick fogs, especially in colder weather, blanketed the cities. Societies to campaign against the smoke scourge gradually emerged. Laws were passed in Britain, the U.S., and Germany, but with inconsequential impact. […].

The 'smoke problem' intensified as new coal-burning industrial cities proliferated from the later eighteenth century onwards. Soon a new source of air pollution, the automobile, appeared. By 1940, Los Angeles had more than a million cars. At the time, no one realized the effect of all that exhaust, so when the city was blanketed with what later became known as smog on July 26, 1943, residents feared it was some kind of chemical attack. (Figure 8.2 illustrates a day of smog in downtown Los Angeles in the 1970s.) Four years later, the county established the first air pollution

FIGURE 8.1 Plume of air emissions from a U.S. power plant. (From EPA (Environmental Protection Agency), Climate change: Regulatory initiatives, Office of Air and Radiation, Washington, DC, 2016.)

control district in the country. California went on to become a leader in regulating air pollution […]. But it took two other smog incidents to galvanize action in the United States and Great Britain. On October 27, 1948 thick smog began to cover the river town of Donora, Pennsylvania. A storm rolled in four days later that cleared the air, but in the aftermath 20 died and 6000 were sickened. Similarly, on December 5, 1952 a fog enveloped London, killing about 4000 people before it dissipated four days later. Parliament acted with dispatch, passing the U.K. Clean Air Act in 1956, effectively reducing the burning of coal […]" [4].

Congress enacted the first Clean Air Act (CAAct) in 1963. Two years later, national emissions standards for cars were set. But it wasn't until the 1970 CAAct that Congress set the framework for air pollution regulation tied to public health. A subsequent section of this chapter will describe the details and policy implications of the CAAct. Suffice it to say here that this act is the most complex and sweeping in scope of the U.S. environmental health statutes.

Global policies on control of air pollution are described in this chapter, but in order to better appreciate the importance of environmental health policies, some words about sources of air pollution are necessary, together with the toxic properties of the main contaminants of air pollution.

8.2 SOURCES OF EMISSIONS OF AIR POLLUTANTS

As the foregoing history of air pollution implies, the Industrial Revolution commenced the first major release of air pollution, followed by releases due to the invention and global distribution of internal combustion engines in mobile vehicles. Neither industrial operations nor internal combustion engines were designed for zero release of substances released during operation. The global air pollution problem continued to increase due to factors such as human population growth, international trade increase, industrial operations expansion, energy production increase, and exponential growth of vehicles.

In the U.S., as subsequently described in the history of the CAAct, the early focus on sources of air pollution was industrial plants, followed later by knowledge of pollution caused by tailpipe emissions from automobiles and other vehicles powered by internal combustion engines.

FIGURE 8.2 Air pollution in downtown Los Angeles, California, 1970s. (From Howe, Kravchenko, Van Dyke. Blog. Los Angeles Air Pollution, 2015.)

Although there are copious contemporary sources of air pollution, the sources are generally grouped into two broad categories: *Point sources* INS: (also called stationary sources) include items such as factories and electric power plants, and *mobile sources* include cars and trucks, lawn mowers, and airplanes. Mobile sources comprise highway vehicles and nonroad equipment. For administrative purposes, the EPA divides point sources into eight broad site groups [5]:

- Agriculture, Food, and Forestry
- Electric Utilities
- Foam, Fiber, Plastic, and Rubber Products
- Chemical Production and Distribution
- Metals Production
- Petroleum Refineries and Distribution
- Solvent Use and Surface Coating
- Sterilizers

Within each of these groups, the EPA develops regulations and takes other actions pursuant to requirements of the CAAct. There is no parallel grouping of mobile sources of air pollution.

Agriculture is a major source of air pollution that is less often discussed in its context as an environmental health hazard. A study reports that emissions from farms outweigh all other human sources of fine-particulate air pollution in much of the U.S., Europe, Russia, and China [6]. The emissions are caused by use of nitrogen-rich fertilizers and animal waste that combine in the air with industrial emissions to form particulate matter (PM). Agricultural air pollution comes mainly in the form of ammonia, which enters the air as a gas from heavily fertilized fields and livestock waste. It then combines with pollutants from combustion—mainly nitrogen oxides and sulfates emitted from vehicles, power plants, and industrial processes—to create fine PM of micrometer diameter. As will be described in a subsequent section, fine PM can significantly contribute to acute and chronic illnesses of the respiratory system, particularly in children, including pneumonia, upper respiratory diseases, asthma, and chronic obstructive pulmonary diseases (COPDs). In a separate study, investigators estimate that globally PM may cause at least 3.3 million deaths annually [7]. As a matter of hazard intervention, reductions in the air pollutants from stationary and mobile sources will reduce the hazard of agriculturally released particulates.

Given the effects of climate change (Chapter 6) it is also important that forest fires be recognized as an important source of air pollution. The Intergovernmental Panel on Climate Change notes that in some regions of the globe, changes in temperature and precipitation are projected to increase the frequency and severity of fire events. Pollutants from forest fires can affect air quality for thousands of kilometers. Forest and bush fires cause burns, damage from smoke inhalation, and other injuries. Toxic gaseous and particulate air pollutants released from large fires can be accompanied by an increased number of patients seeking emergency services, and adverse effects on morbidity and mortality [8].

8.3 TOXICOLOGY AND STANDARDS FOR CRITERIA AND OTHER KEY AIR POLLUTANTS

The CAAct requires the EPA to set National Ambient Air Quality Standards (NAAQS) for six common air pollutants. These commonly found air pollutants (also known as "criteria pollutants") are found throughout the U.S. They are carbon monoxide, lead, nitrogen oxides, ozone, particle pollution (often referred to as particulate matter), and sulfur oxides. The EPA calls these pollutants "criteria" air pollutants because the agency must set NAAQS for them based on the human health effects and/or environmental impact [9].

The CAAct established two types of national air quality standards. *Primary standards* set limits to protect public health, including the health of at risk populations such as people with preexisting heart or lung disease (such as asthmatics), children, and older adults. *Secondary standards* set limits to protect public welfare, including protection against visibility impairment, damage to animals, crops, vegetation, and buildings. The CAAct requires periodic review of the science upon which the standards are based and the standards themselves [10]. Air quality standards are legally enforceable under provisions of the CAAct.

The human health effects of the Criteria Air Pollutants (CAPs) are summarized in the following sections. Shown in Table 8.1 are the EPA standards in 2016 for the six, taking note that PM has two standards [9]. Additional details regarding each of the standards are available from the EPA.

Carbon monoxide (CO) is a colorless, odorless gas emitted from combustion processes. Nationally and, particularly in urban areas, the majority of CO emissions to ambient air come from mobile sources. CO can cause harmful health effects by reducing oxygen delivery to the body's organs (like the heart and brain) and tissues. At extremely high levels, CO can cause death [11].

Lead emissions vary in source. At the national level, major sources of lead in the air originate from ore and metals processing and piston-engine aircraft operating on leaded aviation fuel. Other sources are waste incinerators, utilities, and lead-acid battery manufacturers. The highest air concentrations of lead are usually found near lead smelters. Inhalation or ingestion of lead is distributed throughout the body in the blood and accumulates in the bones. Depending on the level of exposure, lead can adversely affect the nervous system, kidney function, immune system, reproductive and developmental systems, and the cardiovascular system. The effects most commonly encountered in current populations are neurological effects in children and cardiovascular effects (e.g., high blood pressure and heart disease) in adults. Infants and young children are especially sensitive to even low levels of lead, which are associated with behavioral problems, learning deficits, and lowered IQ [12].

Oxides of nitrogen (NO_X) is the general term for a group of highly reactive gases, all of which contain nitrogen and oxygen in varying amounts. The NO_X are created when fuel is burned at high temperatures, including internal combustion engines.

TABLE 8.1
EPA's Primary and Secondary Standards for Alphabetized Criteria and Other Pollutants

Pollutant	Primary/Secondary	Averaging Time	Level	Form
Carbon monoxide	Primary	8 h	9 ppm	Not to be exceeded more than once per year
		1 h	35 ppm	
Lead	Primary and secondary	Rolling 3-month average	0.15 μg/m^3	Not to be exceeded
Nitrogen dioxide	Primary	1 h	100 ppm	98th percentile of 1-h daily maximum concentrations, averaged over 3 years
	Primary and secondary	1 year	53 ppm	Annual mean
Ozone	Primary and secondary	8 h	0.070 ppm	Annual fourth-highest daily maximum 8-h concentration, averaged over 3 years maximum 8-h daily
Particle pollution ($PM_{2.5}$)	Primary	1 h	12.0 μg/m^3	Annual mean, averaged over 3 years
	Secondary	1 h	15.0 μg/m^3	Annual mean, averaged over 3 years
	Primary and secondary	24 h	150 μg/m^3	98th percentile, averaged over 3 years
Particle pollution (PM_{10})	Primary and secondary	24 h	150 μg/m^3	Not to be exceeded more than once per year on average over 3 years
Sulfur dioxide	Primary	1 h	75 ppb	98th percentile of 1-h daily maximum concentrations, averaged over 3 years
	Secondary	3 h	0.5 ppm	Not to be exceeded more than once per year

Source: EPA (Environmental Protection Agency), Criteria air pollutants, Office of Air and Radiation, Washington, DC, 2016.

Fossil fueled electric utilities, motor vehicles, and industrial operations are the primary sources of NO_X. Nitrogen dioxide (NO_2) can irritate the lungs and reduce resistance to respiratory infections such as influenza [13].

Ozone (O_3) is a highly reactive gas that results primarily from the action of sunlight on nitrogen oxides and hydrocarbons emitted in combustion of fuels. Ozone exposure can produce significant decreases in lung function, inflammation of the lungs' lining, respiratory discomfort, and impair the body's immune system, making people more susceptible to respiratory illness, including pneumonia and bronchitis. At sufficiently high levels, repeated exposure to ozone for several months can cause permanent structural damage to the lungs. Hospital admissions and emergency room visits increase on days of high ozone pollution in outdoor air [14].

Particulate matter (PM) is a general term that refers to very small, carbonaceous, solid particles; dust; and acid aerosols. The size of particles is directly linked to their potential for causing adverse health effects. Particles less than 10 μm in diameter pose the greatest problems, because their inhalation can reach the alveoli of the lungs, with some entering the bloodstream. PM 2.5 μm or less in diameter ($PM_{2.5}$) is produced by incomplete combustion of fossil fuels and biomass, and constitutes one of the biggest health concerns. One-hundredth the thickness of a human hair, $PM_{2.5}$ can penetrate deep into the lungs and blood stream and is dangerous at any concentration. Numerous health studies have linked particle pollution exposure to a variety of problems including: premature death in people with heart or lung disease; nonfatal heart attacks; irregular heartbeat; aggravated asthma; decreased lung function; and increased respiratory symptoms, such as irritation of the airways, coughing or difficulty breathing [15]. The International Agency for Research on Cancer (IARC) concluded in 2013 that PM is carcinogenic to humans [16]. People with heart or lung diseases, children, and older adults are the most likely to be affected by particle pollution exposure.

Sulfur dioxide emissions occur when sulfur-containing fuels are combusted. Exposure to SO_2 at high levels is associated with breathing difficulties, respiratory illness, reduced pulmonary resistance to infectious agents, and aggravation of existing cardiovascular disease. The major source of SO_2 emissions are electric utilities.

In addition to the six CAPs, the EPA has authority to regulate the release of other air pollutants, such as air toxics released from electric power plants and regulate releases of **greenhouse gases (GHGs)**. These are authorities specified in the CAAct and will be discussed as policy issues later or implied in this chapter.

8.4 GLOBAL PREVALENCE OF AIR POLLUTION

The problem of air pollution is global in scope. WHO has estimated that in year 2012, ambient air pollution was responsible for 3.7 million deaths, representing 6.7% of total deaths. Worldwide, ambient air pollution was estimated to cause about 16% of the total lung cancer deaths, 11% of COPD deaths, more than 20% of ischemic heart disease and stroke, and about 13% of respiratory infection deaths [17]. Although some progress toward reducing unhealthful air emissions has been made, a substantial air pollution problem remains, with millions of tons of toxic air pollutants released globally annually.

As further elaboration of the global prevalence of air pollution, WHO has established an air quality database that covers 3000 cities in 103 countries. More than 80% of people

living in urban areas that monitor air pollution are exposed to air quality levels that exceed WHO guidelines. As urban air quality declines, the risk of stroke, heart disease, lung cancer, and chronic and acute respiratory diseases, including asthma, increases. WHO was able to compare a total of 795 cities in 67 countries for levels of small and fine particulate matter (PM_{10} and $PM_{2.5}$) during the 5-year period 2008–2013. Data were then analyzed to develop regional trends [17a].

WHO's analysis of this database indicates that while all regions of the world are affected, populations in low-income cities are the most impacted. According to the analysis 98% of cities in low- and middle-income countries with more than 100,000 inhabitants do not meet WHO air quality guidelines (AQGs). However, in high-income countries, that percentage decreases to 56%. The following key trends for the period 2008–2013 were noted:

- "Global urban air pollution levels increased by 8%, despite improvements in some regions.
- In general, urban air pollution levels were lowest in high-income countries, with lower levels most prevalent in Europe, the Americas, and the Western Pacific Region.
- The highest urban air pollution levels were experienced in low- and middle-income countries in WHO's Eastern Mediterranean and South-East Asia Regions, with annual mean levels often exceeding 5–10 times WHO limits, followed by low-income cities in the Western Pacific Region.
- In the Eastern Mediterranean and South-East Asia Regions and low-income countries in the Western Pacific Region, levels of urban air pollution has increased by more than 5% in more than two-thirds of the cities.
- In the African Region, urban air pollution data remains very sparse, however available data revealed PM levels above the median. The database now contains PM measurements for more than twice as many cities than previous versions" [17a].

Perspective: These data and observations from WHO portray a grim image of the human toll exerted by air pollution, with increases in several key areas of the globe.

8.4.1 Prevalence of Air Pollution in the U.S.

Data on trends in air quality and source emissions are collected by the EPA [17b]. The agency creates air quality trends using measurements from monitors located across the country. Shown in Table 8.2 are air quality trends based on concentrations of common pollutants. The data shows that both air quality and source emissions have improved nationally since 1980. All six CAPs (CO, O_3, Pb, NO_2, PM, SO_2) show significant downward trends between 1980 and 2014. Particularly noteworthy for children's health is the significant decrease in outdoor air levels of lead, an outcome due to the phase-out of lead additives in gasoline, commencing in 1974 and continuing through 1996, attributable to the CAAct Amendments of 1970. Reductions in outdoor air lead levels produced corresponding decreases in blood lead levels in children, thereby lessening lead toxicity in children.

All six CAPs (CO, O_3, Pb, NO_2, PM, SO_2) show significant downward trends between 1980 and 2014. Particularly noteworthy for children's health is the significant decrease in outdoor air levels of lead.

The EPA also tracks trends in greenhouse emissions, per requirements of the United Nations Framework Convention on Climate Change (Chapter 6). An overview of the EPA's national GHG inventory for 1990–2014 revealed that in 2014, U.S. GHG emissions totaled 6870 million metric tons of CO_2 equivalents, with U.S. emissions increasing by 1.0% from 2013 to 2014. Recent trends can be attributed to multiple factors: increased fuel use, year-to-year changes in the prevailing weather, and an increase in miles traveled by on-road vehicles. GHG emissions in 2014 were 9% below 2005 levels [18].

TABLE 8.2
Trends in U.S. Air Quality and Source Emissions

	Percent Change in Air Quality			Percent Change in Emissions	
	1980 vs. 2014	2000 vs. 2014		1980 vs. 2014	2000 vs. 2014
CO	–85	–60	CO	–69	–46
O_3	–33	–18	Pb	–99	–50
Pb	–98	–87	NOx	–55	–45
NO_2 (annual)	–60	–43	VOC	–53	–16
NO_2 (1-h)	–57	–29	PM_{10}	–58	–16
PM_{10} (24-h)	—	–30	$PM_{2.5}$	–	–33
$PM_{2.5}$ (annual)	—	–35	SO_2	–81	–70
$PM_{2.5}$ (24-h)	—	–36			
SO_2 (1-h)	–80	–62			

Source: EPA (Environmental Protection Agency), Air quality—National summary, Office of Air and Radiation, Washington, DC, 2016.

The overall pattern of air pollution trends in the U.S. indicates improved air quality for the six CAPs and a small decrease in emissions of GHGs.

8.4.2 Prevalence of Air Pollution in the EU

The European Environment Agency prepares an annual report about the state of air quality in Europe [19]. The 2015 report presents an overview and analysis of air quality in Europe, with a focus on the latest year for which there are available and processed data, namely 2013. It reviews the progress made towards meeting the requirements of the Air Quality Directives. The analysis covers up to 39 European countries. The present analysis indicates that air quality policies have delivered many improvements. Reduced emissions have improved air quality in Europe, and, for a number of pollutants, exceedances of European standards are rare. However, a large proportion of European populations and ecosystems are still exposed to air pollution in exceedance of European standards and WHO AQGs.

Particulate matter: The EU limits and target values for PM continued to be exceeded in large parts of Europe in 2013. The EU daily limit value for PM with a diameter of 10 μm or less (PM_{10}) was exceeded in 22 of the 28 EU Member States, and the target value for $PM_{2.5}$ was exceeded in 7 Member States. A total of 17% of the EU's 28 urban population were exposed to PM_{10} levels above the daily limit value and approximately 61% were exposed to concentrations exceeding the more strict WHO AQG value for PM_{10} in 2013. Regarding PM2.5, 9% of the urban population in the EU-28 was exposed to $PM_{2.5}$ levels above the EU target value (which changes to a limit value from 2015 onward) and approximately 87% were exposed to concentrations exceeding the stricter WHO AQG value for $PM_{2.5}$ in 2013 [19].

Ozone: The EU ozone (O_3) target value for the protection of human health was exceeded in 18 of the 28 EU Member States in 2013. Conformity with the WHO AQG value for O_3 was observed in less than 3% of all stations in Europe in 2013. Some 15% of the EU-28 urban population lives in areas in which the EU's O_3 target value threshold for protecting human health was exceeded in 2013. The EU urban population exposed to O_3 levels exceeding WHO's AQG was significantly higher, comprising 98%.

Nitrogen dioxide: The annual limit value for NO_2 was widely exceeded across Europe in 2013, with 93% of all exceedances occurring close to roads. A total of 19 of the 28 EU Member States recorded exceedances of this limit value at one or more stations. Of the EU-28 urban population, 9% live in areas in which the annual EU limit value and WHO's AQG for NO_2 were exceeded in 2013.

Benzo[a]pyrene, an indicator for polycyclic aromatic hydrocarbons: Exposure to benzo[a]pyrene (BaP) pollution is quite significant and widespread, in particular in central and Eastern Europe. Approximately half of the BaP measurement stations in Europe were in exceedance of the EU target value in 2013, mostly in urban areas. About 20% of the total European population was exposed to BaP annual mean concentrations above the European target value in 2012 and about 88% live in areas with concentrations above the estimated reference level. Considering only urban populations, in 2013, 25% of the EU-28 urban population was exposed to BaP concentrations above the target value, and as much as 91% was exposed to BaP concentration.

Other pollutants: Sulfur dioxide, carbon monoxide, toxic metals, and benzene. The EU-28 urban population was exposed to only a few exceedances of the SO_2 EU daily limit value in 2013. However, 37% of the EU-28 urban population was exposed to SO_2 levels exceeding WHO's AQG in 2012. Exposure of the European population to CO concentrations above the EU limit value and WHO AQG is very limited, localized, and sporadic. Concentrations of As, Cd, Pb, and Ni in air are generally low in Europe, with few exceedances of limit or target values. However, these pollutants contribute to the deposition and accumulation of toxic metal levels in soils, sediments, and organisms. Exceedances of the limit value for benzene (C_6H_6) were likewise rare.

Although, as this report from the European Environment Agency indicates, some improvements in air quality are evident in the EU Member States, there remain episodes of poor air quality. One example is in England's capitol, London, which has a human population of about 8.8 million and is a global center of culture and finance. The city has been voted the most desirable place to work in the world; it is the second most visited city on the planet and was recently crowned the most innovative global city. However, the city has also the dubious distinction of containing the most polluted street on earth. It only took until January 4, 2016 for Oxford Street to exceed the legal level of air pollution for the whole of 2016. London's air pollution problem is caused primarily by traffic and diesel fumes. About 50% of the NO_2 emissions in the city are caused by traffic [20]. The city has commenced polices to restrict motor vehicle traffic.

Similar to London, episodes of poor air quality have occurred in Paris, the capital of France, and a global center for art, fashion, gastronomy, and culture. The city's population is approximately 2.2 million people. In March 2015, air pollution in Paris was briefly worse than in any other city in the world according to a pollution-monitoring source. According to the source, an air quality index (AQI) number greater than 150 is considered "critical," while anything exceeding 100 is considered "harmful." In March 2016, the AQI in Paris was 125, a harmful level. In response, the city's government implemented some short-term measures, which included making public transport free in the greater Paris region in an effort to reduce pollution from cars [21].

8.4.3 Prevalence of Air Pollution in China

China—the world's most populous country with approximately 1.4 billion people—is a global economic power, with a population steeped in culture and tradition. China's capitol, Beijing, is the country's seat of central government, education, and culture, with a metropolitan population of approximately 25 million people. China has undergone rapid economic

development, which resulted in air and other pollution problems. However, air quality data are difficult to obtain, owing to historical unavailability of access to data systems maintained by China's central and regional governments. This has begun to change, as evidenced by the findings from a study of air quality in five major cities conducted by a team of researchers at Peking University Beijing, China, [22]. The investigators found both good and bad news in the report, titled *Air Quality Assessment Report: A Statistical Analysis of Air Pollution in Five Chinese Cities.* The team scrutinized 3 years of air quality data for the measure known as $PM_{2.5}$, the air pollutant that is especially hazardous to health. By using two independent data sets, the researchers answered a second question: Is the Chinese government's air quality data trustworthy? The answer: Yes, at least in these five cities. That was one piece of good news.

The researchers noted that $PM_{2.5}$ levels had declined over the last 3 years in all five cities. In Beijing, they reduced from 99 to 81 μg/m^3, and in Shanghai from 61 to 50 μg/m^3. In Guangzhou, levels declined from 54 to 39 μg/m^3. These reductions were because of two factors: stricter emissions regulations that took effect on January 1, 2015, and China's slowing economy.

Unfortunately, the air pollution readings remained higher in all five cities than WHO's upper safety limit for $PM_{2.5}$ of 35 μg/m^3. China uses a considerably more liberal standard, classifying up to 75 μg/m^3 as "good." Many readings regularly exceeded that level. The researchers defined a level of under 35 μg/m^3 as "good," and under 75 μg/m^3 as "light" pollution, and found that Guangzhou and Shanghai had the most "good" or "light" days. About 80% of days each year fell into those categories. Chengdu and Shenyang had about 60%. Beijing came last with 50%. In addition, Beijing and Chengdu suffered the most prolonged spells of heavy pollution, which the team defined as readings of 150 μg/m^3 or greater. Even Shanghai and Guangzhou did not have more than 37% "good" air days [22].

Much of Beijing shut down on December 8, 2015 after the city's government issued its first red alert for pollution, closing schools and construction sites and restricting the number of cars on the road. The red alert warned that severe pollution would affect the Chinese capital for several days. According to the U.S. Embassy in Beijing, the AQI stood at 250 Tuesday morning, classed as "very unhealthy" and 10 times higher than WHO's recommended levels [23]. Other red alerts occurred in 2016. Figure 8.3 shows a day of air pollution exceedance in Beijing in 2016.

8.4.4 Prevalence of Air Pollution in India

India is a nation rich in culture, tradition, and commerce. The country's human population of 1.327 billion in 2016 makes it the second most populous nation, second to China [24]. As of 2016, the country's capitol, Delhi, has a population of approximately 18.7 million people [25]. Motor vehicles are a major source of air pollution emissions, with Delhi having in 2012 an estimated 7.3 million vehicles (cars, two and four wheelers, and trucks), with the country's nine major cities numbering approximately 26 million motor vehicles [26]. India's economy has grown very rapidly in recent years. Since 1991 it has been among the top 10% of the world's countries in terms of economic growth [27].

But as with other countries, economic growth has been accompanied by environmental problems, especially air pollution. Rapid expansion of industrial, urban, and traffic

FIGURE 8.3 Beijing, China, on a day of severe air pollution in 2016. (From China Travel Go, Beijing, China.)

emissions significantly increased the levels of air pollution, with levels in Delhi reaching those dangerous to health. WHO ranked Delhi's air quality in 2015 as the world's 11th worst [28]. In particular, levels of $PM_{2.5}$ and O_3 often exceed levels recommended by WHO. According to a report by India's Central Pollution Control Board (CPCB), about 78% of the total 141 cities in India exceed the $PM_{2.5}$ standard, 90 cities have critical levels, and 26 have the most critical levels, thereby exceeding the PM standard by more than three times the recommended amount. This prevalence of cities exceeding the $PM_{2.5}$ standard represents a national health emergency, according to the CPCB [27]. A study by Greenpeace [29] found that fine PM levels in New Delhi were about 128 $\mu g/m^3$, in comparison to Beijing's 81 $\mu g/m^3$ and Washington, DC's 12 $\mu g/m^3$. In contrast, WHO recommends that nations not exceed an annual average of 10 $\mu g/m^3$.

Studies report that inhaling PM reduces the life expectancy of Indians by an average of 3.4 years, with Delhiites losing 6.3 years (the highest among all Indian states), and those living in the polluted states of West Bengal and Bihar losing 6.1 years and 5.7 years, respectively [29]. A Greenpeace study estimates that outdoor air pollution in India is contributing to more than half a million premature deaths annually [29]. A separate study reported more than half of India's population lives in places with such polluted air that each person loses an average of 3.2 years in life expectancy, equating to 660 million Indians who could lose 2.1 billion years of life as a result of air pollution [30].

As a matter of public health, a sharp rise in cases of chest and throat disease in India is being blamed by doctors on worsening air pollution in the country. According to India's National Health Profile 2015, there were almost 3.5 million cases reported of acute respiratory infection (ARI) last year, an increase of 140,000 over the previous year and a 30% increase since 2010. The rise has occurred despite steady improvements in medical care and nutrition, as well as a shift away from using wood as fuel in rural areas. Together this has mitigated many factors long blamed for the high levels of respiratory diseases in India [31].

Economists have put the economic burden of estimated premature mortalities associated with the exposure of $PM_{2.5}$ and O_3 in the country at about US$640 (350–800) billion in 2011—a factor 10 times higher than the total expenditure on health by public and private expenditure, which stood at approximately US$60 billion [28]. The effects of air pollution on public health, together with economic costs, have led Indian authorities to make efforts to cope with the nation's air pollution, which are described in a subsequent section of this chapter.

8.4.5 Global Indoor Air Pollution Prevalence

Although ambient outdoor air pollution can be a hazard to human health, less thought is given to the consequences of polluted indoor air. While indoor air in households and offices is generally not a problem in the industrialized countries, household air can be a public health hazard in some instances. According to WHO, almost three billion people, mostly in low- and middle-income countries, still rely on solid fuels (wood, animal dung, charcoal, crop wastes, and coal) burned in inefficient and highly polluting household stoves for cooking and domicile heating. Higher-income countries do face the health problems associated with household air pollution, mainly from the burning of solid heating fuels (e.g., coal) in rural or mountainous areas, but these countries generally have systems in place and resources to address these problems [32].

The inefficient stoves used for cooking and heating practices produce high levels of household (indoor) air pollution that includes a range of health damaging pollutants such as fine particles and carbon monoxide. In poorly ventilated dwellings, smoke within and around the home can exceed acceptable levels for fine particles 100-fold. Exposure is particularly high among women and young children, who spend the most time near the domestic hearth. According to estimates by the WHO, in 2012 alone no fewer than 4.3 million children and adults died prematurely from illnesses caused by such household air pollution. In addition to the adverse health effects from the widespread use of kerosene stoves, heaters, and lamps, these practices also result in many serious injuries and deaths from scalds, burns, and poisoning [33].

In response to the morbidity and mortality associated with household air pollution WHO developed indoor air quality recommendations and AQGs for household fuel combustion that aim to help public health policymakers, as well as specialists working on energy, environmental, and other issues understand the best approaches to reducing household air pollution [33].

The recommendations include general considerations for policy, a set of four specific recommendations, and a best-practice recommendation addressing linked health and climate impacts. Among the general considerations, or overarching advice, is that policies should promote community-wide action, and that the safety of new fuels and technologies must be assessed rather than assumed. The set of four WHO recommendations pertaining to household air pollution are excerpted below. Recommendation 1: Emission Rate Targets: Emission rates from household fuel combustion should not exceed the following targets (ERTs) for particles with aerodynamic diameters of less than 2.5 μm ($PM_{2.5}$) and carbon monoxide (CO), based on the values for kitchen volume, air exchange, and duration of device use per day set out in the cited reference and which are assumed to be representative of conditions in low- and middle-income countries. Recommendation 2: Policy during transition to technologies and fuels that meet WHO's air quality guidelines: Governments and their implementing partners should develop strategies to accelerate efforts to meet these air quality guidelines emission rate targets (see Recommendation 1). Recommendation 3: Unprocessed coal should not be used as a household fuel (unprocessed coal is that which has not been treated by chemical, physical, or thermal means to reduce contaminants). Recommendation 4: Household use of kerosene (paraffin) is discouraged [33]. Good practice

recommendation: Considering the opportunities for synergy between climate policies and health, including financing, WHO recommends that governments and other agencies developing and implementing policy on climate change mitigation consider action on household energy and carry out relevant assessments to maximize health and climate gains.

WHO observes that tackling household air pollution willdemand significant resources. For governments of low- and middle-income countries, this calls for coordinated efforts by ministries, nongovernmental organizations and the public sector, international development and finance organizations, and others. Consonant with this observation is ongoing research by the EPA and NIEHS on the health impacts of indoor air pollution and work supported by the NGO Global Alliance for Clean Cookstoves.

8.5 ASSOCIATIONS BETWEEN AMBIENT (OUTDOOR) AIR POLLUTION AND HUMAN HEALTH

As observed by WHO, air pollution is a major environmental risk to health. By reducing air pollution levels, countries can reduce the burden of disease from stroke, heart disease, lung cancer, and both chronic and acute respiratory diseases, including asthma. The lower the levels of air pollution, the better the cardiovascular and respiratory health of the population will be, both long and short-term. The WHO AQGs provide an assessment of health effects of air pollution and thresholds for health-harmful pollution levels. Ambient (outdoor air pollution) in both cities and rural areas was estimated to cause 3.7 million premature deaths worldwide in 2012. Some 88% of those premature deaths occurred in low- and middle-income countries, and the greatest number in WHO's Western Pacific and South-East Asia regions [34]. The ensuing sections elaborate the effects of air pollution on the morbidity and mortality of exposed populations. Special emphasis will be given to the effects of air pollution on children's health.

8.5.1 Effects on Morbidity

The effects of polluted air on human health are numerous and significant. The health effects of contaminated air are well known to the U.S. public from news reports and the continuous release of new scientific information. What's best known to the public are the deleterious effects of air pollutants on the lungs. These effects are generally well known because of news media reports on lung disease related to air pollution and, more importantly, from weather reports that advise the public when air pollutants have reached hazardous levels. When such conditions occur, persons are advised to remain indoors and reduce activity levels when outdoors. Also, government agencies promote vehicle use reductions on days when pollution levels are hazardous. The sum of these news media and governmental acts is a general awareness among the U.S. public of the health hazards of air pollution, usually focused on the effects on the lungs.

Although air quality in the U.S. has generally improved since 1980 (Table 8.2), millions of Americans live in areas where urban smog, particle pollution, and toxic pollutants can pose serious health concerns. Adverse health effects can occur from inhalation exposure to PM, noxious gases (SO_2, NO_x, CO), ground-level O_3, and other hazardous toxic substances. Air pollution can affect human health in many ways. Numerous health studies have linked chronic exposure to air pollution to a variety of health problems including the following: (1) aggravation of respiratory and cardiovascular disease; (2) decreased lung function; (3) increased frequency and severity of respiratory symptoms such as difficulty breathing and coughing; (4) increased susceptibility to respiratory infections; (5) effects on the nervous system, including the brain, such as IQ loss and impacts on learning, memory, and behavior; (6) cancer; and (7) premature death. Some sensitive individuals appear to be at greater risk for air pollution-related health effects; for example, those with preexisting heart and lung diseases (e.g., heart failure/ischemic heart disease, asthma, emphysema, and chronic bronchitis), diabetics, older adults, or children [35]. People exposed to acute, high levels of certain air pollutants may experience:

- Irritation of the eyes, nose, and throat
- Wheezing, coughing, chest tightness, and breathing difficulties
- Worsening of existing lung and heart problems, such as asthma
- Increased risk of heart attack [36]

Given cancer's role in morbidity, some recent research findings on associations between air pollution and cancer merit special comment. In 2013 the IARC, a WHO agency, classified outdoor air pollution as carcinogenic to humans. The agency concluded that there was sufficient evidence that exposure to outdoor air pollution causes lung cancer. IARC also noted a positive association with an increased risk of bladder cancer. PM, a major component of outdoor air pollution, was evaluated separately and was also classified as carcinogenic to humans [16]. These were persuasive statements from the world's most respected cancer agency.

A later study by the American Association for Cancer Research in 2016 investigated cancer rates in a cohort of Hong Kong residents. The investigators enrolled 66,280 people who were age 65 or older when they were initially recruited between 1998 and 2001. Researchers followed the study subjects until 2011, ascertaining causes of death from Hong Kong registrations. Annual concentrations of $PM_{2.5}$ at their homes were estimated using data from satellite readings and fixed-site monitors. After adjusting for confounding factors, results showed that for every 10 $\mu g/m^3$ of increased exposure to $PM_{2.5}$, the risk of dying from any cancer rose by 22%. Increases of 10 $\mu g/m^3$ of $PM_{2.5}$ were associated with a 42% increased risk of mortality from cancer in the upper digestive tract and a 35% increased risk of mortality from accessory digestive organs, which include the liver, bile ducts, gall bladder, and pancreas. For women, every 10 $\mu g/m^3$ increase in exposure to $PM_{2.5}$

In 2013, the IARC classified outdoor air pollution as carcinogenic to humans. The agency concluded that there was sufficient evidence that exposure to outdoor air pollution causes lung cancer.

was associated with an 80% increased risk of mortality from breast cancer; and men experienced a 36% increased risk of dying of lung cancer for every 10 μg/m^3 increased exposure to $PM_{2.5}$ [37].

In a study by university of Ottawa researchers, air pollution exposure was linked to lung cancer incidence in nonsmokers. Though cigarette smoking is the number one cause of lung cancer, about 1 in 10 people who develop lung cancer have never smoked. In this study, investigators followed more than 180,000 nonsmokers for 26 years. Throughout the study period, 1100 people died from lung cancer. The participants lived in all 50 U.S. states and in Puerto Rico, and based on their zip codes, the researchers estimated exposure units of μg/m^3 PM. Pollution levels overall averaged 17 units across the study period. After taking into account other cancer risk factors, such as second-hand smoke and radon exposure, the investigators found that for every 10 extra units of PM exposure, a person's risk of lung cancer rose by 15%–27% [38].

However, cancer incidence can be reduced when air pollution levels decrease. The California Air Resources Board (CARB) reported that Californians' overall cancer risk from toxic air pollution declined 76% over more than two decades, a trend the agency attributes to the state's array of air pollution regulations. State scientists measured the drop from 1990 to 2012 by tracking airborne concentrations of the seven toxic air contaminants that are most responsible for increasing cancer risks. Concentrations of diesel PM, the largest contributor to airborne cancer risk in the state, declined more than 68% in California over the 23-year study period, largely because of California's requirements for cleaner diesel fuels and strict emissions control rules for diesel trucks adopted in 2008 [39].

Perspective: The health effects of air pollution are a major global health problem. Decades of health investigations have elucidated myriad effects on public health of pollutants released into ambient (outdoor) air. While early health studies rightly focused on effects on lung function and lung diseases, research on fine PM revealed serious effects on cardiovascular disease. Later, research revealed an association between air pollution and lung and other cancers. However, reductions in air pollution levels can and do reduce or eliminate morbidly and mortality.

8.5.2 Effects on Mortality

While the effects of air pollutants on lungs are, and will remain, significant in terms of the public's health, health evidence emerged that fine PM exerts an even greater public health burden as a contributor to cardiovascular and heart disease. Particularly alarming is the association between PM in air and its contribution to sudden heart failure. Research now implicates moderate levels of air pollution as triggers of fatal heart attacks. It is possible that heart attacks, not lung disease, may be the most serious medical threat posed by ambient air pollution.

For example, Rossi et al. examined air pollution levels for the years 1980–1989 in Milan, Italy, for association with deaths on days of elevated pollution [40]. Among the findings, a significant association was found for heart failure deaths (7% increase/100 μg/m^3 increase in total suspended particulate [TSP]). Similarly, Neas et al. analyzed daily mortality rates among Philadelphia, Pennsylvania, residents from 1973–1980 [41]. Investigators found that a 100 μg/m^3 increase in the 48-h mean level of TSP was associated with deaths due to cardiovascular disease. In another study, investigators examined air pollution levels in Seoul, Korea, and stroke mortality data over a 4-year period [42]. They reported "[t]hat PM(10) and gaseous pollutants are significant risk factors for acute stroke death and that the elderly and women are more susceptible to the effect of particulate pollutants."

Investigators at the University of Southern California investigated a large database in regard to chronic health effects of air pollution [43]. Researchers examined data from 22,906 residents of Los Angeles and adjacent areas. They determined air pollution exposure in 267 different zip codes where participants lived, and compiled causes of death for the 5856 participants who died by the year 2000. The effects of exposure to $PM_{2.5}$ were examined across the study areas. Among participants, for each increase of 10 μg/m^3 of fine particles in the neighborhood's air, the risk of death from any cause rose by 11%–17%. Ischemic heart disease mortality risks rose by 25%–39% for the 10 μg/m^3 increase in air pollution. The investigators believed PM may promote inflammatory processes, including atherosclerosis, in key tissues.

In A study by Harvard School of Public Health investigators, found an increase in overall mortality associated with each 10 μg/m^3 increase in $PM_{2.5}$ modeled as the overall mean or as exposure in the year of death [44]. $PM_{2.5}$ was associated with increased lung cancer and cardiovascular deaths. Of note, the investigators' database included $PM_{2.5}$ levels that had decreased because of environmental controls. Findings showed improved overall mortality rates were associated with decreased $PM_{2.5}$. Although further research is needed to clarify the association between air pollution and fatal heart attacks, there is already sufficient data to move forward with public health prevention actions, such as public awareness and physician education campaigns.

Further troubling findings about the adverse health effects of ambient air ozone was published by Bell et al. [45]. Using data from a national air pollution database, investigators estimated a national average relative rate of mortality associated with short-term exposure to ambient ozone for 95 large U.S. urban communities for the period 1987–2000. Findings showed that a 10-ppb increase in the previous week's ozone was associated with a 0.52% increase in daily mortality and a 0.64% increase in cardiovascular and respiratory mortality. These findings extend the known association between air pollutants and human health impacts, and suggest that current ambient air quality standards should be further lowered in the interest of public health.

Regarding global mortality from air pollution, in 2014 WHO reported that in 2012 around seven million people died—one in eight of total global deaths—as a result of air

In 2014 WHO reported that in 2012 around seven million people died, one in eight of total global deaths, as a result of air pollution exposure. WHO asserted that air pollution is now the world's largest single environmental health risk.

pollution exposure. This finding more than doubles previous estimates and confirms that air pollution is now the world's largest single environmental health risk. In particular, the new WHO data revealed a strong link between both indoor and outdoor air pollution exposure and cardiovascular diseases, such as strokes and ischemic heart disease, as well as between air pollution and cancer. This is in addition to air pollution's role in the development of respiratory diseases, including ARIs and COPD [46]. For comparison, the seven million global deaths caused by air pollution approximates the population of Hong Kong, China in the year 2013.

On a more positive note, a study reported in 2009 by researchers at Brigham Young University and Harvard School of Public Health found that average life expectancy in 51 U.S. cities had increased nearly 3 years over recent decades, with approximately 5 months of that increase attributable to cleaner air. Investigators evaluated the impact of resulting decreases in particulate pollution on average life spans in cities for which air pollution data were available. In cities that had previously been the most polluted air and cleaned up the most, the cleaner air added approximately 10 months to the average resident's life [47].

8.5.3 Effects on Children's Health

The effects of air pollution on children's health is a particularly important subject, as any disease or disability in children reduces their quality of life and that of their parents, and can lead to expensive health care costs and issues of social development. The early work on the relationship between air pollution and children's health was focused on lung function and disease. In an early study Gauderman et al. reported on the effect of air pollution on lung development of children 10–18 years of age [48]. Children ($n = 1759$) recruited from schools in 12 southern California communities served as the study population. Results showed that over the 8-year period of study, deficits in the growth of FEV(1) (forced expiratory volume in 1 s) were statistically significant with exposure to NO_2, acid vapor, $PM_{2.5}$, and elemental carbon. Investigations of air pollution and asthma were an area of continuing interest and research.

The increase in asthma prevalence, particularly in children, has occurred globally, including countries as geographically and culturally diverse as the U.S., Mexico, Denmark, and Australia. According to the CDC 17.7 million adults in the U.S. are diagnosed with asthma, which is 7.4% of the population. Correspondingly, 6.3 million children under age 18 years are diagnosed, which is 8.6% [49]. While estimating the number of people in the world with asthma remains difficult due to the many gaps in the data, WHO's Global Burden of Diseases Study published in 2012 estimated asthma prevalence equated to 334 million people in the world and that the related burden is high [50].

Researchers at the University of Southern California investigated the pollution–asthma link in 208 children who resided in 10 Southern California cities from 1993 onward [51]. Air samplers were placed outside the home of each student in order to measure NO_2 levels. Further, the distance of each child's home from local freeways, as well as how many vehicles traveled within 150 m of the child's home were determined. Aerodynamic models were used to estimate traffic-related air pollution levels at each child's home. Results showed a link between asthma prevalence in the children and NO_2 levels at their homes. For each increase of 5.7 ppb in average NO_2, the risk of asthma increased by 83%. Further, the closer the students lived to a freeway, the higher the students' asthma prevalence. Asthma risk increased by 89% for every 1.2 km (about three-quarters of a mile) closer the students lived to a freeway.

A major study by researchers at the Medical Research Council and Asthma UK Centre in Allergic Mechanisms of Asthma found that 8- and 9-year-olds living in cities with high levels of fumes from diesel cars have up to 10% less lung capacity than normal. Over 6 years, researchers examined the lung function of 2400 children at 25 schools across east London, and found a direct correlation between air pollutant exposure and reduced lung growth. The tests checked the volume of air each child could breathe, as well as levels of inflammation in their lungs, with urine tests to check for heavy metals, which are produced by motor vehicles [52].

In addition to investigations of associations between air pollution and effects on lung function and asthma, additional organ systems and health outcomes gradually accrued. For example, the effect of air pollution on the occurrence of birth defects was reported by Ritz et al. [53]. The investigators reviewed data from the California Birth Defects Monitoring Program on neonates and fetuses delivered in southern California during the period 1987–1993. Monthly exposures to air pollutants were estimated from existing ambient air monitoring stations. Findings showed that odds ratios for cardiac ventricular defects increased in dose–response with increasing prenatal second month CO exposure. Also, second month O_3 exposure was associated with increased risk of aortic artery and valve defects, pulmonary artery and valve anomalies, and spinal defects.

In another study involving children born in California during the period of 1975–1987, birth outcomes were evaluated in regard to prenatal exposure to O_3, CO, and PM. Investigators reported that O_3 exposure during the second and third trimesters of pregnancy and CO exposure during the first trimester were associated with reduced birth weights. Specifically, a 12-ppb increase in 24-h O_3 averaged over the entire pregnancy was associated with a 47.2 g lower birth weight. A 1.4-ppm difference in first trimester CO exposure was associated with a 21.7 g lower birth weight [54].

Researchers at Tel Aviv University reported evidence linking high exposure of air pollution to an increased risk of congenital malformations. For the study, researchers analyzed data on 216,730 people born in Israel between 1997 and 2004. Air pollution, including levels of SO_2, PM_{10}, NO_x, and O_3, were obtained from all monitoring stations during the study period. Researchers analyzed exposure to air pollution during the

first trimester and throughout the entire pregnancy. Findings revealed that exposure to PM_{10} and NO_X pollutants throughout full-term pregnancies was associated with an increased risk of congenital malformations—specifically those related to the circulatory system [55].

In a different kind of reproductive outcome study, researchers at the University of York examined data from 183 countries, extrapolating the impact of maternal exposure to different levels of outdoor pollution on preterm birthrates [56]. The researchers concluded that $PM_{2.5}$ was a "potentially substantial global risk factor" for a baby being born earlier than 37 weeks of gestation, a point in pregnancy that increases the risk of infant mortality and physical and neurological problems. The team calculated that in 2010, exposure to $PM_{2.5}$ was strongly associated with 18% of preterm births globally, or about 2.7 million premature births. The majority of those births were in South and East Asia, the Middle East, and North Africa and West sub-Saharan Africa.

In a German study, the association between air pollution and type-1 diabetes in children was investigated. A study by the Institute for Diabetes Research at the Helmholtz Centre in Munich analyzed data from 671 young patients with type-1 diabetes, recorded between April 2009 and May 2013 in the Bavarian diabetes register DiMelli (Diabetes Incidence Cohort Registry). The focus of the analysis was to compare the time of diagnosis in small children with contact to certain air pollutants around their homes. After controlling for potential confounding factors, the researchers found that small children from residential environments with high levels of ambient air pollution ($PM < 10$, NO_2) developed type-1 diabetes 3 years earlier on average than children in the same age group from areas with low levels of pollution [57].

A series of studies have been reported on associations between air pollution and children's brain processes and mental health. This is a nascent body of research that is reported here, but not elaborated on. Associations between air pollution have been reported for children's mental illness [58], attention deficit [59], brain pathology [60], and autism [61]. It is important to note that the autism association has been challenged by other investigators [62]. For all these studies, additional investigations are needed.

The spectrum of adverse effects in children exposed to air pollution continues to expand. This expansion makes it all the more important to apply public health measures of primary prevention, i.e., hazard interdiction. The primary measure is to eliminate or reduce children's exposure to noxious air pollutants. Findings from a study of young children in California illustrate the health benefits of reduced air pollution levels. In one study, an assessment was made of whether long-term reductions in pollution were associated with improvements in respiratory health among children. As part of the Children's Health Study, investigators annually measured lung function in 2120 children from three separate cohorts corresponding to three separate calendar periods: 1994–1998, 1997–2001, and 2007–2011. Over the 13 years spanned by the three cohorts, improvements in 4-year growth of both FEV1 and FVC were associated with declining levels of NO_2 and of $PM_{2.5}$ and PM_{10}. Further, proportions of children with clinically low FEV1 declined significantly, from 7.9% to 6.3% to 3.6% across the three periods [48].

Globally, the United Nations Children's Fund (UNICEF) reported that about 300 million children in the world breathe highly toxic air pollution, placing them at adverse health effects that can persist for life [63]. For comparison, this number is slightly less than the U.S. population in 2016. The vast majority of these children, about 220 million, reside in South Asia, in places where air pollution is at least six times the level that WHO considers safe.

Another UN agency, the WHO, evaluated the causes of death of young children globally, reporting in 2017 that exposure to polluted environments in 2012 was associated with more than one in four deaths among children younger than 5 years old [64]. Worldwide, 1.7 million children's deaths were attributable to environmental hazards, such as exposure to contaminated water, indoor and outdoor pollution, and other unsanitary conditions. More specifically:

- "570,000 children under 5 years died from respiratory infections, such as pneumonia, attributable to indoor and outdoor air pollution and second-hand smoke—smoke that was released by burning tobacco products, such as cigarettes.
- 361,000 children under 5 years died due to diarrhea, a result of poor access to clean water, sanitation and hygiene.
- 270,000 children died during their first month of life from conditions that could have been prevented through access to clean water, sanitation, and clean air.
- The deaths from malaria of 200,000 children under 5 years could have been prevented through environmental actions, such as reducing breeding sites of mosquitoes.
- 200,000 children under 5 years died from unintentional injuries attributable to the environment, such as poisoning" [64].

Concerning the health risk of individual air pollutants, the EPA has developed a database to assist local, state, tribal, and federal governments involved in air pollution decision making. The National-Scale Air Toxics Assessment (NATA) is a screening tool that estimates cancer and other health risks from exposure to toxic air pollutants, called *air toxics* by the EPA [65]. Air toxics are those air pollutants known or suspected to be carcinogens or known to cause other health effects, such as birth defects or respiratory problems. Risk assessment methods (Chapter 19) are used by the EPA to estimate human health risks from lifetime exposure to air pollutants with year 1999 levels as the baseline for their assessment.

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The EPA released its first NATA, based on year 1996 air emissions data, in year 2002. The second release occurred in 2006, using 1999 national emissions data. The 2006 NATA covers 177 of the CAAct's list of 187 air toxics as well as diesel PM. The assessment includes estimates of cancer or noncancer health effects for the 133 air toxics and diesel PM for which the EPA concluded that sufficient data existed.

Major findings revealed by the 2006 NATA assessment include both national estimates of health risk, as well as health risks associated with individual air pollutants. On a national scale, the 2006 NATA estimates that people in most of the U.S. have a lifetime cancer risk between 1 and 25 in a million due to inhalation exposure to air toxics. The EPA notes that persons residing in transportation corridors can have a risk greater than 50 in a million [65]. For comparison, the EPA estimates the national risk of contracting cancer from exposure to radon is approximately 2000 in a million. Concerning individual air toxins from a national perspective, benzene is the most significant air toxin for which cancer risk could be estimated, contributing 25% of the average individual cancer risk.

For most of the noncancer health effects, estimated exposure levels to the air toxins covered by the 2006 NATA were generally below those of health concern to the EPA. However, more than 92% of the U.S. population has hazard index (HI) values for respiratory toxicity greater than 1.0 and more than 17% have HI values greater than 10. The EPA observes that because these exposures exceed the no-effect level (HI = 1.0), this result suggests that some people may experience an increased risk of respiratory irritation or other adverse respiratory effects from exposure to some air toxins. Of note, acrolein is the most significant air toxin that causes respiratory problems, contributing about 90% of the nationwide average cancer hazard in the year 2006 NATA assessment [65].

The NATA database and findings from research investigations like those cited in this chapter provide public health and environmental protection authorities with essential data from which to set federal, state, and local air pollution control policies.

8.6 ASSOCIATIONS BETWEEN AIR POLLUTION AND ECOSYSTEM HEALTH

Research shows that air pollution may affect ecosystems. Air pollutants such as sulfur may lead to excess amounts of acid in lakes and streams, and can damage trees and forest soils. Nitrogen in the atmosphere can harm fish and other aquatic life when deposited on surface waters. Ozone damages tree leaves and negatively affects scenic vistas in protected natural areas. Mercury and other heavy metal compounds that are emitted into the air from fuel combustion and deposited on land and in water accumulate in plants and animals, some of which are consumed by people [66]. The Massachusetts Department of Environmental Protection has elaborated on the most significant effects of air pollution on ecosystems, as follows [36]:

Acid rain is precipitation containing harmful amounts of nitric and sulfuric acids. These acids are formed primarily by NO_x and SO_x released into the atmosphere when fossil fuels are burned. These acids fall to the Earth either as wet precipitation (rain, snow, or fog) or dry precipitation (gas and particulates). Some are carried by the wind, sometimes hundreds of miles. In the environment, acid rain damages trees and causes soils and waterbodies to acidify, making the water unsuitable for some fish and other wildlife. It also speeds the decay of buildings, statues, and sculptures.

Eutrophication is a condition in a waterbody where high concentrations of nutrients (such as nitrogen) stimulate blooms of algae, which in turn can cause fish kills and loss of plant and animal diversity. Air emissions of NO_x from power plants, cars, trucks, and other sources contribute to the amount of nitrogen entering aquatic ecosystems.

Haze is caused when sunlight encounters tiny pollution particles in the air. Haze obscures the clarity, color, texture, and form of what can be seen. Some haze-causing pollutants (mostly fine particles) are directly emitted to the atmosphere by sources such as power plants, industrial facilities, trucks and automobiles, and construction activities. Others are formed when gases emitted to the air (such as SO_2 and NO_x) form particles as they are carried downwind.

Effects on wildlife. Toxic pollutants in the air, or deposited on soils or surface waters, can impact wildlife in a number of ways. Like humans, animals can experience health problems if they are exposed to sufficient concentrations of air toxins over time. Air toxics can contribute to birth defects, reproductive failure, and disease in animals. Persistent toxic air pollutants (those that break down slowly in the environment) are of particular concern in aquatic ecosystems. These pollutants accumulate in sediments and may biomagnify in tissues of animals at the top of the food chain to concentrations many times higher than in the water or air.

Ozone depletion. In the stratosphere ozone forms a layer that protects life on earth from the sun's harmful ultraviolet (UV) rays. The Earth's ozone layer has been damaged by releases of ozone depleting chemicals, including chlorofluorocarbons, hydrochlorofluorocarbons, and halons. These substances were formerly (and sometimes still are) used in coolants, foaming agents, fire extinguishers, solvents, pesticides, and aerosol propellants. UV can damage sensitive crops, such as soybeans, and reduce crop yields.

Crop and forest damage. Air pollution can damage crops and trees in a variety of ways. Ground-level ozone can lead to reductions in agricultural crop and commercial forest yields; reduced growth and survivability of tree seedlings; and increased plant susceptibility to disease, pests and other environmental stresses (such as harsh weather). Crop and forest damage can also result from acid rain and from increased UV radiation caused by ozone depletion.

Global climate change. Releases of GHGs (Chapter 6) into Earth's atmosphere are causing climate change and impacting human and ecosystem health as a consequence of global temperature rise, increased number and severity of weather events, and impacts on sea life and food production.

Regarding acid rain, the 1990 amendments to the CAAct contain provisions to control acid rain. As previously noted, a marketplace cap and trade policy was implemented by the

EPA as the principal policy to mitigate acid rain. Subsequent studies have shown a dramatic decrease in the emissions of the two primary pollutants that form acid rain. A NASA study found that stringent air regulations and technological improvements reduced NO_2 emissions by 40% and SO_2 emissions by 80% between 2005 and 2014 [67]. In addition to public health benefits, reductions in acid rain have produced ecological benefits. For example, scientists from the U.S. and Canada reported that the acidity of soils in some parts of the Eastern U.S. and Canada has declined, abating years of acid rain's harm to plants and aquatic life by reversing the depletion of a critical nutrient in soil, calcium. Less acidic soil promotes plants' growth and crop yields [68].

Ground-level ozone (O_3) is another important air pollutant, which damages human health and crops. It is estimated that global losses to soybean, maize, and wheat crops due to ground-level ozone pollution could be US$17–35 billion per year by 2030 [69].

8.7 AIR QUALITY MONITORING TECHNOLOGY AND MODELS*

Described in the previous sections of this chapter are the impacts of air pollution on human and ecosystem health. Also described are policies developed for the purpose of preventing these impacts. For both assessment of impacts and development of air pollution policies, air quality data are needed by policymakers and public health authorities. Described in this section is air quality monitoring (AQM) technology, supplemented by air quality models that provide the necessary data.

8.7.1 AQM Technology

While the targets of some air quality monitors may have shifted or expanded, and improvements like onboard memory, digital data transmission, and component miniaturization have allowed monitoring stations to accommodate more equipment with less direct observation by technicians, the majority of the AQM in the U.S. has largely remained unchanged in terms of technology for the last several decades [70,66]. Many existing AQM stations are large (the size of one or more shipping containers), and contain expensive air monitoring equipment that requires a controlled environment in which to operate (such as an air-conditioned shed or trailer). The cost of obtaining and maintaining the instrumentation for, as well as supplying constant power to, these kinds of monitoring stations can be substantial.

In all AQM networks there is, therefore, a compromise between monetary limitations and establishing AQM stations in sufficient density to provide meaningful data. The end result for those trying to protect public health is that there is rarely enough direct observational data to completely cover the population they are trying to protect. There is almost always a need to extrapolate the concentrations of ambient air pollutants at a location of interest from observations that may have been made kilometers away. While this distance is insignificant on a global scale, it can become very meaningful on an urban scale (e.g., [72,73]).

Improvements in design and the availability of more energy efficient equipment have decreased the energy demand of many types of air quality monitors. This has allowed additional (small-scale) monitoring in areas of limited power supply, extended periods of deployment on battery power, and deployment without a constant power supply (as in cases in which power is supplied by a small solar array or wind turbine and a rechargeable battery). In addition, there has been a relatively recent emergence in small, affordable, yet fairly reliable sensors, although new sensor technologies have not yet advanced to the point that they can supplant established monitoring methods (e.g., [74,75]).

An example of one such domestic monitoring program is the Village Green Project of EPA. The project has paired energy efficient, relatively inexpensive monitors (powered by on-board solar and wind generators) with cellular modems, all contained within a park bench structure. The prototype AQM platform/bench provides access to real-time air quality data to the public at large via the web. In addition, the overall appearance of the bench structure (which houses its solar panels in a canopy that provides shade to the bench) mitigates the probability of aesthetic protests to its presence. This allows direct monitoring to occur where people are likely to be, rather than at a more remote location that is less likely to generate complaints [76].

While the majority of the atmospheric monitoring effort has been focused on ambient (outdoor) air, recent reports from the WHO indicate that over four million deaths can be linked to exposure to harmful indoor air pollutants (global annual estimate). To put that in perspective, more deaths are caused by exposure to harmful indoor air pollutants annually than HIV/AIDS, malaria, and tuberculosis *combined* [77]. Understandably, the WHO's reports have refocused global monitoring efforts to include more indoor air monitoring. The improvements and miniaturization of technology discussed above have been integral to creating sampling systems that are small enough to be allowed into people's homes [78,79].

Overall, AQM has very limited predictive capability. To completely prevent exposure to the public via monitoring alone, an event would have to be detected at a monitoring station (observed by a citizen scientist, etc.). The event would then have to be reported immediately to an emergency action network, and the network would have to merge the observed event with meteorological data quickly enough that they could determine the portion of the population at risk of exposure, and then notify that portion of the public of the event with sufficient lead time that they could take protective measures. In practice, emergency action networks and notifications to affected populations can help to mitigate the exposures, but an accurate and predictive model has the potential to completely *prevent* exposures.

* The authors express their appreciation to this section's author, Seth Ebersviller, Ph.D., Assistant Professor of Environmental Safety and Occupational Health Management, University of Findlay, Findlay, OH

8.7.2 Air Quality Modeling

While the importance of the atmospheric models focused on climate change to public health cannot be understated, this section will focus on the troposphere-based models that support most of the regulatory and public health efforts on the regional and urban scale. It is important to note that it is impossible to completely validate a photochemical air quality model against an air shed. There are too many types that are not monitored, are too unstable to be measured, or exist at concentrations too low to be measured by standard AQM equipment. Acceptance of photochemical air quality models, therefore, typically follow rationale such as: "This model is as well-formulated as any model I know and it uses inputs and assumptions more likely than any other set, and therefore, until additional information becomes available that will change the model's formulation or the inputs, it makes sense to act as if this model's forecasts are accurate" [80]. The predictive aspects of air quality modeling, though, warrant the uncertainty by providing warning of potentially harmful events, which allows preventative measures to mitigate the severity of exposures, or to avoid them completely. One must always remember, however, that the predictions are only as good as the models that make them and the emissions inventories or monitoring network that feeds the models [71].

Air quality models vary greatly in scale, complexity, and application. On the surface, though, all air quality models attempt to merge predictions of the pollutants being emitted into the atmosphere with the scientific community's current understanding of the processes that affect their fate in the environment. Conceptually, this is true whether the specific purpose of the model is to predict the amount of volatile organic compounds (VOCs) off-gassing from furniture or the concentration of ozone that will be generated over an urban area if emissions from mobile sources are cut by 5%.

Dispersion models are typically used to predict how pollutants or toxins will disperse downwind of their point of release. Most regulatory bodies use dispersion models as part of their environmental impact assessment when considering new permitting for stationary sources. Emergency management personnel also use dispersion models in emergency planning and response applications. Dispersion models allow them to predict the path most likely to be taken by accidental releases of hazardous material, radiological events, and plumes from fires.

Photochemical air quality models (sometimes called air shed models) have become widely used by regional, state, and central regulatory bodies to predict the effects of perturbations to the current ambient concentrations of pollutants, as well as estimate the effectiveness of proposed changes to pollution control strategies before they are implemented. Photochemical models use extensive lists of chemical species known or likely to be present in an air parcel (called an emission inventory) and apply mathematical calculations that approximate the chemical and physical processes present in the atmosphere. The result is dependent upon the model and parameter used, but usually includes a prediction of at least some of the CAPs included in the NAAQS.

Historically, it has been difficult for air quality modelers to share their advancements because of incompatibilities in their programming and/or model species—problems which still persist today. Due to these issues, for true "apples to apples" comparisons of model outputs, modelers have to translate their programming from one platform to another (which is a time-consuming and tedious task). So, while there is a long and storied history of atmospheric models, and any number of novel current models and reaction mechanisms created by researchers, we will focus on examples that represent the current state of the science and more well-established models (i.e., those maintained by consensus working groups and/or government agencies).

To solidify its regulatory utility, the EPA identified a need for a centralized coordination of development efforts in the realm of atmospheric modeling. In response to this need, in 2001 the EPA contracted with University of North Carolina to form a collaborative, community-oriented cooperative of scientists, modelers, and programmers. The Community Modeling and Analysis System (CMAS) is "a community of environmental and air quality modelers" that creates "open-source, advanced modeling systems, CMAS enables collaborative development and linking of models for meteorology, emissions, air quality, hydrology, and environmental and health effects" [81].

The Master Chemical Mechanism (MCM) is definitely of note in the realm of atmospheric modeling. The MCM (managed by the University of Leeds, UK) is an attempt to generate a nearly explicit tropospheric chemical mechanism describing the complete gas-phase reactions of primary VOCs, including their resultant generation of ozone and other secondary pollutants. This daunting task is an attempt to minimize the modeling species present in the atmospheric chemistry mechanism, thereby increasing the model's utility in predicting species important to protecting public health. The mechanism itself only includes the atmospheric chemical processes, but has been incorporated into air shed models around the world [82].

8.7.3 Where Monitoring and Modeling Meet: Policy

Historically, there has been a divide between the AQM and air quality modeling communities. It is vital to remember, though, that all monitoring and modeling implementations have a yin and yang relationship. Without monitoring data with which they can compare their outputs, models would have no way to check their predictions. Likewise, secondary species (such as hydroxyl radicals and ozone) are not emitted by any source. Without modeling, therefore, monitoring networks are largely incapable of assigning responsibility for secondary species to a single source within (or external to) their air shed. When they work collaboratively, monitoring and modeling can provide insights into the behavior of atmospheric systems that would not be possible for one field alone—such as the migration of air pollution from mainland China to the west coast of the U.S. [83]

Dramatic revisions were made to the CAAct in 1990, at which time the scope of the EPA's monitoring and regulatory missions were expanded, and roles were created and/or

expanded for local and tribal governments (though tribal governments can only develop and implement the parts of the CAAct that are appropriate for their lands) [71,84].

When a state or region is found to be in exceedance of regulatory limits on airborne pollutants, they must submit a state implementation plan (SIP) to the federal government. A SIP is a detailed plan in which the local agency outlines proposed strategies for reducing emissions from sources under its regulatory purview to reattain compliance with the NAAQS within a prescribed amount of time. The EPA is responsible for reviewing and either accepting or rejecting state, tribal, and local agency SIPs. If a SIP does not provide sufficient evidence supporting its proposed policy changes, or if the proposed changes fail to meet the necessary requirements within a prescribed amount of time, the EPA can issue sanctions against the state and, if necessary, assume enforcement of the CWAct in that area [71,84]. Under the CWAct, the local agency is required to hold stakeholder meetings and open comment periods to allow the public (as well as local industries) an opportunity to comment on their proposed strategies while they are still in their draft stage.

Exceedingly few environmental systems are linear in nature. What may seem to be an "easy" policy fix may, when the new policy is implemented, have limited beneficial effect. Local agencies are required, therefore, to use photochemical air quality models to generate short- and long-term predictions of the outcomes for their proposed remediation strategies in support of their SIPs. The modeling component of the SIP allows local regulatory bodies to investigate the probable effects of proposed policy changes before they are implemented, which helps local agencies avoid prolonged elevated exposures to the population if their first proposed strategies have unanticipated effects. By implementing the most effective emission reduction policy the first time, the local government saves money as well as time, and can provide incentives for local citizens and industries to comply with the new policies [71,84].

8.8 POLICIES ON AIR POLLUTION CONTROL

The history of air pollution demonstrates that when societies experience what is perceived as excessive air pollution, polices will eventually flow from this discontent. Policies can range from decisions made by individuals (e.g., annual vehicle emissions maintenance) to global policies that involve international agreements on controlling air pollution. National policies on air pollution control have occurred globally, as well as within the U.S. The CAAct, as amended, is an example. While the form and details of air pollution control policies may differ, there is common harmony on implementing actions that will protect public health. Societies afflicted with noxious air pollution do not remain silent. Complaints arise and are made known to policymakers, who in response develop policies that are intended to control the sources of pollution. Without the complaints of persons exposed to objectionable levels of air pollution, little effort would have occurred, because control of sources runs against the grain of economic benefits derived from the sources of pollution. For example, adding pollution controls to automobiles added costs to their manufacture, resulting in increased costs to the consumer. Similarly, requiring pollution controls on electric power plants adds to the cost of electricity paid by the consumer. These costs of pollution control must be considered in light of the benefits derived from decreased effects on human and ecosystem health.

This section describes policies on control of air pollution. Attention is given to the CAAct, as amended, given this act's key role in controlling air pollution in the U.S. Also described are the air pollution struggles in two countries with emerging global economies, China and India, and where air pollution polices are nascent.

8.8.1 U.S. Primary Policy: CAAct, 1955

The CAAct, as amended, is the central environmental health policy on air pollution control in the U.S. This is a complex, comprehensive law that impacts human and ecosystem health throughout the U.S. as well as globally. Regarding the latter, the CAAct has served as a model for comparable policies in part or whole in Europe and elsewhere. Further, air pollution in the U.S. eventually traverses international borders and can add to locally generated pollution levels. This section presents a précís summary of the CAAct, its key elements that related to public health, and policy issues that attend the act's administration and application.

8.8.1.1 History of the CAAct

Pollution of the air we breathe is a problem that likely dates from antiquity, perhaps from the time when humans first came into contact with smoke from fires. One source cites an action in the year 1306 when citizens of London petitioned their government to take action to reduce levels of smoke in ambient air. In response, King Edward I issued a royal proclamation to prohibit artificers (i.e., craftsmen) from burning sea coal, as distinguished from charcoal, in their furnaces [86]. This is an example of government taking action against the effects of air pollution, which can be defined as the contamination of the atmosphere by gaseous, liquid, or solid wastes. Given this fourteenth century example of one government's attempts to improve citizens' air quality, it is not surprising to learn that in the twentieth century the U.S. public's concern about air pollution also led to legislative action.

It is ironic that U.S. federal air pollution control legislation was influenced by a "killer smog"* that occurred in London during the winter of 1952, an event in which it was first reported that more than 4000 people died from breathing polluted air caused by a temperature inversion.† However, a reassessment of mortality data for December 1952–February 1953 found that more than 12,000 excess deaths occurred due to acute exposure to heavily contaminated ambient air. The

* The word *smog* was first recorded in 1905 in a newspaper report of a meeting of the Public Health Congress, where Dr. H.A. des Vœux gave a paper entitled "Fog and Smoke" in which he coined the word smog [86].

† A temperature inversion, which occurs when a cold layer of air settles under a warmer layer, can slow atmospheric mixing and allow pollutants to accumulate hazardously near ground level.

primary constituent in the polluted air was smoke from home heating coal-burning stoves and fireplaces.

The state of California provided early and sustained leadership on controlling air pollution. Many of the state's concerns were focused on air pollution in Los Angeles. In 1943, the first recognized episodes of smog occurred in Los Angeles, resulting in limited visibility of approximately three blocks and reports of eye irritation, respiratory discomfort, nausea, and vomiting. The source of the pollution was unknown, but speculated to be an industrial facility. In 1947, California Governor Earl Warren signed into law the Air Pollution Control Act, which authorized the establishment of an air pollution control district (APCD) in every California county, leading to creation of the Los Angeles County APCD, the first of its kind in the U.S. [4]. This is an example of a state taking action to control an environmental hazard before similar action was taken by the federal government. In 1952, Dr. Arie Haagen-Smit, a professor of chemistry at the California Institute of Technology, discovered the nature and causes of photochemical smog. He determined that nitrogen dioxides and hydrocarbons in the presence of UV radiation from the Sun forms smog, a key component of which is ozone.

As described by Fromson [85], the first serious congressional recognition of the need for air pollution control occurred with the Air Pollution Control Act of 1955. This act provided research and technical assistance for the control of air pollution. The tragic events of London's killer smog in 1952 also raised awareness of the need to address the growing air pollution problem in the U.S. A similar episode of fatal air pollution had occurred during October 23–30, 1948, in Donora, Pennsylvania, where 20 people died and half the city's 12,000 residents became ill from breathing industrial contaminants trapped under a layer of temperature-inverted air [87].

The Air Pollution Control Act of 1955 declared that states had the primary responsibility for air pollution control. The federal government's role was advisory, providing technical services and financial support to state and local governments. The U.S. Department of Health, Education and Welfare was vested with these responsibilities under the Act.

The next major federal air pollution legislation occurred with the enactment of the CAAct Amendments of 1963. Whereas the Air Pollution Control Act of 1955 was primarily limited to research and technical and financial assistance to state and local governments, the CAAct Amendments enhanced federal responsibility for controlling air pollution. At the same time, the act continued Congress's intent that "[t]he prevention and control of air pollution at the source is the primary responsibility of state and local governments" [86].

The Clean Air Act requires the EPA to set mobile source limits, ambient air quality standards, standards for new pollution sources, and significant deterioration requirements, and to focus on areas that do not attain standards [86].

Following passage of the CAAct Amendments of 1963, the attention of Congress and environmental groups turned to air pollution caused by automobile emissions [86]. Given the passage of time, it may be difficult for some persons to comprehend the incredulity that accompanied the discovery in California of automobiles' contribution to air pollution, and, more specifically, smog. The discovery of vehicle emissions as the primary constituents of Los Angeles' smog prompted federal laboratory research that found increased cancer rates in cancer-resistant mice. These findings were the subject of a 1962 report to Congress from Surgeon General Luther L. Terry. The report added weight to the need for further congressional action to control air pollution.

In 1965, Congress enacted the Motor Vehicle Air Pollution Control Act. The act required federal standards to be promulgated for controlling pollutants emitted from automobiles. The emission standards were to be established on the basis of "technological feasibility and economic costs" of controlling automobile emissions [87]. Upon promulgation of the emission standards, manufacturers of new motor vehicles or new motor engines were prohibited from selling or importing a nonconforming product into commerce.

The federal CAAct was enacted by Congress in 1970, heavily amended in 1977, and again substantively amended in 1990 (Table 8.3) [89]. The Act's titles are listed in Table 8.4 [89]. The effects of unclean air on the public's health remain key motivations for keeping the act enforced. The Act, as amended, is a comprehensive, complex statute that controls air pollution emissions and regulates government, business, and community lifestyles that affect the releases of air contaminants into outdoor ambient air.

The CAAct adopted the policy of developing NAAQS for individual air contaminants; then placed most of the responsibility on the states to achieve compliance with the standards. The CAAct established two kinds of national air quality standards. *Primary standards* are based on protection of human health, including the health of sensitive populations such as children, elderly persons, and persons with infirmities (e.g., asthma). *Secondary air quality standards* set limits to protect public welfare, including protection against decreased visibility, damage to buildings, and deleterious ecological effects.

The 1977 CAAct amendments added special provisions for geographic areas with air cleaner than national standards in order to prevent their deterioration in air quality, and special provisions were added pertaining to *nonattainment areas*; that is, geographic areas that had failed to meet national air quality standards [88]. Under the 1977 amendments to the CAAct, states were required to develop SIPs that would meet the air quality standards by 1982, except for ozone, for which the deadline was 1987 [89].

The 1990 CAAct amendments substantively revised the earlier version of the CAAct. Signed into law on November 15, 1990, by President George H.W. Bush, these amendments added comprehensive provisions to regulate emissions of air toxicants, acid rain, and substances thought to be a threat to the ozone layer. In addition, the 1990 amendments added an elaborate permit program and markedly strengthened enforcement provisions and requirements for geographic areas that fail to meet air quality standards (i.e., nonattainment areas),

TABLE 8.3
Clean Air Act and Amendments

Year	Act	Year	Act
1955	Air Pollution Control Act	1973	Reauthorization
1959	Reauthorization	1974	Energy Supply and Environmental Contamination Act
1960	Motor Vehicle Exhaust Study	1977	Clean Air Act Amendments
1963	Clean Air Act Amendments	1980	Acid Precipitation Act
1965	Motor Vehicle Air Pollution Control Act	1981	Steel Industry Compliance Extension Act
1966	Clean Air Act Amendments	1987	Clean Air Act 8-Month Extension
1967	Air Quality Act	1990	Clean Air Act Amendments
1970	Clean Air Act Amendments	1995–6	Minor Technical Adjustments

Source: McCarthy, J.E. et al., Clean air act. Summaries of environmental laws administered by the EPA, Congressional Research Service, Washington, DC, 1999.

TABLE 8.4
Clean Air Act's Titles

Title	Name of Title
I	Air Pollution Prevention and Control
II	Emission Standards for Moving Sources
III	General
IV	Acid Deposition Control
V	Permits
VI	Stratospheric Ozone Protection

Source: McCarthy, J.E. et al., Clean air act. Summaries of environmental laws administered by the EPA, Congressional Research Service, Washington, DC, 1999.

mobile source emissions, and automobile fuels [88]. Of special relevance to children's health, these amendments finally banned the sale in the U.S. of gasoline that contained lead additives, ending one of the twentieth century's worst environmental health missteps, the use of tetraethyl lead as a gasoline additive.

The 1990 amendments also changed the way hazardous air pollutants are regulated. In effect, the Act, as amended, recognizes two kinds of outdoor ambient air pollutants: the six CAPs and, basically, everything else. The latter category comprises what are called *Hazardous Air Pollutants* (HAPs). Before 1990, regulation of HAPs was a two-step process. The EPA had to first establish that a pollutant was likely to be hazardous at ambient levels. Once this determination was made (and survived an elaborate hearing process), the second step was to choose the emission sources to be regulated.

Congress became increasingly impatient with the EPA's science and risk-based approach for regulating HAPs, because under the pre-1990 CAAct, only a handful of HAPs had been regulated. Sharply curtailing the EPA's discretion on how to regulate HAPs, Congress specified more than 180 HAPs in the Act. Moreover, with respect to these substances, Congress shifted the burden of proof. "Whereas before, EPA had to go through an elaborate process to prove a compound guilty before it could be regulated, now EPA must go through an elaborate process to prove a compound innocent before it can avoid regulation. Secondly, Congress required that maximum available control technology (MACT) be installed on all sources, regardless of extent of resulting exposure or toxicity. Risk assessment has been related to a residual risk provision that provides for additional action should MACT controls still leave a risk to the maximally exposed individual beyond a relatively stringent level. This shift of the burden of proof requirement of MACT across the board and downgrading of the importance of risk assessment clearly falls within the Precautionary Principle, as does the use of a stringent risk criterion and of the maximally exposed individual rather than the population as the target of concern" [88].

The 1990 CAAct amendments also contained a significant environmental policy now called *cap and trade*, a marketplace incentive that was introduced in Chapter 6. In the CAAct amendments, Congress, concerned that acid rain generation and deposition was causing consequential detrimental environmental effects on ecosystems, directed the EPA to implement a marketplace approach to reducing sulfur dioxide emissions, the main ingredient of acid rain.

On March 10, 2005, the EPA announced the Clean Air Interstate Rule (CAIR). Through the use of the cap and trade approach, CAIR targeted substantial reductions in levels of sulfur dioxide (SO_2) and nitrogen oxides (NO_X) emissions in more than 450 counties in the eastern U.S. and helped them meet the EPA's air quality standards for ozone and fine particles. CAIR covered 28 eastern states and the District of Columbia. States were to achieve the required emission reductions by using one of two compliance options: (1) meet the state's emission budget by requiring power plants to participate in an EPA-administered interstate cap and trade system that caps emissions in two stages, or (2) meet an individual state emissions budget through measures of the state's choosing.

8.8.1.2 Key Provisions of the CAAct Relevant to Public Health

TITLE I—AIR POLLUTION PREVENTION AND CONTROL

Part A—Air Quality and Emissions Limitations

§109: EPA must promulgate primary National Ambient Air Quality Standards (NAAQS) necessary to protect the public health, allowing for an adequate margin of safety and promulgate secondary NAAQS to protect the public welfare, which includes "effects on soils, water, crops, animals, weather, visibility, economic values, and personal comfort and well-being" (§302(h)). §110: Each state must submit State Implementation Plans (SIPs) to EPA for the implementation, maintenance, and enforcement of primary and secondary NAAQS. §110©: EPA must promulgate a federal implementation plan if a state fails to submit a SIP or revise a SIP that EPA deems inadequate. §111(a)(2): The term "new source" means any stationary source, the construction or modification of which is commenced after the publication of regulations prescribing a standard of performance under this section which will be applicable to such source. (4) The term "modification" means any physical change in, or change in the method of operation of, a stationary source which increases the amount of any air pollutant emitted by such source or which results in the emission of any air pollutant not previously emitted. §112: National Emission Standards for Hazardous Air Pollutants—§112(b): The CAAct lists 189 Hazardous Air Pollutants (HAPs) and directs EPA to periodically revise the list. EPA must publish and periodically modify a list of categories and subcategories of major and area sources of HAPs, which are defined in §112(a). §§112(d)(1): EPA must promulgate emission standards for categories and subcategories of major and area sources of HAPs. §112(d)(2): The standards must require the maximum degree of reduction in HAP emissions achievable for new or existing sources in the category or subcategory. §112(d)(5): EPA may promulgate area source standards that provide for using generally available control technologies or management practices in lieu of meeting the §112(d)(2) requirements. §112(e), (I): Strict deadlines are set for promulgation of, and compliance with, the emission standards. §112(f): EPA must report to Congress on residual risks to public health remaining after application of the emission standards. If Congress fails to act, EPA must promulgate additional standards. EPA must promulgate residual risk standards for pollutants classified as known, probable, or possible human carcinogens if the §112(f) emission standards fail to reduce the lifetime cancer risk of the "most exposed" individual to less than one-in-one million. §112(g)(2): Source modifications must comply with maximum achievable control technology. §113: EPA is authorized to issue administrative compliance and penalty orders, and seek injunctions and civil and criminal penalties. §179(b) authorizes the EPA Administrator to "[i]mpose a prohibition, applicable to a nonattainment area, on the approval by the Secretary of Transportation of any projects or the awarding by the Secretary of any grants, under Title 23, United States Code, other than projects or grants for safety." §182(C)(c)(6): De Minimis rule.* The new source review provisions under this part shall ensure that increased emissions of volatile organic compounds resulting from any physical change in, or change in the method of operation of, a stationary source located in the area shall not be considered de minimis for purposes of determining the applicability of the permit requirements established by the act [.]. §211(k): EPA is required to promulgate regulations that establish requirements for reformulated gasoline to be used in gasoline fueled vehicles in specified nonattainment areas.

Part B—*Ozone Protection*. The 1990 Amendments replaced Part B with Title VI

Part C—Prevention of Significant Deterioration of Air Quality

§161: SIPs must contain requirements to prevent significant deterioration of air quality in regions designated as attainment or unclassifiable. §§162, 164(a): A three-tiered classification system is established. Class I areas, which are subject to the greatest emission limitations, include national parks exceeding 6000 acres and national wilderness and memorial parks exceeding 5000 acres. All other areas are classified as Class II areas, except that such areas may be redesignated as Class III areas in certain limited circumstances. §165: Preconstruction permits are required for the construction in Prevention of Significant Deterioration (PSD) areas of "major emitting facilities" on which construction began after 7 August 1977. §165(a)(4) Permits must require facilities to employ best available control technology (BACT)

ENFORCEMENT EXAMPLE

(Washington, DC—July 18, 2016) EPA and the U.S. Department of Justice announced a $425 million settlement with subsidiaries of Tesoro Corp. and Par Hawaii Refining that will increase public health protections by reducing air pollution at six refineries and resolving alleged Clean Air Act violations at those same refineries. Under the settlement, the companies will spend about $403 million to install and operate pollution control equipment and Tesoro will spend about $12 million to fund projects that will improve public health in local communities previously impacted by pollution. Tesoro will also pay a civil penalty of more than $10 million to resolve its alleged Clean Air Act violations [81a].

* Short for *de minimis non curat lex*: the law takes no account of trifles. The phrase "de minimus" literally means "of minimum impact." A de minimis standard exempts producers of environmental pollution if the amounts are below some level thought by regulatory agencies to be without public health or environmental consequence [32].

for regulated pollutants. §166(a): EPA must promulgate regulations to prevent the significant deterioration of air quality resulting from hydrocarbon, carbon monoxide, photochemical oxidant, and nitrogen oxide pollution emissions. §167: Allows EPA to enforce Prevention of Significant Deterioration (PSD), including prohibition of construction of facilities. §169A(a): EPA must promulgate regulations to address the impairment of visibility in Class I areas resulting from man-made air pollution.

Part D—Plan Requirements for Nonattainment Areas
§107(d): States are divided into areas; areas are designated as attainment, nonattainment, or unclassifiable. §172(a): Nonattainment areas are further classified based on severity of nonattainment and the availability and feasibility of pollution control measures necessary for attainment. §172(a)(2): Nonattainment areas for primary NAAQS must achieve attainment as expeditiously as practicable, but not later than 5 years after designation. Nonattainment areas for secondary NAAQS must achieve attainment as expeditiously as practicable. EPA may extend the attainment deadlines in certain cases. §172©: Requirements for the content of nonattainment-area SIPs are set forth. §173©: Before a new major stationary source, or a modification to an existing source, may be constructed in a nonattainment area, offsetting emission reductions must be obtained from the same source or other sources in the same nonattainment area. §181–192: Special provisions exist for areas that are nonattainment for ozone, carbon monoxide, PM, sulfur oxides, nitrogen dioxide, and lead.

Title II—Emission Standards for Moving Sources
§§202(a)(b): EPA must establish emission standards for new motor vehicles and engines, subject to specified limitations for hydrocarbon, carbon monoxide, and NO_X emissions by "light-duty" vehicles. EPA may set standards for heavy-duty vehicles after model year 1983, reflecting the greatest degree of emission reduction achievable for that model year. §211: EPA may require motor vehicle fuels to be registered and tested. §211(a): No manufacturer or processor may sell any EPA-designated fuel or additive that has not been registered by EPA. §219(k)(2)(D): Heavy Metals–The gasoline shall have no heavy metals, including lead and manganese. §246: SIPs for states in certain ozone and carbon monoxide nonattainment areas must require a specific percentage of fleet vehicles to be "clean fuel vehicles," beginning with model year 1998.

Title III—General
§304: Except as provided in this subsection, any person may commence a civil action on his own behalf against any person (including the U.S. or any other governmental instrumentality or agency) who is alleged to have violated or to be in violation of (A) an emission standard or limitation under the CAAct or (B) an order issued by the Administrator or a state with respect to such a standard or limitation. §312: The Administrator, in consultation with specified other federal agents, must conduct a comprehensive analysis of the impact of this act on the public health, economy, and environment of the U.S. §312(a): No grant which the Administrator is authorized to make to any applicant for construction of sewage treatment works in any area in any state may be withheld, conditioned, or restricted by the Administrator on the basis of any requirement of this Act, except as provided in §312(b). §318A(b): Before publication of notice of proposed rulemaking with respect to any standard or regulation to which this section applies, the Administrator must prepare an economic impact assessment respecting such standard or regulation. §319: Not later than 1 year after the date of enactment of the CAAct Amendments of 1977 and after notice and opportunity for public hearing, the Administrator must promulgate regulations establishing an AQM system throughout the U.S.

Title IV—Acid Deposition Control
§401(b): The stated goal is to reduce annual sulfur dioxide emissions from fossil fuel-fired electric power plants by 10 million tons below 1980 levels and annual NO_X emissions by 2 million tons below 1980 levels. §404(a): In Phase I, beginning January 1, 2000, 110 plants will receive allowances to emit SO_2 based on 1985–87 fuel consumption. §403(b): In Phase II, beginning January 1, 2000, utilities will receive reduced SO_2 allowances, totaling 8.9 million tons. Allowances may be used, sold, or carried forward. §407: EPA must establish NO_X emission limits for certain types of boilers and issue revised New Source Performance Standards (NSPS) for NO_X emissions from fossil fuel-fired steam-generating units (§111).

Title V—Permits
§172(c): Sources required to obtain permits include "major sources," "affected sources," sources subject to CAAct §111, air toxic sources regulated under CAAct §112, sources required to have new source or modification permits under Title I Parts C or D, and other sources designated by EPA. §§ 502(a),(b),(d): EPA must promulgate standards for a state-administered permit program. States must submit permit programs to EPA for approval.

Title VI—Stratospheric Ozone Protection
§602(a), (b): EPA must publish and revise lists of ozone-depleting substances, designating them Class I or Class II. §604, §605: The Class I list must include specified chlorofluorocarbons, halons, carbon tetrachloride, and methyl chloroform. The Class II list must initially include specified hydrochloroflurocarbons. Class I substances are to be phased out by January 1, 2000 (January 1, 2002, for methyl chloroform) and Class II substances by January 1, 2030 (subject to certain exceptions).

* * *

An environmental health policy of note concerns what is called *New Source Review*. The 1977 CAAct amendments contained a provision (Title I, Part A, §111), called the New Source Review

(NSR), that gained relatively little attention until the 1990s. The NSR applies when electric power companies make renovations to their facilities and operations. Under the provision, such plants can be considered as newly built plants and therefore must meet more stringent emission standards. The amount of pollution and the amount of electricity produced by older electricity generating units compound the problem of how to adequately implement the CAAct's NSR provisions. Under provisions in the CAAct, EPA requires electricity generating units built or modified after August 17, 1971, to meet uniform national emissions standards for regulated substances emitted from the units. The General Accounting Office (GAO)* found that 1396 older electricity generating units, those built or modified after August 17, 1971, still operate. These older electricity generating plants emitted 59% of the sulfur dioxide, 47% of the carbon dioxide, and 42% of the carbon dioxide from fossil fuel units in year 2000, while generating 42% of all electricity produced by fossil fuel units [90].

For approximately 20 years, the EPA interpreted the CAAct as permitting electric utilities to undertake routine maintenance, repair, and replacement activities. In 1996, the Clinton-era EPA proposed rules to reform the NSR, followed in 1999 by litigation against seven utilities companies, alleging that they had engaged in modifications of electric generation units without first obtaining NSR permits. The litigated utilities rebutted the EPA's claims by asserting that their renovations did not meet NSR requirements [91]. Later, in 2003, the EPA announced it would drop investigations into 70 power plants for past violations of the CAAct, deciding, rather, to judge the power plants on the basis of new, less stringent air pollution rules set under the NSR regulations [92].

On June 13, 2002, the EPA announced changes to the NSR provision; its Administrator stating, "EPA is taking actions now to improve NSR and thereby encourage emissions reductions" [93]. The EPA asserted that the proposed changes would make it easier for companies to make modifications in plant operations and maintenance, but without triggering the NSR provision. The companies would be permitted to operate as long as air emissions were not increased. It seems noteworthy that the EPA announcement contains no language suggesting that older utility plants would be expected to bring themselves into compliance with emission standards expected of new plants.

Following considerable litigation and changes in policy by the EPA, the NSR process has stabilized. At its core, the NSR process is a permitting policy. New sources are evaluated in accord with EPA regulations and a NSR review follows. There are three types of NSR permitting requirements. A source may have to meet one or more of these permitting requirements [94].

1. PSD permits are required for new major sources or a major source making a major modification in areas that meet the NAAQ Standards;
2. Nonattainment NSR permits are required for new major sources or major sources making a major modification in areas that do not meet one or more of the NAAQ Standards; and
3. Minor source permits.

The EPA establishes the basic requirements for an NSR program in its federal regulations. States may develop unique NSR requirements and procedures tailored for their air quality needs as long as the program is at least as stringent as the EPA's requirements. The EPA must approve these programs in the SIP. Other states may be delegated the authority to issue permits on behalf of the EPA and are often referred to as "delegated states."

Permits are legal documents that facility owners and operators must follow. NSR permits specify what construction is allowed, emission limits, and often how the source must be operated. Most NSR permits are issued by state or local air pollution control agencies. In some cases, the EPA will issue permits directly.

In another area of policy implementation under the CAAct, the George W. Bush administration implemented major changes for regulating emissions from diesel engines. The two major emission components of greatest relevance to human health are PM and sulfur. The Clean Air Nonroad Diesel Rule, adopted in 2004, requires off-road equipment powered by diesel engines to meet stringent new air pollution regulations [95]. Such equipment is found in construction, agricultural, and industrial equipment. The EPA asserts that this rule will remove about 99% of the sulfur in sources of diesel fuel, which in turn will effect a lower emission of PM from diesel engines. The Clean Air Nonroad Diesel Rule complements EPA's Clean Diesel Truck and Bus Rule of December 21, 2000. The latter rule requires diesel-powered trucks and buses to dramatically lower emissions from diesel engines. The agency also estimates that the overall benefits of the nonroad diesel program will outweigh the costs by a ratio of 40 to 1 [95]. The EPA opines that the benefits to public health of reduced diesel engine pollution will be significant and beneficial, particularly to individuals with lung disease or respiratory impairment.

* * *

Having given excerpts from the CAAct, it is useful to provide a short EPA summary of the act [96]. The CAAct is the comprehensive federal law that regulates air emissions from stationary and mobile sources. Among other things, this law authorizes EPA to establish National Ambient Air Quality Standards (NAAQS) to protect public health and public welfare and to regulate emissions of hazardous air pollutants.

One of the goals of the act was to set and achieve NAAQS in every state by 1975 in order to address the public health and welfare risks posed by certain widespread air pollutants. The setting of these pollutant standards was coupled with directing the states to develop state implementation plans (SIPs), applicable to appropriate industrial sources in the state, in

* The GAO Human Capital Reform Act of 2004 changed the agency's name to Government Accountability Office, effective July 7, 2004 [90a].

order to achieve these standards. The act was amended in 1977 and 1990 primarily to set new goals (dates) for achieving attainment of NAAQS since many areas of the country had failed to meet the deadlines.

§ 112 of the CAAct addresses emissions of hazardous air pollutants. Prior to 1990, CAA established a risk-based program under which only a few standards were developed. The 1990 CAAct Amendments revised § 112 to first require issuance of technology-based standards for major sources and certain area sources. "Major sources" are defined as a stationary source or group of stationary sources that emit or have the potential to emit 10 tons per year or more of a hazardous air pollutant or 25 tons per year or more of a combination of hazardous air pollutants. An "area source" is any stationary source that is not a major source.

For major sources, § 112 requires that EPA establish emission standards that require the maximum degree of reduction in emissions of hazardous air pollutants. These emission standards are commonly referred to as "maximum achievable control technology" or "MACT" standards. Eight years after the technology-based MACT standards are issued for a source category, EPA is required to review those standards to determine whether any residual risk exists for that source category and, if necessary, revise the standards to address such risk.

8.8.1.3 EPA's Air Quality Index

A good illustration of an intersection between environmental policy and public health practice is the EPA's AQI [97]. As developed by EPA, the AQI is a scale of 0–500, divided into several color-coded categories. A region's AQI score at any time is based on the highest of five CAPs: PM, SO_2, CO, NO_2 and ground-level O_3. The intervals and the terms describing the AQI air quality levels are as shown in Table 8.5. Using the state of Georgia as an example, the Ambient Monitoring Program at the Georgia Environmental Protection Division (EPD), Air Protection Branch, is responsible for measuring air pollutant levels throughout the state. When these levels are reported, the EPD utilizes the AQI to gauge their public health importance and make adjustments to applicable air quality programs.

AQI figures inform the public about whether air pollution levels in a particular location are Good, Moderate, Unhealthy for Sensitive Groups, Unhealthy, or Very Unhealthy. In addition, the AQI can inform the public about the general health effects associated with different pollution levels and describe possible precautionary steps to take if air pollution rises into the unhealthy ranges. Local news media provide alerts when AQI levels are unhealthy, which helps individuals make health-based decisions in support of daily activities. The AQI construct has become a useful metric globally, although some differences exist in deriving AQIs.

8.8.1.4 CAAct Regulations on GHGs

As described in Chapter 6, the EPA has promulgated regulations under the provisions of the CAAct, as amended, to control air emissions that contribute to climate change. Also discussed in Chapter 6, many of these regulations were subject to litigation, with outcomes generally favorable to EPA. The agency has undertaken a comprehensive approach to developing standards for GHG emissions from mobile and stationary sources under the CAAct. The following are the key proposed or completed actions taken by the EPA to implement CAAct requirements for carbon pollution and other GHGs [98].

Clean Power Plan: On August 3, 2015, the EPA issued the Clean Power Plan, which put the nation on track to cut harmful pollution from the power sector by 32% below 2005 levels, while also cutting smog-and soot-forming emissions that threaten public health by 20%.

Final GHG Tailoring Rule: On May 13, 2010, the EPA set GHG emissions thresholds to define when permits under the NSR PSD and Title V Operating Permit programs are required for new and existing industrial facilities. This final rule "tailors" the requirements of these CAAct permitting programs to limit covered facilities to the nation's largest GHG emitters: power plants, refineries, and cement production facilities.

Timing of Applicability of the PSD Permitting Program to GHGs: On December 23 2010, the EPA issued a series of rules that put the necessary regulatory framework in place to ensure that (1) industrial facilities can get CAAct permits covering their GHG emissions when needed and (2) facilities emitting GHGs at

TABLE 8.5
AQI Values and their Meanings

AQI Values	Levels of Health Concern	Colors
When the AQI is in this range	…air quality conditions are:	… as symbolized by this color
0–50	Good	Green
51–100	Moderate	Yellow
101–150	Unhealthy for sensitive persons	Orange
151–200	Unhealthy	Red
201–300	Very unhealthy	Purple
301–500	Hazardous	Maroon

Source: EPA (Environmental Protection Agency), Learn about new source review, Office of Air and Radiation, Research Triangle Park, NC, 2016.

levels below those established in the Tailoring Rule do not need to obtain CAAct permits.

EPA and National Highway Traffic Safety Administration (NHTSA) Standards to Cut GHG Emissions and Fuel Use for New Motor Vehicles: The EPA and the NHTSA are taking coordinated steps to enable the production of a new generation of clean vehicles—from the smallest cars to the largest trucks—through reduced GHG emissions and improved fuel use.

Renewable Fuel Standard (RFS) Program: The EPA is also responsible for developing and implementing regulations to ensure that transportation fuel sold in the U.S. contains a minimum volume of renewable fuel. By 2022, the RFS program is estimated to reduce GHG emissions by 138 million metric tons.

Landfill Air Pollution Standards: On August 14, 2015, the EPA issued two proposals to further reduce emissions of methane-rich gas from municipal solid waste landfills. The proposals would require new, modified, and existing landfills to begin capturing and controlling landfill gas at emission levels nearly a third lower than current requirements.

Oil and Natural Gas Air Pollution Standards: The EPA has proposed a suite of requirements that provide greater certainty about CAAct permitting requirements for the oil and natural gas industry. The proposals are part of the EPA's strategy to reduce emissions of the methane and smog-forming volatile organic compounds from this rapidly growing industry.

Geologic Sequestration of Carbon Dioxide: Geologic sequestration is the process of injecting CO_2 from a source, such as a coal-fired electric generating power plant, into a well thousands of feet underground and sequestering the CO_2 underground indefinitely. The EPA has finalized requirements for geologic sequestration, including the development of a new class of wells.

GHG Endangerment Findings: On December 7, 2009, Administrator Lisa Jackson signed a final action, under § 202(a) of the CAAct, finding that six key well-mixed GHGs constitute a threat to public health and welfare, and that the combined emissions from motor vehicles cause and contribute to the climate change problem.

GHG Reporting Program: The GHG Reporting Program collects GHG data from large emission sources across a range of industry sectors, as well as suppliers of products that would emit GHGs if released or combusted.

8.8.2 EU's Policies on Air Pollution Control

The EU's primary operative policy on air pollution control is Directive 2008/50, which updated and consolidated several previous EU directives and regulations. Excerpts from this directive that are relevant to health purposes follow [99].

DIRECTIVE 2008/50/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 21 May 2008 on ambient air quality and cleaner air for Europe

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
[…]HAVE ADOPTED THIS DIRECTIVE:
CHAPTER I
GENERAL PROVISIONS

Article 1

Subject matter

This Directive lays down measures aimed at the following:
1. Defining and establishing objectives for ambient air quality designed to avoid, prevent or reduce harmful effects on human health and the environment as a whole; 2. assessing the ambient air quality in Member States on the basis of common methods and criteria; 3. obtaining information on ambient air quality in order to help combat air pollution and nuisance and to monitor long-term trends and improvements resulting from national and Community measures; 4. ensuring that such information on ambient air quality is made available to the public; 5. maintaining air quality where it is good and improving it in other cases; 6. promoting increased cooperation between the Member States in reducing air pollution.

Article 2

Definitions

For the purposes of this Directive:
1. "ambient air" shall mean outdoor air in the troposphere, excluding workplaces as defined by Directive 89/654/EEC (20) where provisions concerning health and safety at work apply and to which members of the public do not have regular access;

(*Continued*)

(*CONTINUED*)

2. "pollutant" shall mean any substance present in ambient air and likely to have harmful effects on human health and/or the environment as a whole; 3. "level" shall mean the concentration of a pollutant in ambient air or the deposition thereof on surfaces in a given time; 4. "assessment" shall mean any method used to measure, calculate, predict or estimate levels; 5. […] 17. "agglomeration" shall mean a zone that is a conurbation with a population in excess of 250,000 inhabitants or, where the population is 250,000 inhabitants or less, with a given population density per km^2 to be established by the Member States […]

Article 3

Responsibilities

Member States shall designate at the appropriate levels the competent authorities and bodies responsible for the following: (a) assessment of ambient air quality; (b) approval of measurement systems (methods, equipment, networks and laboratories); (c) ensuring the accuracy of measurements; (d) analysis of assessment methods; […]

Article 4

Establishment of zones and agglomerations

Member States shall establish zones and agglomerations throughout their territory. Air quality assessment and air quality management shall be carried out in all zones and agglomerations.

CHAPTER II
ASSESSMENT OF AMBIENT AIR QUALITY

SECTION 1

Assessment of ambient air quality in relation to sulfur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter, lead, benzene and carbon monoxide

Article 5

Assessment regime

1. The upper and lower assessment thresholds specified in Section A of Annex II shall apply to sulfur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter (PM10 and PM2.5), lead, benzene and carbon monoxide. Each zone and agglomeration shall be classified in relation to those assessment thresholds. […]

Article 6

Assessment criteria

1. Member States shall assess ambient air quality with respect to the pollutants referred to in Article 5 in all their zones and agglomerations, in accordance with the criteria laid down in paragraphs 2, 3 and 4 of this Article and in accordance with the criteria laid down in Annex III.
[…] (b) Each Member State shall set up at least one measuring station or may, by agreement with adjoining Member States, set up one or several common measuring stations, covering the relevant neighbouring zones, to achieve the necessary spatial resolution; […]

Article 7

Sampling points

1. The location of sampling points for the measurement of sulfur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter (PM10, PM2.5), lead, benzene and carbon monoxide in ambient air shall be determined using the criteria listed in Annex III. 2. […]

Article 8

Reference measurement methods

1. Member States shall apply the reference measurement methods and criteria specified in Section A and Section C of Annex VI.

(*Continued*)

(*CONTINUED*)

2. Other measurement methods may be used subject to the conditions set out in Section B of Annex VI.

SECTION 2

Assessment of ambient air quality in relation to ozone

Article 9

Assessment criteria

1. Where, in a zone or agglomeration, concentrations of ozone have exceeded the long-term objectives specified in Section C of Annex VII during any of the previous five years of measurement, fixed measurements shall be taken. […]

Article 10

Sampling points

1. The siting of sampling points for the measurement of ozone shall be determined using the criteria set out in Annex VIII. […]
(c) the number of sampling points in each zone or agglomeration amounts to at least one sampling point per two million inhabitants or one sampling point per 50,000 km2, whichever produces the greater number of sampling points, but must not be less than one sampling point in each zone or agglomeration; (d) nitrogen dioxide is measured at all remaining sampling points except at rural background stations as referred to in Section A of Annex VIII. […]

Article 11

Reference measurement methods

1. Member States shall apply the reference method for measurement of ozone, set out in point 8 of Section A of Annex VI. Other measuring methods may be used subject to the conditions set out in Section B of Annex VI.
2. Each Member State shall inform the Commission of the methods it uses to sample and measure VOC, as listed in Annex X.

CHAPTER III
AMBIENT AIR QUALITY MANAGEMENT

Article 12 […]

Article 13

Limit values and alert thresholds for the protection of human health

1. Member States shall ensure that, throughout their zones and agglomerations, levels of sulfur dioxide, PM10, lead, and carbon monoxide in ambient air do not exceed the limit values laid down in Annex XI. […]
Critical levels
1. Member States shall ensure compliance with the critical levels specified in Annex XIII as assessed in accordance with Section A of Annex III. […]

Article 15

National PM2.5 exposure reduction target for the protection of human health
1. Member States shall take all necessary measures not entailing disproportionate costs to reduce exposure to PM2.5 with a view to attaining the national exposure reduction target laid down in Section B of Annex XIV by the year specified therein. […]

Article 16

PM2.5 target value and limit value for the protection of human health
1. Member States shall take all necessary measures not entailing disproportionate costs to ensure that concentrations of PM2.5 in ambient air do not exceed the target value laid down in Section D of Annex XIV as from the date specified therein. […]

(*Continued*)

(*CONTINUED*)

Article 20

Contributions from natural sources

1. Member States shall transmit to the Commission, for a given year, lists of zones and agglomerations where exceedances of limit values for a given pollutant are attributable to natural sources. Member States shall provide information on concentrations and sources and the evidence demonstrating that the exceedances are attributable to natural sources. […]

CHAPTER IV
PLANS

Article 23

Air quality plans

1. Where, in given zones or agglomerations, the levels of pollutants in ambient air exceed any limit value or target value, plus any relevant margin of tolerance in each case, Member States shall ensure that air quality plans are established for those zones and agglomerations in order to achieve the related limit value or target value specified in Annexes XI and XIV. […]

Article 24

Short-term action plans

1. Where, in a given zone or agglomeration, there is a risk that the levels of pollutants will exceed one or more of the alert thresholds specified in Annex XII, Member States shall draw up action plans indicating the measures to be taken in the short term in order to reduce the risk or duration of such an exceedance. […]

Article 25

Transboundary air pollution

1. Where any alert threshold, limit value or target value plus any relevant margin of tolerance or long-term objective is exceeded due to significant transboundary transport of air pollutants or their precursors, the Member States concerned shall cooperate and, where appropriate, draw up joint activities. […]

CHAPTER V
INFORMATION AND REPORTING

Article 26

Public information

1. Member States shall ensure that the public as well as appropriate organisations such as environmental organisations, consumer organisations, organisations representing the interests of sensitive populations, other relevant health-care bodies and the relevant industrial federations are informed, adequately and in good time, of the following: (a) ambient air quality in accordance with Annex XVI; […] (d) air quality plans as provided for in Article 22(1) and Article 23 and programmes referred to in Article 17(2). The information shall be made available free of charge. […]
2. Member States shall make available to the public annual reports for all pollutants covered by this Directive. […]

Article 30

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

* * *

It must be recalled that this is a directive from the European Commission to the EU's Member States. As such, a directive is a legal act of the EU, which requires member states to achieve a particular result without dictating the means of achieving that result. And although Directive 2008/50 contains some rather specific directions, e.g., air pollution sampling procedures and content of documents made available to the public; nevertheless, the specifics of implementation reside with each Member State.

Of note, in 2016 the European Parliament enacted a directive that will reduce air pollution and prevent an estimated 400,000 premature deaths a year across the EU, according to supporters of the legislation. The legislation sets targets for emissions of SO_2, NO_x, VOCs, NH_3, and fine PM. Legislators estimate an almost 50% improvement in health impact by 2030 [100].

Perspective: The EU directive is a comprehensive statement of methods and procedures to control air pollution sources across the EU Member States. The directive specifies air sampling procedures, application of standards for individual air pollutants, development of plans for control of sources, transboundary episodes of air pollution, procedures for actions during episodes of extreme pollution, and sharing of air pollution information with the public and other Member States. The implementation of this directive is the responsibility of individual Member States, leading to an inevitable variation in policies and practices between nations.

8.8.3 China's Policies on Air Pollution Control

ENFORCEMENT EXAMPLE

On July 20, 2016 a Chinese court issued the country's first ruling against an air polluter. A court in Shandong Province imposed an unprecedented penalty of nearly 22 million yuan ($3.3 million) on a local glass manufacturer for its toxic emissions. The court found Shandong-based Zhenhua Limited responsible after its factory emitted exhaust gases containing more than 255 (metric) tons of SO_2, 589 tons of NO_x, and 19 tons of dust between November 2013 and February 2015. The penalty is four times the estimated cost for restoring the damage it caused, but the court also demanded a public apology from the company [102].

As described by Hernandez [101], China's air pollution has attracted the world's attention in recent years due to the images of its main cities shrouded in haze and heavy smog (Figure 8.3). In fact, a recent official report shows that in 2014, only 8 of 74 cities monitored by China's Ministry of Environmental Protection (MEP) met air quality standards. The origins of China's modern air pollution problem can be linked to the "Reform and Open Policy" of 1978, which introduced a new era of rapid and ambitious economic development. During more than three decades, continued economic growth has been accomplished with an excessive use of energy that has placed an enormous burden on the ecological system.

In the 1970s, China adopted a modern management of environmental problems, which was modeled on the approaches of the western world. Following the country's participation in the Stockholm Conference on the Human Environment in 1972, the management of the physical environment has evolved from a focus on eliminating existing pollution to preventing it.

Prevention and control of air pollution (PCAP) policy frameworks in China are constituted of laws, standards, regulations and action plans. Five-Year Plans (FYPs) are especially relevant for the definition of guidelines for economic and social policy, including environmental protection. Before the 12th FYP in 2012, some of the most crucial initiatives promulgated included: Prevention and Control of Atmospheric Pollution Law (1987, 1995, 2000), the NAAQS (GB3095-1996) and the Emission Standards of Air Pollutants for Thermal Power Plants (GB13223-2003).

In general terms, the execution of the policy framework is the responsibility of the MEP and the local Environmental Protection Bureaus in different jurisdictions. Other ministries and agencies (e.g., Ministry of Science and Technology) have specific roles when the policy incorporates varied aspects such as energy, industry, and technology.

In China the legal framework has different levels, in which the National People's Congress has the main role of producing laws, which pass to the State Council and the ministries to formulate policies, regulations, and standards that usually guide the provincial and local governments. The main national laws directly concerning PCAP are: the Environmental Protection Law (2015), the Air Pollution Prevention and Control Law (2015), the Environmental Impact Assessment Law (2003), the Law on Promoting Clean Production (2012), and the Energy Conservation Law (2007). It is important to note that the Air Pollution Prevention and Control Law, which was promulgated in 1987, is the principal guiding law in the area today. It was later revised in 1995 and amended in 2000 to aid the reduction of SO_2 and provide mechanisms to control cross-boundary pollution.

Of relevance to China's evolving policies on air pollution control are the results from a study of the association between burning coal and adverse health effects on the country's population. As background, China annually consumes almost as much coal as all other countries combined, and coal burning in the country is the biggest source of both air pollution and GHG emissions. Coal is responsible for about 40% of $PM_{2.5}$ in China's atmosphere. The researchers' primary aim was to identify the main sources of air pollution leading to premature deaths in China. The Chinese and American researchers reported that coal combustion was the single worst health impact of any source of air pollution in China and caused 366,000 premature deaths in 2013. The study attributed 155,000 deaths in 2013 related to ambient $PM_{2.5}$ to industrial coal burning and 86,500 deaths to coal burning at power plants. The study concluded that fuel combustion of both coal and biomass in households was another major cause of disease that year, resulting in 177,000 deaths. The researchers

also found that transportation was a major cause of mortality related to $PM_{2.5}$, with 137,000 deaths attributed to it in 2013 [103].

8.8.4 India's Policies on Air Pollution Control

Interest in air quality management policies began in India during the 1970s. After the 1972 Stockholm Conference on the Human Environment, it became clear that India was in need of a uniform environmental law. As a result, the Air (Prevention and Control of Pollution) Act was passed by India's Parliament in 1981. The act's stated goal is to provide for the prevention, control, and abatement of air pollution. The act established the Central Pollution Control Board (CPCB) and State Pollution Control Boards (SPCBs). The latter are boards specific to the individual states of India, an arrangement akin to U.S. state air pollution agencies.

All of these entities fall under the control of the Ministry of Environment and Forest (MoEF). The CPCB, working together with the SPCBs, provides technical advice to MoEF in order to fulfill the objectives outlined in the Air Act of 1981. The Air Act mandates the CPCB and SPCBs to:

- Establish NAQQS for India's criteria pollutants
- Assist government in planning future environmental prevention and control strategies
- Conduct research to better understand environmental issues
- Undertake nationwide air sampling to ascertain the ambient air quality in India and identification of the problem areas
- Conduct air quality inspections in areas of concern

The first Indian ambient air quality standards were adopted in 1982 by the CPCB and revised in 1994 and again in 2009. SPCBs can set more stringent standards than the existing national standards in their respective states. Another legal document, the, does not specifically mention fuels or emission standards, but does authorize central and state governments to regulate activities that can harm the environment. Current ambient air quality standards are based on the authority of the Environment Act, 1986 [104].

Policies to reduce ambient air pollution in Delhi have begun, principally using methods to control pollution from motor vehicles. Delhi, home to some 16 million people, is currently the world's 11th most polluted city. In 2014 WHO named it the world's air polluted city. The toxic air in Delhi is estimated to cause about 30,000 premature deaths annually. $PM_{2.5}$ levels are 13 times more than WHO's guideline. India's government is proposing to spend $2.95 billion to bring down traffic congestion in its capital city [105]. In January 2016 New Delhi's government imposed an even–odd policy that restricts cars to alternate days according to whether they carry odd- or even-numbered license plates. This kind of schedule reduces automobile traffic density and thereby lowers ambient air pollution [106]. This even–odd policy was litigated by some public interest groups, with India's Supreme Court ruling that it would not stop the policy [107]. In a separate policy, in response to public interest litigation, India's Supreme Court ordered a temporary ban on the sale of large diesel cars in New Delhi to combat toxic smog in the city [108].

India's central government and the country's state governments are developing more comprehensive policies on air pollution control, an outcome much in response to complaints from the Indian public.

8.9 CASE STUDY: VW CORPORATION & DIESEL EMISSIONS, 2014–2016

Diesel engines are a form of internal combustion device that has found favor as a power source for motor vehicles, especially light to heavy trucks. Diesel engines offer several advantages over gasoline-powered engines: efficiency, durability, and maintenance, but possess a disadvantage in terms of emissions of combustion products. In 2014, more than 16.4 million passenger cars and light trucks were sold in the U.S. Diesel-powered cars accounted for about 3% of total auto sales in the U.S. but 50% in Europe [109]. In 2014, Volkswagen (VW) accounted for more than half of U.S. diesel car sales. The 2014 year-end U.S. truck vehicles-in-use data indicate 9.1 million are powered by diesel engines, and among the largest trucks, (Class 8) diesel vehicles-in-use accounted for 3.6 million [110].

Given the large number of diesel-powered vehicles in the U.S., it is important to understand the implications for air pollution. Diesel-powered vehicles and equipment account for nearly half of all NO_x and more than two-thirds of all PM emissions from U.S. transportation sources. PM is created during the incomplete combustion of diesel fuel. Its composition often includes hundreds of chemical elements, including sulfates, ammonium, nitrates, elemental carbon, condensed organic compounds, and even carcinogenic compounds and heavy metals such as arsenic, selenium, cadmium and zinc. PM irritates the eyes, nose, throat, and lungs, contributing to respiratory and cardiovascular illnesses and even premature death. Diesel engines contribute to the problem by releasing particulates directly into the air and by emitting NOx and SOx, which transform into "secondary" particulates in the atmosphere [111].

Diesel emissions of NO_x contribute to the formation of ground level O_3, which irritates the respiratory system, causing coughing, choking, and reduced lung capacity. Ground level O_3 pollution, formed when NO_x and hydrocarbon emissions combine in the presence of sunlight, presents a hazard for both healthy adults and individuals suffering from respiratory problems. Urban ozone pollution has been linked to increased hospital admissions for respiratory problems such as asthma, even at levels below the federal standards for O_3. Diesel exhaust has been classified a potential human carcinogen by the EPA and the IARC [111]. Emissions from diesel engines are regulated by the EPA under provisions of the CAAct.

In summary, diesel-powered vehicles are an important component of the U.S. transportation system, with off-road

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equipment such as construction equipment constituting a second source of diesel emissions. Given this important role, and the public health portent, control of diesel air emissions is regulated in the U.S. and Europe. The regulations require government agencies to measure emissions under test and road conditions. In 2015 a German car manufacturer was found to have violated U.S air pollution regulations on diesel emissions.

In 2015 the California Air Resources Board (CARB) had become suspicious that some VW vehicles with diesel engines were in violation of the state's vehicle emissions regulations. In May 2015 CARB reached out to investigators at West Virginia University, who discovered that the VW engines were programed to perform well on emission tests, but failed when on-road tests were performed. These findings led the EPA to issue in September 2015 a violation notice to the Justice Department for enforcement under the provision of the CAAct. In 2016 the U.S. Department of Justice initiated litigation against VW for CAAct violations [112]. VW is also likely to be litigated by U.S. states and European governments.

VW subsequently admitted that 11 million of its vehicles were equipped with software that was used to cheat on emissions tests. The software sensed when the car was being tested and then activated equipment that reduced emissions. But the software turned the equipment down during regular driving, increasing emissions far above legal limits. The adjustable components are meant to reduce emissions of NO_x, a pollutant that can cause emphysema, bronchitis, and other respiratory diseases.

In response VW has recalled 482,000 VW and Audi brand cars in the U.S. In 2016 VW agreed to pay up to $14.7 billion to settle claims stemming from its diesel emissions cheating scandal, in what would be one of the largest consumer class action settlements ever in the U.S. The proposed settlement involving the federal government and lawyers for the owners of about 475,000 VW vehicles, includes a maximum of $10.03 billion to buy back affected cars at their pre-scandal values, and additional cash compensation for the owners, according to two people briefed on the settlement's terms. Further, VW would also pay $2.7 billion into an EPA fund to compensate for the environmental impact of its cars. Additionally, VW agreed to spend $2 billion on new cleaner-vehicle projects [113].

A study conducted by *The Guardian* newspaper concluded that VW's rigging of emissions tests for 11 million cars resulted in nearly one million tons of air pollution every year, roughly the same as the UK's combined emissions for all power stations, vehicles, industry, and agriculture. Further, U.S. vehicles would have emitted between 10,392 and 41,571 tons of air pollutants annually, assuming they were driven the average annual U.S. mileage. If the VW vehicles had complied with EPA standards, they would have emitted just 1039 tons of NO_x in total annually [114].

Perspective: This case study illustrates the harm to health and environment that can occur when ethics are suspended for purpose of enhanced commerce. While the VW Corporation will suffer enormous financial penalties and short-term diminished sales and image, the company's impact on human and ecological health will never be accurately gauged, given the vicissitudes of environmental policies.

8.10 COSTS AND BENEFITS OF U.S. AIR POLLUTION CONTROL

The economic costs of air pollution in the U.S. are huge. A 2007 study estimated the total damage costs associated with emissions of some air pollutants (PM, NO_x, NH_3, SO_2, VOCs) in the U.S. at between $71 billion and $277 billion per year (0.7%–2.8% of GDP) [115]. A separate study used air pollution emissions data for the years 2002, 2005, 2008, and 2011 to estimate monetary damages due to air pollution exposure for $PM_{2.5}$, SO_2, NO_x, NH_3, and VOC from electric power generation, oil and gas extraction, coal mining, and oil refineries. In 2011, damages associated with emissions from these sectors totaled $131 billion (shown in year 2000 $), with SO_2 emissions from power generation being the largest contributors to social damages. The investigators noted that damages have decreased significantly since 2002, even as U.S. energy production increased, suggesting that, among other factors, policies that have driven reductions in emissions have reduced damages [116].

The foregoing numbers illustrate the economic burden of air pollution in the U.S. But there are costs to regulating the sources of air pollution emissions. The 1990 CAAct amendments (§812) require the EPA to estimate the costs and benefits of the CAAct. In response, the EPA has estimated that the total direct compliance costs of the CAAct from 1970–1990 were $500 billion, while the total monetized benefits exceeded $22,000 billion [117]. In 1999, the EPA released a prospective study on the anticipated costs and benefits of the 1990 CAAct Amendments from 1990–2010. The EPA study assumed a significant decrease in air pollutants over this period, estimating a net benefit as being $510 billion, with an expectation that benefits will again exceed direct compliance costs by approximately four to one [118]. In 2003, the White House's Office of Management and Budget estimated that over the period 1992–2002 federal air pollution rules resulted in an annual benefit of $117–177 billion, with costs estimated at $17–120 billion, a benefits/cost ratio of about 6:1, a significant ratio, given that the benefits were primarily in terms of human health gains [119].

The costs of air pollution control are essentially apportioned across the economic sectors of the U.S. public. Businesses increase the price they charge for their products, government authorities charge motorists for the cost of vehicle emissions inspections, and taxes are increased to pay for government inspectors and allied personnel who are charged

with enforcing air pollution regulations. Some will argue that these kinds of "hidden costs" are somehow unfair and without merit. Such arguments find a hearing in the court of cost–benefit analysis, where analysts attempt to associate the costs of regulatory impacts (e.g., more stringent air pollution regulations) against the benefits to society (e.g., improvements in the public's health). This kind of analysis is a most difficult calculus because of the many uncertainties in economic models used in the analysis and limited data on health benefits. As a matter of environmental health policy, current cost–benefit analysis must be improved by enriching the databases on associations between environmental hazards and their consequences to the public's health. Having these kinds of data benefits policymaking, in general, and advances the possibility of using the Precautionary Principle more effectively.

8.11 GLOBAL ECONOMIC IMPACT OF AIR POLLUTION

The burden of air pollution to humankind is not confined to impacts on human and ecosystem health. Air pollution also brings economic consequences to nations and individuals. Economists who have estimated these costs often characterize them as "staggering." The Organization for Economic Cooperation and Development (OECD) has provided estimates of the costs of air pollution. According to OECD, outdoor air pollution could cause six to nine million premature deaths and represent a global economic cost of around $2.6 trillion a year by 2060 unless action is taken. Further, the OECD examined the economic consequences of air pollution and found that it could cost 1% of gross domestic product—or $2.6 trillion a year—by 2060. The economic cost would rise with a surge in related annual healthcare bills to $176 billion from $21 billion in 2015 and with lost work days rising to 3.7 billion from 1.2 billion. A reduction in crop yields as a result of polluted air would also weigh on most countries' economies, according to the OECD [120].

In a separate report the OECD estimated that the cost of air pollution to society in 2010 was estimated at US$ 1.4 trillion in China and US$0.5 trillion in India. In Europe, exposure to air pollution from road transport costs about US$137 billion per year and harm caused by air pollution from Europe's 10,000 largest polluting facilities in 2009—including through lost lives, poor health and crop damage—was about US$140–230 billion [121].

8.12 HAZARD INTERVENTIONS

There are multiple interventions that if implemented can reduce or eliminate the hazard of air pollution to human and ecosystem health. Controlling the releases of air pollutants from stationary and mobile sources via national policies is vital. National, state/province, and local laws and ordnances are required, given the breadth of pollution sources and the severity of adverse health and welfare consequences of uncontrolled air pollution. The CAAct, as amended, is an example of such a national environmental health policy. However, such policies are impotent if not enforced, which is what has occurred in some developing countries.

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Some specific interventions have been offered by WHO as examples of successful policies in transport, urban planning, power generation, and industry that reduce air pollution [34]:

- *For industry*: clean technologies that reduce industrial smokestack emissions; improved management of urban and agricultural waste, including capture of methane gas emitted from waste sites as an alternative to incineration (for use as biogas);
- *For transport*: shifting to clean modes of power generation; prioritizing rapid urban transit; walking and cycling networks in cities as well as rail interurban freight and passenger travel; shifting to cleaner heavy duty diesel vehicles and low-emissions vehicles and fuels, including fuels with reduced sulfur content;
- *For urban planning*: improving the energy efficiency of buildings and making cities more compact, and thus energy efficient;
- *For power generation*: increased use of low-emissions fuels and renewable combustion-free power sources (like solar, wind, or hydropower); cogeneration of heat and power; and distributed energy generation (e.g., mini-grids and rooftop solar power generation); and
- *For municipal and agricultural waste management*: strategies for waste reduction, waste separation, recycling and reuse or waste reprocessing; as well as improved methods of biological waste management such as anaerobic waste digestion to produce biogas are feasible, low cost alternatives to the open incineration of solid waste. Where incineration is unavoidable, then combustion technologies with strict emission controls are critical.

Regulation of motor vehicle traffic is a common intervention used by cities when motor vehicle traffic contributes to ambient air pollution levels of health concern. The alternate days policy is frequently the chosen policy. Examples of cities that have used this particular intervention are: Mexico City, Madrid (Spain), Milan and Rome (Italy), Sarajevo (Bosnia and Herzegovina), Beijing (China), New Delhi (India), Paris (France), and others [122,123,124].

Trees are another form of intervention, given their capacity to uptake CO_2 and some other air pollutants. Indeed, the conversion of CO_2 to O_2 is a life-sustaining force of nature. While scientists have known for years that trees work as natural filters, no city or state has replanted forests to reduce smog. However, the large-scale planting of trees along the edges of a city could help to reduce air pollution that forms ozone,

or smog. The city of Houston, Texas, is considering returning American elm, green ash, and other native trees to about 1000 acres of grasslands near the city for purpose of decreasing ground-level ozone [125]. On a smaller scale, trees have been planted atop an apartment building in Turin, Italy for air pollution reduction. Specifically, a new five-story apartment building is covered with 150 trees, each surrounded by custom-shaped terraces. The apartment building is a large-scale version of a treehouse. The trees help filter pollution from traffic on busy nearby streets, absorbing around 200,000 L of CO_2 emissions every hour in one of Europe's most polluted cities. As the seasons change, the leaves help shade the apartments or bring in warmth, creating a microclimate for the building [126].

There are hazard interventions that an individual can adopt as policy. These include:

- Use social media to support applicable air pollution policies.
- Advocate for elected policymakers who favor environmental policies. Don't support platitudinous individuals whose deeds and words are incongruous.
- Reside in areas distant from major thoroughfares to avoid vehicle emissions.
- Purchase motor vehicles that emit little to no air pollutants.
- Use public transportation whenever and wherever possible.
- Advocate planting of new trees and maintenance of trees in general.
- Don't practice behaviors that produce air pollution, e.g., smoking.
- Utilize EPA and similar databases to ascertain the sources of air pollution in your area.
- Use common household plants for effective removal of VOCs in indoor air [127].

8.13 SUMMARY

Described in this chapter are the policies and impacts of global air pollution. As characterized by WHO, air pollution is the single greatest environmental hazard to humanity, with an estimated eight million premature deaths annually caused by exposure to polluted air. This figure comprises both ambient (outdoor) air pollution and indoor air pollution; the latter condition accounting for four million premature deaths annually. The effects of air pollution on morbidity and mortality were described, with children, elderly persons, and persons with existing infirmities among the most at health risk from exposure to air pollution. As to the impact of poor air quality on the public's health, a considerable and impressive body of health data has accrued over time. These data associate specific air contaminants with adverse health effects on the heart, lungs, and cardiovascular system. Air pollution also can cause deleterious effects on ecosystems, which are magnified by climate change. As illustrated in this chapter, industrialized nations have developed and implement policies to control emissions from stationary and mobile sources of air pollution.

In the U.S. the CAAct, as amended, is the most complex and comprehensive of the federal environmental statutes. Its provisions affect daily the whole of the U.S. population. For instance, the act controls the emissions of air contaminants from sources that range from internal combustion engines to emissions from electricity generating plants. This means that the provisions of the CAAct affect anyone who uses an automobile or relies upon electricity for personal or business purposes. No other federal environmental statute has such a broad sweep of societal impacts. The CAAct contains a strong commitment to federalism, requiring the states to enforce many of the act's provisions such as issuing permits to facilities that emit air contaminants into ambient air. There is also a strong framework of quality standards that are linked to the emission standards. For geographic areas that do not meet air quality standards, the act authorizes such penalties as an area's potential loss of highway transportation funds.

The European Commission has issued directives and regulations that are referred to the EU's Member States for implementation. This arrangement produces variation in how individual Member States implement national polices to control air pollution. And having policies on air pollution control without serious implementation is meaningless. As illustrated in this chapter, countries that are striving to increase national economic development plans can find themselves in conflict with air pollution goals.

8.14 POLICY QUESTIONS

1. Assume you are a senior member of the local health department. Review three journal articles on asthma in children. Using what you consider to be the key public health issues gleaned from the articles, prepare a summary of findings that can be presented to a local underserved community.
2. Under §202, Title II, of the CAAct, the EPA must establish emission standards for new motor vehicles and engines. (a) Do you agree that the EPA should have this authority? Why or why not? Be specific. (b) Using Internet and EPA resources, determine the emissions standards for your personal vehicle.
3. Ethanol is used as a gasoline additive for the purpose of lowering vehicle emissions. Using Internet resources, discuss the benefits and disadvantages of using ethanol as a gasoline additive.
4. Assume that you are in charge of communications for the local health department. Develop a one-page health alert that can be released to the public and medical community during periods of high ambient air levels of ozone.
5. Summarize for your 10-year-old nephew the primary effects of the CAPs on human health. List the three most important ways he can prevent these health effects.

6. For pollution control purposes, several federal environmental statutes include the embedded policy of granting permits to those who pollute a kind of command and control policy. Select one such statute and discuss two alternatives to a permit policy. Using critical thinking, discuss the likely effectiveness of each alternative.
7. The EPA's assertion that the CAAct applies to regulation of GHGs was challenged in federal courts, eventually being a matter decided by the U.S. Supreme Court in Massachusetts v. EPA. Discuss in a two-page analysis the Supreme Court's decision and the key themes of the Court's justices.
8. Prepare an essay of appropriate depth that compares the benefits of industrial development versus the costs to public health due to increased air pollution emissions. Is there a way to balance costs vs. benefits? Be specific.
9. EPA data show that air quality has generally improved in the U.S. during recent years. Discuss why this desirable trend has occurred; focus your analysis on the one factor most responsible for the trend.
10. The state in which you reside requires annual vehicle emission inspections. Do you consider this a regulatory overreach? If so, why? If not, why? Be specific.
11. Your company has recently decided to expand its overseas markets. You have been offered a plum position as director of marketing for a country with a nascent economy and impressive growth potential. However, the country's air pollution is near WHO's list of most polluted countries. (a) Assume you have no dependents, do you accept the job? If so, why? If not, why? (b) Assume you have a family with young children. Do you accept the job? If so, why? If not, why?
12. How clever you are! As an amateur inventor, you've invented and patented a heating element that uses solar power and can store the energy until needed. Your friend suggests that the element could replace primitive cooking stoves in developing countries, thereby eliminating indoor air pollution. A UN representative suggests that your patent be donated to the UN for their distribution to developing countries. What is your decision? Provide details.
13. Assume that you reside in a large city that has historically struggled to meet federal air quality standards for pollutants caused by dense automobile traffic. Residents of the city are organizing protests against being subjected to polluted air. As a newly elected member of the city council, you are responsible for preparing a list of potential polices on how to improve the city's air quality. In an essay of appropriate depth, outline your top three policy suggestions. Be specific on how each suggestion would improve air quality.
14. In regard to the previous question, which specific air pollutants would be of the greatest concern to you as a member of city council? Describe the basis for your selection and the degree of concern.
15. Your sister and her family are relocating to a new city for residence. She has two young children, ages 4 and 6 years old. She asks your advice about how to choose between two possible residences in the new city. One residence abuts a major road, but offers good real estate value; the second possible residence is on a cul-de-sac, but costs 10% more in purchase cost and annual taxes. Knowing that your sister has limited income, what advice do you offer? Why?
16. Discuss the relationship between human population increase and any implications for global air pollution. Be specific and provide supporting data.
17. Fire events were mentioned as one source of outdoor air pollution. Using internet resources, are there currently any uncontrolled forest fires in your state? If so, what are the implications for air pollution problems? And who would be the population(s) most at health risk? If your state is currently without any forest fires, select a state that currently has forest fires.
18. Your parents reside in a rural area. The area is site to a large forest, two lakes, and a small river that abuts your parent's property. There are a variety of plants and feral animals. Across the state is a large electric power plant, whose air pollution emissions have been frequently investigated by the state's department of environmental protection. The county's health department has expressed concerns about air pollutants. What concerns would you have in regard to ecological consequences of the plant's air pollution?
19. It is asserted in this chapter that air pollution is the planet's greatest environmental hazard. Do you agree with this assertion? If so, why? If not, what in your opinion is a greater hazard? Be specific in your answer in respect to "hazard."
20. After wafting through this chapter, discuss the three most important lessons you learned. Was your personal environmental health behavior changed by the content of this chapter? If so, how? If not, why?

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9 Water Quality and Security

9.1 INTRODUCTION

Water to drink, air to breathe, and food to consume are the three necessities for life. Life is impossible if any one of these three is absent. Our primordial ancestors likely used surface water sources for their drinking water, relying on springs, streams, and rainwater sources. As human civilizations grew, wells were dug, along with using these same prior resources. Over time, water for drinking was joined by waster used for transportation and use in industrial and agricultural operations. As human civilizations grew in number and complexity, some sources of water became contaminated with human wastes, chemicals, biological agents, and other unhealthful pollutants. Figure 9.1 shows an example of a water pollution point source that could cause adverse human and ecological health effects, depending on the content of the discharged water. This chapter describes the global problems of water quality and security and attendant policies meant to prevent the problems. In the context of this chapter water pollution refers to quality and security of surface and groundwater sources. Issues of ocean pollution are described elsewhere in Chapter 12, (Waste Generation and Management).

9.2 WATER CONTAMINATION AND SECURITY

Water security is defined by the UN as "the capacity of a population to safeguard sustainable access to adequate quantities of acceptable quality water for sustaining livelihoods, human well-being, and socio-economic development, for ensuring protection against water-borne pollution and water-related disasters, and for preserving ecosystems in a climate of peace and political stability" [1]. Pollution typically refers to chemicals or other substances or materials in concentrations greater than would occur under natural conditions. Major water pollutants include pathogens, nutrients, heavy metals, organic chemicals, oil, and sediments; heat, which raises the temperature of the receiving water, can also be a pollutant. Pollutants are typically the cause of major water quality degradation around the world [1]. The global state of water security was characterized in 2010 by the UN as follows [2]:

- Every day, two million tons of sewage and industrial and agricultural waste are discharged into the world's water, the equivalent of the weight of the entire human population.
- Lack of adequate sanitation contaminates water courses worldwide and is one of the most significant forms of water pollution. Worldwide, 2.5 billion people live without improved sanitation.
- More than 70% of these people who lack sanitation, or 1.8 billion people, live in Asia.
- Worldwide, infectious diseases such as waterborne diseases are the number one killer of children under 5 years old and more people die from unsafe water annually than from all forms of violence, including war.
- Unsafe water causes four billion cases of diarrhea annually, and results in 2.2 million deaths, mostly of children less than 5 years old [2].
- According to one estimate, in 2016 two-thirds of the global population (4.0 billion people) live under conditions of severe water scarcity at least 1 month of the year. Nearly half live in India and China. Half a billion people in the world face severe water scarcity all year round [3].

Elaboration follows about the major forms of water pollutants and two other factors, algal contamination and drought, that impact water security.

Biological contaminants consist of various pathogens that pollute surface and groundwater water sources. Pathogens in water, especially surface waters, have existed from the time that humans and other animals first excreted their body wastes into rivers, lakes, streams, and oceans. Bacteria and viruses in urine and feces contaminated water sources and impacted water security. Specific pathogens cause specific diseases, for example, cholera and diarrhea. As human societies increased in number and complexity, wastewater management becomes necessary and continues to be a global necessity. Chlorination or ozonation of water supplies generally has been effective in purifying water of bacterial contaminants. But as noted by the UN, the most significant sources of water pollution are the lack of adequate treatment of human wastes and inadequately managed and treated industrial and agricultural wastes.

Unsafe water causes four billion cases of diarrhea annually and results in 2.2 million deaths, mostly of children less than 5 years old [3].

Chemical contaminants have been constituents of water from the time that humans began working with metals and other natural resources, producing materials such as metal weapons that led to waste being discarded into bodies of water. The Industrial Revolution of the eighteenth and nineteenth centuries and the Chemical Age that followed World War II were social developments that led to large amounts and an increased variety of chemicals discarded into lakes, rivers, oceans, and other bodies of water. In many parts of the world, this form of environmental pollution continues. Releases of chemical contaminants into waterbodies are controlled under national and regional policies, as described in subsequent sections of this chapter.

FIGURE 9.1 Water pollution discharged from a point source. (From National Oceanic and Atmospheric Administration, Categories of pollution: Point source, NOAA Ocean Service Education program, Washington, DC, 2016.)

Chemical contaminants in U.S. waterbodies reflect the industrial, agricultural, and personal activities of the country's population. Two surveys by the U.S. Geologic Survey (USGS) have identified water pollutants of contemporary origin. In one survey, conducted from 2011 to 2014, USGS discovered insecticides known as neonicotinoids in more than half of both urban and agricultural streams sampled across the U.S. and Puerto Rico [4]. Neonicotinoids are a class of pesticide that have properties of nicotine and have been suggested as a factor in the decline in numbers of bees and other pollinators.

In a second USGS survey, the agency investigated pharmaceutical contaminants in a sample of streams in the southeastern U.S. [5]. The USGS noted that pharmaceuticals are a growing aquatic-health concern and largely attributed to wastewater treatment facility discharges. Five biweekly water samples from 59 small streams in the southeastern U.S. were analyzed for 108 pharmaceuticals and degradants using high-performance liquid chromatography and tandem mass spectrometry. The antidiabetic metformin was detected in 89% of samples and at 97% of sites. At least one pharmaceutical was detected at every site (median of 6, maximum of 45), and several were detected at ≥10% of sites at concentrations reported to affect multiple aquatic end points. The results highlight a fundamental biochemical link between global human health crises like diabetes and aquatic ecosystem health [5]. In recognition of the growing problem of pharmaceuticals in the nation's waterbodies, the EPA announced in 2016 that the agency is considering a rule for the management of hazardous waste pharmaceuticals by health-care facilities (including pharmacies) and reverse distributors. The rule would prohibit the annual flushing of more than 6400 tons of hazardous waste pharmaceuticals by banning health-care facilities from flushing hazardous waste pharmaceuticals down the sink and toilet [6].

In addition to biological and chemical contaminants of water sources, two current factors that are deleteriously impacting water security are algal contamination and drought.

Concerning *harmful algal blooms* (HABs), one source observes, "Several decades ago relatively few countries appeared to be affected by HABs, but now most coastal countries are threatened, in many cases over large geographic areas and by more than one harmful or toxic species. Many countries are faced with a bewildering array of toxic or harmful species and impacts, as well as disturbing trends of increasing bloom incidence, larger areas affected, more fisheries resources impacted, and higher economic losses. The causes behind this expansion are debated, with possible explanations ranging from natural mechanisms of species dispersal to a host of human-related phenomena such as pollution, climatic shifts, increased numbers of observers, and transport of algal species via ship ballast water" [7].

The EPA observes that HABs are a major environmental problem in all 50 U.S. states [8]. Known as red tides, blue-green algae, or cyanobacteria, HABs have severe impacts on human health, aquatic ecosystems, and the economy. Algal blooms can be toxic. HABs can be green, blue, red, or brown. HABs are overgrowths of algae in water. Some produce dangerous toxins in fresh or marine water but even nontoxic blooms hurt the environment and local economies. HABs can produce extremely dangerous toxins that can sicken or kill people and animals, create dead zones in the water, raise treatment costs for drinking water, and hurt industries that depend on clean water. Climate change might lead to stronger and more frequent algal blooms.

HABs need sunlight, slow-moving water, and nutrients (nitrogen and phosphorus). Nutrient pollution from human activities makes the problem worse, leading to more severe blooms that occur more often. The primary sources of nutrient pollution are as follows:

- *Agriculture*: Animal manure, excess fertilizer applied to crops and fields, and soil erosion make agriculture one of the largest sources of nitrogen and phosphorus pollution in the country.
- *Storm water*: When precipitation falls on our cities and towns, it runs across hard surfaces—like rooftops, sidewalks, and roads—and carries pollutants, including nitrogen and phosphorus, into local waterways.
- *Wastewater*: Our sewer and septic systems are responsible for treating large quantities of waste, and these systems do not always operate properly or remove enough nitrogen and phosphorus before discharging into waterways.
- *Fossil Fuels*: Electric power generation, industry, transportation, and agriculture have increased the amount of nitrogen in the air through use of fossil fuels.
- *Households*: Fertilizers, yard and pet waste, and certain soaps and detergents contain nitrogen and phosphorus, and can contribute to nutrient pollution if not properly used or disposed of. The amount of hard surfaces and type of landscaping can also increase the runoff of nitrogen and phosphorus during wet weather.

More than 100,000 miles of rivers and streams; close to 2.5 million acres of lakes, reservoirs, and ponds; and more than 800 square miles of bays and estuaries in the U.S. have poor water quality because of nitrogen and phosphorus pollution [8]. As noted by the National Oceanic and Atmospheric Administration (NOAA) in 2016, HABs and hypoxic events (severe oxygen depletion) are some of the most scientifically complex and economically damaging coastal and lake issues. Almost every state in the U.S. now experiences some kind of HAB event and the number of hypoxic waterbodies in the U.S. has increased 30-fold since the 1960s, with more than 300 coastal systems now impacted. A 2006 study found that the economic impacts from a subset of HAB events in U.S. marine waters averaged to be 82 million USD (2005)/year [9].

In 1998, Congress recognized the severity of these threats and authorized the Harmful Algal Bloom and Hypoxia Research and Control Act (HABHRCA 1998; embedded in Public Law 105-383). The Harmful Algal Bloom and Hypoxia Research and Control Amendments Act of 2004 (HABHRCA 2004, Public Law 108-456), and 2014 (HABHRCA 2014, Public Law 113-124) reaffirmed and expanded the mandate for NOAA to advance the scientific understanding and ability to detect, monitor, assess, and predict HABs and hypoxia events. However, Congress has not appropriated funds in support of the law, requiring NOAA and other federal agencies to provide monetary support from existing agency funds.

Drought is the second environmental threat to global water security. A drought is an extended period of dry weather caused by a lack of rain or snow. As temperatures rise due to global climate change, more moisture evaporates from land and water, leaving less water behind. Climate change affects a variety of factors associated with drought. According to the Union of Concerned Scientists, in 2015 drought ranked second in terms of national weather-related economic impacts, with annual losses nearing $9 billion per year in the U.S. [10]. Beyond direct economic impacts, drought can threaten drinking water supplies and ecosystems, and can even contribute to increased food prices. Within the last decade, drought conditions have hit the Southeastern U.S., the Midwest, and the Western U.S. In 2011, Texas had the driest year since 1895. In 2013, California had the driest year on record [10].

There are different types of drought. One form is *hydrological drought*, or how decreased precipitation affects stream flow, soil moisture, reservoir and lake levels, and groundwater recharge. Farmers are most concerned with *agricultural drought* which occurs when available water supplies are not able to meet crop water demands. Agricultural droughts can occur for a variety of reasons, including low precipitation, the timing of water availability, or decreased access to water supplies. For instance, earlier snowmelt may not change the total quantity of water available but can lead to earlier runoff that is out of phase with peak water demand in the summer. Thus, it is possible to suffer an agricultural drought in the absence of a *meteorological drought*, which occurs when dry weather patterns dominate a geographic area [10].

Global climate change affects a variety of factors associated with drought. There is high confidence that increased temperatures will lead to more precipitation falling as rain rather than snow, earlier snow melt, and increased evaporation and transpiration. Thus the risk of hydrological and agricultural drought increases as temperatures rise. Much of the U.S. Mountain West has experienced declines in spring snowpack, especially since mid-century. These declines are related to a reduction in precipitation falling as snow (with more falling as rain), and a shift in timing of snowmelt. Earlier snowmelt, associated with warmer temperatures, can lead to water supply being increasingly out of phase with water demands. While there is some variability in the models for western North America as a whole, climate models unanimously project increased drought in the U.S. Southwest. The Southwest is considered one of the more sensitive regions in the world for increased risk of drought caused by climate change [10].

In July 2016, the U.S. drought monitor (Drought.gov) estimated that 22% of the contiguous U.S. was experiencing moderate to extreme drought, with the U.S. Southwest experiencing the most extreme drought conditions. Global data on the prevalence of drought are scarce. The following example demonstrates one country's drought struggles. In January 2014, the Government of Kenya declared an impending drought with an estimated 1.6 million people affected. After a poor performance of the long rains between March and May 2014 in the arid and semi-arid zones, the drought situation continued to affect both pastoral and marginal agriculture livelihood zones with an impact on households' food availability as well as livestock productivity. These conditions in Kenya have not eased, causing food shortages and inadequate access to potable water supplies [11].

9.3 GLOBAL STATE OF WATER QUALITY AND SECURITY

WHO observes that global freshwater consumption rose sixfold between 1900 and 1995—at more than twice the rate of population growth—and that for many of the world's poor, one of the greatest environmental threats to health is lack of access to safe water and sanitation. The agency estimates that more than one billion people globally lack access to safe drinking water supplies, while 2.6 billion lack adequate sanitation; diseases related to unsafe water, sanitation, and hygiene result in an estimated 1.7 million deaths every year [12].

In July 2016 the U.S. drought monitor (Drought.gov) estimated that 22% of the contiguous U.S. was experiencing moderate to extreme drought.

According to the UN, declining water quality has become a global issue of concern as human populations grow, industrial and agricultural activities expand, and climate change threatens to cause major alterations to the hydrological cycle [12]. Globally, the most prevalent water quality problem is eutrophication, a result of high-nutrient loads (mainly phosphorus and nitrogen), which substantially impairs beneficial uses of water. Major nutrient sources include agricultural runoff, domestic sewage (also a source of microbial pollution), industrial effluents, and atmospheric inputs from fossil fuel burning and bush

fires. Lakes and reservoirs are particularly susceptible to the negative impacts of eutrophication because of their complex dynamics, relatively longer water residence times, and their role as an integrating sink for pollutants from their drainage basins.

An emerging water quality concern is the impact of personal care products and pharmaceuticals, such as birth control pills, painkillers, and antibiotics, on aquatic ecosystems. Little is known about their long-term human or ecosystem impacts, although some are believed to mimic natural hormones in humans and other species [12].

Poor water quality has a direct impact on water quantity in a number of ways. Polluted water that cannot be used for drinking, bathing, industry, or agriculture effectively reduces the amount of useable water within a given area. Major water pollutants include microbes, nutrients, heavy metals, organic chemicals, oil and sediments; heat, which raises the temperature of the receiving water, can also be a pollutant. Pollutants are typically the cause of major water quality degradation around the world.

Every day, two million tons of sewage and other effluents drain into the world's waters. Every year, more people die from unsafe water than from all forms of violence, including war. The most significant sources of water pollution are lack of adequate treatment of human wastes and inadequately managed and treated industrial and agricultural wastes. The health impact has been estimated by the United Nations Environment Programme (UNEP) to put 323 million people at risk from life-threatening diseases caused by the pollution of rivers and lakes [12a]. According to the UNEP report, cholera, typhoid, and other deadly pathogens are increasing in more than half of the rivers in Africa, Asia, and Latin America. Salinity levels have also risen in nearly a third of waterways. Asia has been worst hit, with up to 50% of all rivers now affected by severe pathogen pollution caused by a confluence of untreated waste water disposal, agricultural pesticides runoff, and industrial pollution [12a].

In general, the quality of water necessary for each human use varies, as do the criteria used to assess water quality. For example, the highest standards of purity are required for drinking water, whereas it is acceptable for water used in some industrial processes to be of lesser quality [13]. As characterized by WHO [14], poor water quality and human and ecological health are interrelated:

- Lacking safe drinking water: almost one billion people lack access to an improved supply;
- Diarrheal disease: two million annual deaths attributable to unsafe water, sanitation, and hygiene;
- Cholera: more than 50 countries still report cholera to WHO;
- Cancer and tooth/skeletal damage: millions exposed to unsafe levels of naturally occurring arsenic and fluoride;
- Schistosomiasis*: an estimated 260 million infected;
- Emerging challenges: increasing use of wastewater in agriculture is important for livelihood opportunities, but also associated with serious public health risks.

In recognition of this dimension of adverse effects, WHO offers guidance on their prevention:

- 4% of the global disease burden could be prevented by improving water supply, sanitation, and hygiene;
- A growing evidence base is needed on how to target water quality improvements in order to maximize health benefits;
- Better tools and procedures are needed to improve and protect drinking water quality at the community and urban level, for example, through water safety plans;
- There is need to make available simple and inexpensive approaches to treat and safely store water at the household level [14].

The state of water quality and security in the U.S. is assessed by the EPA under provisions of the Clean Water Act (CWAct) of 1972, as amended, as described in a subsequent section of this chapter. Data on water quality are provided to the U.S. Congress under provisions of the same act. The data for 2004 are shown in Tables 9.1 and 9.2. Although somewhat dated, these data remain relevant and representative of the water situation in the U.S. The data in these tables are compiled by the EPA from water quality reports from states, territories, and tribes. Specifically, to assess water quality, states, tribes, and other jurisdictions compare their monitoring results to the water quality standards they have set for their waters. Water quality standards consist of three elements: the designated uses (such as drinking, swimming, or fishing) assigned to waters; criteria (such as chemical-specific thresholds that should not be exceeded) to protect those uses; and an antidegradation policy intended to keep waters that do meet standards from deteriorating from their current condition [15]. EPA has not compiled a report to congress after 2004.

Reflection on the data in Table 9.1 [15] provides a troubling characterization, given that 44% of U.S. rivers, 64% of lakes, and 30% of estuaries are assessed as "impaired." The leading causes of impairment are listed in Table 9.2 [15]. One notes that causes of impairment differ according to the kind of waterbody. For example, pathogens, habitat alterations, and organic enrichment are the three leading of water impairment for rivers and streams. For rivers and streams, the three leading of water impairment are agriculture, hydromodification, and unknown/unspecified factors. Looking across the three columns in Table 9.2, pathogens, organic enrichment, and mercury are factors common to two of the three classifications of waterbodies. The data in these two tables provide valuable guides for targeted actions of prevention and policymaking.

* Schistosomiasis is a disease of poverty that leads to chronic ill-health. Infection is acquired when people come into contact with fresh water infested with the larval forms (cercariae) of parasitic blood flukes, known as schistosomes [113].

TABLE 9.1
EPA's Summary in 2004 of Water Quality in U.S. Water Sources

			Condition of Assessed Waters (% of Assessed)		
Waterbody Type	Total Size	Amount Assessed (% of Total)	Good (%)	Good but Threatened (%)	Impaired (%)
Rivers (miles)	3,533,205	563,255 (16)	302,255 (52)	15,698 (3)	246,002 (44)
Lakes (acres)	41.7 million	16,230,384 (39)	5,619,221 (35)	159,761 (1)	10,451,402 (64)
Estuaries (miles square)	87,791	25,399 (29)	17,721 (70)	37 (<1)	7641 (30)

Source: EPA (Environmental Protection Agency), The National water quality inventory: Report to Congress for the 2004 reporting cycle—A profile, Office of Water, Washington, DC, 2004.

TABLE 9.2
Leading Causes and Sources of Impairment in Assessed Waterbodies

Rivers and Streams	Lakes, Ponds, Reservoirs	Estuaries
	Causes	
Pathogens	Mercury	Pathogens
Habitat alterations	PCBs	Organic enrichment
Organic enrichment	Nutrients	Mercury
	Sources	
Agriculture	Atmospheric deposition	Atmospheric deposition
Hydromodification	Unknown/Unspecified	Unknown/Unspecified
Unknown/Unspecified	Agriculture	Municipal discharges

Source: EPA (Environmental Protection Agency), The National water quality inventory: Report to Congress for the 2004 reporting cycle—A profile, Office of Water, Washington, DC, 2004.

9.4 U.S. WATER POLICIES

Protection of water quality and quantity in the U.S. has evolved over the country's history, commencing with wells and cisterns established for use in individual households, water obtained from surface sources such as rivers and lakes used by villages and small towns, and water drawn from surface sources and aquifers for servicing large cities. Commensurate with demands for water came policies for protection of water quality. These policies were largely the province of towns, municipalities, and states. Needless to say, considerable differences existed between states, in particular, regarding policies for protection of water quality. It was not until mid-twentieth century that the U.S. federal government assumed a role in water quality policymaking. Although protection of public health was the anchor for federal water policies, there was a corollary issue of reducing the differences across states in how water policies were developed and implemented. As will be described herein, the U.S. has two primary water protection policies, the CWAct of 1972 and the Safe Drinking Water Act (SDWAct) of 1974.

9.4.1 The Clean Water Act, 1972

The federal CWAct of 1972 is the principal U.S. law that addresses water pollution in U.S. water sources. The CWAct is a policy that does not possess the complexities of the federal Clean Air Act (CAAct, Chapter 8), and as such, has been subject to less controversy and litigation. However, both of these major U.S. policies on water and air share common features of regulating sources of pollution, requiring permits to pollute water or air, and sharing enforcement responsibilities with states.

9.4.1.1 History

Water suitable for human consumption and other uses has historically been of public health importance. Indeed, Hippocrates, the father of medicine, emphasized circa 400 BC the importance of boiling and straining water for health purposes [16]. Modern programs of water quality protection can be dated from the late nineteenth century, when chlorine was found to be an effective water disinfectant when added in low concentrations to drinking water. In 1902, Belgium became the first country to make continuous use of chlorine as an additive to drinking water supplies. Chlorination of public drinking water supplies in the U.S. dates to 1908, when the Boonton reservoir supply in Jersey City, New Jersey was chlorinated, triggering a series of lawsuits that were ultimately decided by courts in favor of water chlorination as a means for water purification [16].

Chlorination of public drinking water supplies must be considered as a "modern" public health triumph. The notion of adding a human poison, chlorine—even at very low concentrations—to a vital resource, drinking water, must have seemed foolhardy to many persons in the early twentieth century. However, as time passed, the marked reduction in waterborne diseases such as cholera, typhus, and dysentery demonstrated the public health benefits of water chlorination and overcame residual public opposition.

Chlorination of public drinking water supplies in the U.S. dates to 1908, when the Boonton reservoir supply in Jersey City, New Jersey was chlorinated.

Prior to the enactment of federal water quality statutes, states bore the responsibility for dealing with water quality problems, including issues of sanitation and drinking water quality. According to one source, many of the states' water pollution control policies from the late nineteenth century through the first half of the twentieth century comprised two steps:

1. First, common-law cases involving adverse effects of pollution upon public health or fish and wildlife resources were brought to court.
2. Second, statutory regulatory authority was then given to state health or fish and wildlife agencies. Sometimes these two authorities were combined and extended by a water pollution control board [17].

This approach by states led to considering each case of water pollution as an individual matter, subject to informal negotiations between polluters and state officials and attendant negotiations, all of which took considerable time and resulted in litigation if the parties could not agree on a pollution control strategy [17]. Little of this informal approach to pollution control was apparent to the general public unless a particular court action attracted news media attention. Another problem with a state-by-state approach to water quality control was different water quality standards between states resulted in the migration of some polluting industries to states with less stringent water standards and controls. Problems with state-based pollution controls contributed to pressure to develop federal water quality standards and regulations in mid-twentieth century.

The federal government's involvement with water pollution control dates to the turn of the twentieth century, when water pollution control regulations were included in the Rivers and Harbors Act of 1899. This act authorized the regulation of industrial discharges of pollution into waters that might cause navigation problems [18]. Later, the Public Health Service Act expressed the first federal policy on the disposal of human wastes, which authorized the Public Health Service to provide technical advice and assistance to communities, and for federal research on sanitary waste disposal methods. Over time, more comprehensive, focused federal water quality legislation was enacted by Congress, as described in this chapter.

TABLE 9.3
Clean Water Act's Titles

Title	Name of Title
I	Research and Related Programs
II	Grants for Construction of Treatment Works
III	Standards and Enforcement
IV	Permits and Licenses
V	General Provisions
VI	State Water Pollution Control Revolving Funds

Source: Copeland, C., Clean Water Act: Summaries of Environmental Laws Administered by EPA, Congressional Research Service, Washington, DC, 1999.

The principal federal law now governing pollution of the nation's waterways is the Federal Water Pollution Control Act, more commonly called the CWAct whose titles are given in Table 9.3 [18]. The original purpose of the act was to establish a federal program to award grants to states for construction of sewage treatment plants. Although originally enacted in 1948, the act was completely revised by amendments in 1972, giving the CWAct most of its current shape. The 1972 legislation declared as its objective the restoration and maintenance of the chemical, physical, and biological integrity of U.S. waters. Two goals were established: zero discharge of pollutants by 1985 and, as an interim goal and where possible, water quality that is both "fishable" and "swimmable" by mid-1983. While those dates have passed, the goals remain, and efforts to attain them are continuing [18].

The CWAct contains a number of complex elements of overall water quality management. Foremost is the requirement in §303 that states must establish ambient water quality standards for waterbodies, consisting of the designated use or uses of a waterbody (e.g., recreational, public water supply, or industrial water supply) and the water quality criteria that are necessary to protect the use or uses. Through permitting, states or the EPA impose wastewater discharge limits on individual industrial and municipal facilities in order to ensure that water quality standards are attained. However, Congress recognized in the CWAct that in many cases pollution controls implemented by industry and municipalities would be insufficient, due to pollutant contributions from other unregulated sources [18].

The Clean Water Act established a program of grants to construct sewage treatment plants and a regulatory and standards program to control discharges of chemical and microbial contaminants into U.S. waters [18].

At the heart of the CWAct is a system of permits, called the National Pollutant Discharge Elimination System (NPDES), which determines how much pollution can be released into surface (e.g., rivers) and underground water supplies. Each source of pollution must comply with permits specific to the source. Permits are therefore tailored to the size of the pollution source, the toxicity or hazard of individual pollutants, the

technology available to reduce pollution levels, and the quality and size of the waterway receiving the pollution discharges [19]. Unfortunately, according to the environmental working group, an organization, that in 2000 studied the status of 6700 permits for major facilities included in the NPDES, about 25% of the permits were not current [20]. That is, more than 1690 polluting facilities were operating without current discharge permits. Given the purpose of pollution discharge permits, it is important to the public's health that they are kept current.

In 2005, the EPA's Inspector General reported that there remains a large backlog of NPDES permits requiring renewal [21]. According to the report, 1120 major permit facilities, 9386 individual minor permit facilities, and 6512 general minor permit facilities need permit renewals.

In a third analysis of CWAct permits, in 2006 the U.S. Public Interest Research Group reported findings similar to those from the EPA Inspector General [22]. The group's research showed more than 62% of industrial and municipal facilities in the U.S. discharged more pollution into U.S. waterways than the CWAct permits allowed. The investigation covered the period between July 2003 and December 2004. The average facility discharged pollution in excess of its permit limit by more than 275%, or almost four times the legal limit.

Reflection on these three reports of problems with CWAct permits indicates a significant weakness in the permitting policy. Permits to discharge pollution into environmental media are ineffective without a commitment to enforce them.

The CWAct has forced the development and use of technologies to reduce the quantities of pollutants released into waterways. The CWAct gave industries until 1977 to install *best practicable control technology* (BPT) to clean up waste discharges. Later amendments to the CWAct (Table 9.4) required a greater level of pollutant cleanups, generally requiring that by 1989 industry utilize the *best available technology* (BAT) that is economically feasible. Failure to meet statutory deadlines can lead to enforcement action, although compliance extensions of as long as 2 years are available for industrial sources utilizing innovative or alternative technology.

Control of pollution discharges has been the key focus of water quality programs. In addition to the BPT and BAT national standards, states are required to implement control strategies for waters expected to remain polluted by toxic chemicals even after industrial dischargers have installed the best available cleanup technologies required under the CWAct, as amended. Development of management programs for these post-BAT pollutant problems was a prominent element in the 1987 CWAct amendments and is a key continuing aspect of the CWAct's implementation [23].

The process of deriving treatment requirements to attain specified water quality is a complicated four step process: (1) the state first establishes the desired highest use for a surface water; (2) then adopts scientific criteria (made available by the EPA) for water quality to support the designated use; (3) determines how much of a pollutant may be discharged into a body of water without violating the criteria; and (4) determines how much of the pollutant may be discharged by a given point source [24]. Some states have chosen to have the EPA administer these requirements rather than assume the responsibilities themselves.

Under §303(d) of the CWAct, states must identify lakes, rivers, and streams for which wastewater discharge limits are not stringent enough to achieve established water quality standards, after implementation of technology-based controls by industrial and municipal dischargers. For each of these waterbodies, a state is required to set a *total maximum daily load* (TMDL) of pollutants at a level which ensures that applicable water quality standards can be attained and maintained [25]. A TMDL sets the maximum amount of pollution a waterbed can receive without violating water quality standards, including a margin of safety. If a state fails to do this, the EPA is required to develop a priority list for the state and make its own TMDL determination.

A TMDL is both a planning process for attaining water quality standards and a quantitative assessment of problems, pollution sources, and pollutant reductions needed to restore and protect a river, stream, or lake. TMDLs may address all pollution sources, including point sources such as municipal sewage or industrial plant discharges; nonpoint sources, such as runoff from roads, farm fields, and forests; and naturally occurring sources, such as runoff from undisturbed lands. The TMDL itself does not establish new regulatory controls on sources of pollution. However, when TMDLs are established, municipal and industrial wastewater treatment plants may be required to install new pollution control technology.

The TMDL program became controversial in part because of requirements and costs now facing states to implement this 30-year-old provision of the law. In 1999, the EPA proposed regulatory changes to strengthen the TMDL program. According to EPA, the completion and EPA approval of a TMDL is one step in the water regulatory or restoration process. While the TMDL calculates numeric targets for attainment of water quality standards, a plan and subsequent

TABLE 9.4
Clean Water Act and Major Amendments

Year	Act
1948	Federal Water Pollution Control Act
1956	Water Pollution Control Act
1961	Federal Water Pollution Control Act Amendments
1965	Water Quality Act
1966	Clean Water Restoration Act
1970	Water Quality Improvement Act
1972	Federal Water Pollution Control Amendments
1977	Clean Water Act
1981	Municipal Wastewater Treatment Construction Grants Amendments
1987	Water Quality Act
2000	BEACH Act

Source: Copeland, C., 1999, Clean Water Act: Summaries of Environmental Laws Administered by EPA, Congressional Research Service, Washington, DC.

actions are keys to meeting these targets. TMDL implementation plans are not required by the CWAct, but are often submitted as part of the TMDL report. In many states, TMDL implementation plans are part of a larger, more comprehensive watershed planning efforts [23].

In an overall management plan, distinct objectives are identified to determine which practices to use in critical areas to achieve needed reductions. Throughout the planning and implementing process the objectives may be refined and adjusted to meet specific needs. TMDL implementation plans can also invoke a wide array of monitoring, tracking and logistical measures. A comprehensive TMDL implementation plan outlines management goals, projects, partners, priorities, schedule, and finding along with tracking, monitoring, and reevaluation processes [23].

9.4.1.2 Clean Water Act Perspective

In addition to the 1972 amendments, several other important amendments to the CWAct have occurred, as listed in Table 9.4. Amendments enacted in 1977, 1987, and 2000 are particularly relevant for public health purposes.

The 1977 amendments to the act focused on toxic pollutants. The CWAct of 1977 established the basic structure for regulating discharges of pollutants into waters of the U.S. Further, §404 established a program to regulate the discharge of dredged and fill material into U.S. waters, including wetlands. The basic premise of §404 is that no discharge of dredged or fill material can be permitted if a practicable alternative exists that is less damaging to the aquatic environment or if the nation's waters would be significantly degraded. Regulated activities are controlled by a permit review process. An *individual permit*, which is the responsibility of the EPA, is usually required for potentially significant impacts. However, for discharges thought to have minimal impact, the U.S. Army Corps of Engineers (USACE) can grant *general permits*, which are issued for particular categories of activities (e.g., minor road crossings, utility line backfill) as an expedited means for regulating discharges [26]. Water areas known as wetlands constitute a vital natural resource in the U.S. and elsewhere. "Wetlands are areas where the frequent and prolonged presence of water at or near the soil surface drives a natural ecosystem, i.e., the kind of soils that form, the plants that grow, and the fish and wildlife that find habitat" [27]. Swamps, marshes, and bogs are common types of wetlands. The Everglades in Florida are perhaps the best known U.S. wetland.

Wetlands serve an important environmental health purpose, one in addition to serving as a habitat for great numbers of birds, fish, mammals, plants, and trees. Wetlands are one of nature's water purifiers. Turbid surface waters that flow into wetlands drain off as freshwater. Regrettably, there has been a steady loss of wetlands acreage. For instance, the U.S. Fish and Wildlife Service estimates that between 1986 and 1997, a net of 644,000 acres of wetlands were lost, with 58,400 acres lost annually [28]. The principal causes of loss of wetlands were urban development, agriculture, silviculture (i.e., the growing and culture of trees), and rural development [28]. As a matter of environmental policy, finding the best balance between protection of wetlands and the need for land development is, and will remain in the future, a difficult calculus for policymakers.

In 1987, the CWAct was reauthorized and again focused on toxic substances. The amendments authorized citizen suit provisions and funded sewage treatment plants under a construction grants program. Prior to 1987, the CWAct only regulated pollutants discharged to surface waters from *point sources* (i.e., pipes, ditches, and similar conveyances of pollutants), unless a permit was obtained under provision in the Act. *Nonpoint sources* (e.g., storm water runoff from agricultural lands) were covered by the Water Quality Act of 1987, which amended the CWAct. Pollution sources are required by the CWAct to treat their wastes to meet the more stringent of two sets of requirements, based on either technologic feasibility or attainment of desired levels of water quality [24]. From 1972 to 2003, the nation has invested more than $300 billion to build and upgrade wastewater treatment systems [29].

Over the years, the sewage collection system in the U.S. has grown to more than a million miles of collection pipes. This system carries about 50 trillion gallons of raw sewage daily, delivered to approximately 20,000 sewage treatment plants [30]. This enormous system of sewage collection and treatment represents a vital public health resource to the U.S. public, preventing human exposure to the pathogens found in raw sewage. It also represents an indispensable global environmental contribution by reducing the pollution load deposited in the planet's oceans and seas.

ENFORCEMENT EXAMPLE

(Washington, DC—March 6, 2015) Coal producer Alpha Natural Resources, Inc. has agreed to $227.5 million in penalties and other costs to settle federal allegations that it illegally dumped large amounts of toxicants into waterways in Pennsylvania and four other states. The company will pay $27.5 million in penalties and spend $200 million upgrading its wastewater treatment systems to reduce illegal discharges. The Pennsylvania state Department of Environmental Protection will get $4.125 million from the fines to use in clean water programs. The fine is the largest assessed under federal clean water rules [33].

In 2000, the CWAct was amended when Congress enacted the Beaches Environmental Assessment and Coastal Health (BEACH) Act, which amended §304 of the act. The act provided the EPA with additional authority to regulate the quality of water used for recreation at beaches. The act applies to those 35 states and U.S. territories that have coastal water or border the Great Lakes [31]. The BEACH Act of 2000 contains eight sections [32]. Those sections with the greatest potential for protecting the public's health are as follows:

1. §2(i)(1)(A) "[e]ach State having coastal recreation waters shall adopt and submit to the Administrator water quality criteria and standards for the coastal recreation waters of the State for those pathogens and pathogen indicators for which the Administrator has published criteria under §(a)." If a state fails to adopt water quality criteria and standards or submits water quality criteria and standards less protective than EPA's, EPA is authorized to propose regulations for such states. Note: According to EPA, as of December 2004, 14 states have adopted adequate water quality standards, 21 states or territories have adopted some to none [31].
2. §3(a)(v)(b)(9) requires EPA to publish new or revised water quality criteria for pathogens and pathogen indicators for the purpose of protecting human health in coastal recreation waters. States are required to promptly notify the public, local governments, and EPA of any exceedance or likely exceedance of applicable water quality standards for coastal recreation waters. Note: In November 2004, EPA issued a final regulation on the assessment and monitoring of pathogens in recreation water [31].
3. §4(a)(1)(A) requires EPA to publish performance criteria for monitoring and assessment of coastal recreation waters adjacent to beaches or similar points of access. Under this section, EPA is authorized to provide grants to states and local governments for implementation of monitoring and assessment programs. Under this section, federal agencies with jurisdiction over coastal recreation waters adjacent to beaches must develop and implement a monitoring and notification program for the coastal recreation waters.

The BEACH Act of 2000 is important for several public health and economic purposes. For the 2004 swimming season, of the 3574 beaches monitored by 28 coastal states and Puerto Rico, 942 had at least one health advisory or closing during the swimming season [32]. A total of 4906 beach notification actions were taken at the 3574 beaches. The EPA estimated in 2004 that Americans annually take a total of 910 million visits to coastal areas and spend about $44 billion at beach locations [30]. Given the large number of beachgoers, exposure to water pathogens would be a considerable public health problem. Further, economic losses due to polluted beach water could be quite large, posing a financial hardship to cities and businesses that benefit from beach recreation. The spirit of the act is in the prevention of disease and disability, the core principle of public health.

9.4.1.3 Key Provisions of the CWAct Relevant to Public Health

Given the CWAct's stated goal and policies, the current act could be said to consist of three major parts. The first major part consists of the provisions in Title I, which establishes research, investigations, training, and information authorities [23,34]. The provisions of Title II and Title VI constitute the second major part. They authorize federal financial assistance for municipal sewage treatment plant construction. The third major part consists of the regulatory requirements, found throughout the act, that apply to industrial and municipal discharges of pollutants.

Title I contains several important authorities delegated to the EPA, including the following: (1) conduct and promote the coordination and acceleration of research, investigation, experiments, training, demonstration, surveys, and studies relating to the causes, effects, extent, prevention, reduction, and elimination of pollution; (2) encourage, cooperate with, and render technical services to pollution control agencies, and public and private agencies; (3) conduct, in cooperation with state water pollution control agencies and other interested agencies, public investigations concerning the pollution of any navigable waters; (4) establish advisory committees of recognized experts; (5) establish, equip, and maintain a water quality surveillance system; and (6) initiate and promote research for measuring the most effective practicable tools and techniques for measuring the social and economic costs and benefits of activities that are subject to regulation under the CWAct [34].

Under *Titles II and VI*, Congress has authorized grants for planning, design, and construction of municipal sewage treatment facilities since 1956 through 1998. Since that time, more than $57 billion has been appropriated for grants to aid wastewater treatment plant construction [23]. Federal grants are made for several kinds of water treatment projects, based on a priority list established by the states. Grants are generally available for up to 55% of total project costs [23]. Federal grants awarded to states are another example of environmental health federalism.

Under provisions of the CWAct, for the purpose of regulation the EPA establishes a list of toxic pollutants and a list of priority pollutants [34a]. Specifically, the act references the Toxic Pollutant List at § 307(a)(1); 33 U.S.C. 1317(a)(1). § 307(a)(1) states: "[…] the list of toxic pollutants or combination of pollutants subject to this Act shall consist of those toxic pollutants listed in Table 1 of the Committee Print Numbered 95-30 of the Committee on Public Works of the House of Representatives." The list was negotiated among parties to a settlement agreement (NRDC et al. vs Train, 6 ELR 20588 Exit, D.D.C. 9 June 1976). Congress subsequently ratified the Settlement Agreement and the toxic pollutant list when it amended the CWAct in 1977. The list was first published on January 31, 1978 in the *Federal Register* (43 FR 4108). The list appears in the Code of Federal Regulations at 40 CFR 401.15. The list is an important starting point for the EPA to consider in developing national discharge standards (such as Effluent Guidelines) or in national permitting programs. The list contains 65 entries [34a].

A separate but related list is the EPA's Priority Pollutants List [34a]. The Priority Pollutants are a set of chemical pollutants the EPA regulates, and for which the EPA has published

analytical test methods. The Priority Pollutant List makes the list of toxic pollutants more usable, in a practical way, for the purposes assigned to EPA by the CWAct. For example, the Priority Pollutant List is more practical for testing and for regulation in that chemicals are described by their individual chemical names. The list of toxic pollutants, in contrast, contains open-ended groups of pollutants, such as "chlorinated benzenes." That chemical group contains hundreds of compounds; there is no test for the group as a whole, nor is it practical to regulate or test for all of these compounds. The list contains 126 entries as of 2017 [34a].

9.4.1.4 Associations between Contaminated Water and Human Health

As noted in 2010 by the Secretary, Department of Health and Human Services (DHHS), contamination of water can come from both point (e.g., industrial sites) and nonpoint (e.g., agricultural runoff) sources. Biological and chemical contamination significantly reduces the value of surface waters (streams, lakes, and estuaries) for fishing, swimming, and other recreational activities, and can cause disease in humans. For example, during the summer of 1997, blooms of *Pfiesteria piscicida* were implicated as the likely cause of fish kills in North Carolina and Maryland. "The development of intensive animal feeding operations (e.g., large scale swine farms) has worsened the discharge of improperly or inadequately treated wastes, which presents an increased health threat in waters used either for recreation or for producing fish and shellfish" [34b].

Two surveillance systems have provided relevant human health data on U.S. water quality. One system is a disease surveillance system operated by the Centers for Disease Control and Prevention (CDC). The other system, which is maintained by the EPA, provides data on water quality measurements. Turning first to the CDC system, since 1971, the CDC, EPA, and Council of State and Territorial Epidemiologists have maintained a collaborative surveillance system for collecting and periodically voluntarily reporting data on occurrences and causes of waterborne-disease outbreaks (WBDOs) related to drinking water supplies. Tabulation of recreational water-associated outbreaks was added to the surveillance system in 1978. This surveillance system is the primary source of data concerning the scope and effects of waterborne disease outbreaks on persons in the U.S. [35].

During the period 2001–2002, a total of 65 WBDOs associated with recreational water were reported by 23 states. The 65 outbreaks caused illness among an estimated 2536 persons; 61 persons were hospitalized, 8 of whom died. According to the CDC, this is the largest number of recreational water-associated outbreaks to occur since reporting began in 1978 [36]. The numbers of recreational water-associated outbreaks have increased significantly during this period ($p < 0.01$). Of these 65 outbreaks, 30 involved gastroenteritis. The etiologic agent was identified in 23 of the 30 outbreaks; 18 of the 30 were associated with swimming or wading pools. About 4 of the 65 outbreaks involved acute respiratory illness associated with chemical exposure at pools.

In addition to the CDC's waterborne disease surveillance system, the EPA is required under §305(b) of the CWAct, as amended, to report to Congress on the nation's water quality conditions. Under §305(b), states, territories, and interstate commissions must assess their water quality biennially and report those findings to the EPA. These entities must compare their monitoring results to the water quality standards they have set for themselves. In the year 2000 report to Congress, the EPA found that 39% of rivers, 45% of lakes, and 51% of estuaries did not meet water quality standards [37]. The leading causes of inadequate water quality included bacteria, nutrients, metals (primarily mercury), and siltation. The EPA cites the following conditions as the primary sources of water degradation: runoff from agricultural lands, sewage treatment plants, and hydrological modifications such as dredging of channels. As a matter of environmental health policy, these statistics indicate that the states, territories, and other governmental entities have a substantial amount of progress to make to improve water quality.

The problem of inadequate sewage treatment is particularly important, given the huge volume of sewage that must be treated in order to prevent waterborne diseases. As stated previously in this chapter, approximately 50 trillion gallons of raw sewage in the U.S. must be treated every day. Unfortunately, many of the sewage systems in the U.S. are old and inadequately designed. To be more specific, some sewage-carrying pipes are almost 200 years old, with 100-year old pipes not uncommon. Moreover, many older municipalities, primarily in the northeastern U.S. and the Great Lakes region, have sewage collection systems designed to carry both sewage and storm water runoff. Such combined systems can overflow during heavy rainfall, resulting in raw sewage becoming mixed with storm water, which can bypass sewage treatment plants.

The EPA estimated in 2004 that 1.3 trillion gallons of raw sewage are dumped annually due to combined sewer overflows. The agency also estimates that 1.8–3.5 million persons in the U.S. become ill annually from swimming in waters contaminated by sanitary sewage overflows [cited in 30]. To prevent this kind of public health problem will require repairing and upgrading the sewage collection and treatment systems in the U.S. There is government and private sector consensus that there is a funding gap of $1 trillion for water infrastructure [cited in 30]. Regrettably, gathering political support for repair and upgrading of municipal infrastructures can be difficult, especially for sewage systems. There is the tendency to pass infrastructure repairs to succeeding governments. Only when emergencies occur, such as the aftermath of hurricanes or release of large amounts of pollutants in an area or under a court order, do political bodies become energized.

Some recent investigations of the health consequences associated with contaminated water have expanded the suite of adverse human health effects. In a study led loy researchers at the Boston University school of medicinebabies born to mothers with high levels of perchlorate during their first trimester are more likely to have lower IQs later in life [38]. The researchers analyzed perchlorate levels in the first trimester of 487 pregnant women in Cardiff, Wales, and Turin, Italy, who had iodine deficiency and thyroid dysfunction

during pregnancy. Their children's IQ scores were evaluated at 3 years old. Children born to mothers' with perchlorate levels in the highest 10% were more than three times as likely to have an IQ score in the lowest 10% of scores. It adds to evidence that the drinking water contaminant may disrupt thyroid hormones that are crucial for proper brain development. Perchlorate, which is both naturally occurring and manmade, is used in rocket fuel, fireworks, and fertilizers. It has been found in 4% of U.S. public water systems (PWS) serving an estimated 5–17 million people, largely near military bases and defense contractors in the U.S. West [38].

A study by school of Public Health, Boston University, researchers compared 1091 tetrachloroethylene (PCE) exposed pregnancies and 1019 unexposed pregnancies among 1766 women in Cape Cod, Massachusetts., where water was contaminated in the late 1960s to the early 1980s by the installation of vinyl-lined asbestos cement pipes, over time releasing PCE [39]. PCE exposure was estimated using water-distribution system modeling. Data on pregnancy complications were self-reported by mothers. Of more than 2000 pregnancies, 9% were complicated by pregnancy disorders associated with placental dysfunction. Pregnancies among women with high PCE exposure had 2.38 times the risk of stillbirth and 1.35 times the risk of placental abruption, compared to pregnancies not exposed to PCE.

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9.4.1.5 Associations between Contaminated Water and Ecosystem Health

UNEP has aided in the coordination of programs of water quality protection. In doing so, the agency has accumulated data on the associations between water quality and impacts on ecosystems. UNEP observes that "over the past decades, the water quality of surface waters and groundwaters has improved over many parts of the world, particularly in industrialized countries, but also in some parts of middle-and lower-income countries. This has been one of the good news stories of environmental management, achieved by widely introducing wastewater treatment and other water quality management measures. Yet there is important unfinished business. Investing in wastewater treatment, assuring access to safe water, preventing water pollution, and restoring aquatic ecosystems, are examples of important unfinished business that require the attention of policymakers and water experts" [40].

UNEP also observes that globally many rivers and other parts of the freshwater system are faced with new threats to their water quality. In emerging and developing countries, water quality is threatened by the increasing discharge of untreated or inadequately treated municipal wastewater as well as by diffuse sources of pollutants from agricultural, urban, and other areas that degrade surface and groundwater.

Regarding ecosystems, water quality degradation poses health risks and undermines ecosystem services provided by surface and subsurface waters. Wastewater loadings deplete dissolved oxygen, increase turbidity, and have other negative effects on freshwater ecosystems thus jeopardizing the services they provide. Impacts might include diminishing stocks of freshwater fish for food, declining aquatic biodiversity, deteriorating water quality for industrial and agricultural use, and higher treatment costs for municipal water supply.

In countries undergoing rapid economic development, a new threat is caused by the increasing discharge of toxic organic chemicals, heavy metals, and other substances to surface waters. Some of these substances may accumulate in freshwater ecosystems or infiltrate to groundwater and thereby pose a long-term risk to human health and aquatic ecosystems.

In industrialized countries, as well as in some developing ones, an increasing threat is the discharge to surface waters of unidentified and unmonitored residues from medicines (e.g., pharmaceuticals) and new chemical products (e.g., cosmetics). Since conventional wastewater treatment might not be able to remove these substances, they may find their way into freshwater systems. Some of these substances might act as endocrine disruptors and be otherwise harmful to people and the environment. Other factors that contribute to water quality degradation and corollary effects on ecosystems include the following:

- Water quality degradation in developing and rapidly industrializing countries is often associated with the growth of mining, manufacturing, and industrial activities. Wastewaters are often discharged without adequate treatment directly or indirectly to different types of waterbodies (rivers, groundwater aquifers, wetlands, etc.). Better waste management practices are required.
- An important factor contributing to water quality degradation worldwide is unsustainable land use and agriculture. In agricultural regions, a main source of water contamination is seasonal runoff of pesticides and fertilizers from cropland and pastureland. Other possible sources of land-based water pollution are deforestation and intensive animal husbandry. Urban areas are also a major source of diffuse water pollutants. Better land management and planning could help minimize these problems.
- Climate change is expected to have an increasing impact on worldwide water quantity and quality. Global climate change is expected to have an increasing influence on not only water quantity but also water quality. Where long-term precipitation diminishes, it is likely that stream flow may decrease and along with it the self-purifying capacity of rivers and lakes [40].

Recent reports link pharmaceuticals discarded into water sources as causing ecosystem effects. For example, a review

study led by a University of york researcher concluded that recent studies have revealed that pharmaceuticals, both human and veterinary, disperse widely in aquatic and terrestrial environments with uptake into a range of organisms. Pharmaceuticals are designed to have biological actions at low concentrations rendering them potentially potent environmental contaminants. In some cases the effects can be dramatic, such as the near extinction of three species of vulture in India after eating the carcasses of livestock that had been treated with the anti-inflammatory diclofenac. However, effects can be more subtle but still have potentially significant impacts. Changes to behavior of fish and birds after exposure to low concentrations of psychiatric drugs can alter foraging patterns, activity levels, and risk taking [41].

A long-term, whole-lake experiment was conducted at the Experimental Lakes Area in northwestern Ontario, Canada, using a before-after-control-impact design to determine both direct and indirect effects of the synthetic estrogen used in the birth control pill, 17α-ethynyloestradiol (EE2). Recruitment of fathead minnow failed, leading to a near-extirpation of this species both 2 years during and 2 years following EE2 additions. Body condition of male lake trout and male and female white sucker declined before changes in prey abundance, suggesting direct effects of EE2 on this endpoint [42].

9.4.1.6 The EPA Water Quality Trading Policy, 2003

On January 13, 2003, the EPA announced a market-based "Water Quality Trading Policy." This is a variant of the cap-and-trade policy discussed in Chapter 6. The Trading Policy was written on the assumption that, if a TMDL were in place, all trading partners would be covered by the TMDL. In this case, waste load allocations and load allocations under the TMDL form the baseline for trading. In all cases, permits must be designed to meet water quality standards as required under CWAct § 301(b)(1)(c). Inclusion of trading provisions in NPDES permits should facilitate meeting this requirement. The policy's aim is to authorize users of a waterbody to trade pollution credits among themselves in order to cost-effectively achieve the pollutant reductions mandated by the TMDL and other programs. The 2003 Policy allows one source [of water pollution] to meet its regulatory obligations by using pollutant reductions created by another source. Entities that discharge into the same watershed may achieve increased flexibility by working together to reduce discharges of certain pollutants [42].

A study of this policy's efficacy by the nongovernmental organization (NGO) Food and Water Watch yielded concern. The NGO noted that water quality trading programs were underway in more than 20 states, covering the release of pollutants like nitrogen and phosphorus into U.S. waterways. Those nutrients are behind algae blooms that suck oxygen out of water supplies, killing fish and other wildlife and sometimes making people sick. But after reviewing more than 1000 documents from pilot trading programs in Pennsylvania and Ohio, Food and Water Watch researchers came to the conclusion that the programs, though they sound reasonable on paper, operate very differently than predicted in the real world.

Specifically, according to researchers, with little state oversight, private contractors have been permitted to run pollution trading markets that offer highly regulated industrial polluters the chance to essentially swap places with farms, concentrated animal feeding operations and feed lots whose runoff is not as tightly controlled under the CWAct. Researchers commented, "The big, big problem that we see on the credit generating side is that agriculture operations never have to monitor, sample, never have to verify that they actually generated the pollution that underlies these credits, […]It's all based on modeling" [44].

9.4.1.7 The EPA Clean Water Rule, 2015

Over the existence of the CWAct subsequent to its refocus and expansion in the 1972 amendment, questions have arisen as to the extent of coverage of the CWAct. More simply, what are the waters of the U.S. that are subject to the provisions of the act? This rather basic question has arisen from state governments, industry, and individual property owners. The question has been litigated and resulted in U.S. Supreme Court decisions that left room for the EPA's interpretation of what constituted "waters of the United States" under the CWAct's provisions. This resulted in EPA's issuance of its Clean Water Rule. As characterized by EPA, "Protection for about 60% of the nation's streams and millions of acres of wetlands has been confusing and complex as the result of Supreme Court decisions in 2001 and 2006. The Clean Water Rule protects streams and wetlands that are scientifically shown to have the greatest impact on downstream water quality and form the foundation of our nation's water resources. EPA and the U.S. Army are ensuring that waters protected under the CWAct are more precisely defined, more predictable, easier for businesses and industry to understand, and consistent with the law and the latest science" [45].

"EPA and the U.S. Army Corps of Engineers finalized the Clean Water Rule to clearly protect the streams and wetlands that form the foundation of the nation's water resources. Protection for many of the nation's streams and wetlands has been confusing, complex, and time-consuming as the result of Supreme Court decisions in 2001 and 2006. The Clean Water Rule ensures that waters protected under the CWAct are more precisely defined, more predictably determined, and easier for businesses and industry to understand " [46]. Specifically, the Clean Water Rule:

- Clearly defines and protects tributaries that impact the health of downstream waters. The CWAct protects navigable waterways and their tributaries. The rule says that a tributary must show physical features of flowing water—a bed, bank, and ordinary high water mark—to warrant protection. The rule provides protection for headwaters that have these features and science shows can have a significant connection to downstream waters.
- Provides certainty in how far safeguards extend to nearby waters. The rule protects waters that are next to rivers and lakes and their tributaries because

science shows that they impact downstream waters. For the first time, the rule sets boundaries on covering nearby waters that are physical and measurable.
- Protects the nation's regional water treasures. Science shows that specific water features can function like a system and impact the health of downstream waters. The rule protects prairie potholes, Carolina and Delmarva bays, pocosins, western vernal pools in California, and Texas coastal prairie wetlands when they impact downstream waters.
- Focuses on streams, not ditches. The rule limits protection to ditches that are constructed out of streams or function like streams and can carry pollution downstream. Not covered are ditches that are not constructed in streams and that flow only when it rains.
- Maintains the status of waters within Municipal Separate Storm Sewer Systems. The rule does not change how those waters are treated and encourages the use of green infrastructure.
- Reduces the use of case-specific analysis of waters. Previously, almost any water could be put through a lengthy case-specific analysis, even if it would not be subject to the CWAct. The rule significantly limits the use of case-specific analysis by creating clarity and certainty on protected waters and limiting the number of similarly situated water features [46].

Perspective: The EPA's Clean Water Rule is one of several key regulations from the agency during the Obama administration. Along with another major regulation, the Clean Power Plan (Chapter 6), both EPA regulations were met with vigorous opposition from some U.S. states and various industrial and agricultural organizations. Conversely, both regulations were generally embraced by environmental groups and some other nongovernment organizations. Both of these key regulations touch on a common denominator, climate change, and both have found analogous journeys of litigation. Regarding climate change, the Clean Power Plan is intended to reduce greenhouse gases (GHGs) into the atmosphere, while the Clean Water rule is intended to construct a definition of which waters of the U.S. are subject to provisions of the CWAct. As ambient air temperatures rise, an effect on water resources will be of concern. While both regulations have been put into effect by the EPA, future court decisions could reshape some aspects; moreover, the Trump administration has vowed to rescind both the Clean Power Plan and the Clean Water rule. Regarding the latter, on February 28, 2017 President Trump instructed the EPA and the U.S. Army Corps of Engineers (USACE) to review and reconsider the rule, stating his directive was, "paving the way for the elimination of this very destructive and horrible rule" that should have only applied to "navigable waters" affecting "interstate commerce" [46a].

9.4.1.8 Cost and Benefits of Water Pollution Control

In 2003, the White House's Office of Management and Budget estimated that over the period 1992–2002 federal water pollution rules resulted in an annual benefit of $0.89–$8.07 billion, with costs estimated at $2.4–$2.9 billion. These figures have considerable uncertainty in the monetary benefits of water pollution control, with less uncertainty in the costs. The benefits/cost ratio therefore ranges from <1 to approximately 2.7 [47].

9.4.2 The Safe Drinking Water Act, 1974

The SDWAct of 1974 is the second of the two major U.S. statutes on water policy. Whereas the CWAct of 1972, as amended, addresses the control of sources of water pollution, the SDWAct of 1974, as amended, focuses on the security of drinking water supplies in the U.S. In a sense, there is a duality of purpose between the two laws: both statutes apply to water in the U.S., but with different aims. Absent either statute, the nation's public health would be in jeopardy.

9.4.2.1 History

The SDWAct* was enacted to protect the quality of drinking water in the U.S. This law focuses on all waters actually or potentially designed for drinking use, whether from surface or underground sources. Congress acted after a nationwide study of community water systems revealed widespread water quality and health risk problems resulting from poor operating procedures, inadequate facilities, and poor management of public water supplies in communities of all sizes. Further, the 1974 act was in response to congressional findings that chlorinated organic chemicals were contaminating major surface and underground water supplies, that widespread underground injection operations were a threat to aquifers, and that the infrastructures of public water supply systems were increasingly inadequate to protect the public health [48].

The SDWAct, as amended in 1986 and 1996, gives the EPA the authority to set drinking water standards. *Drinking water standards* are regulations that the EPA sets to control the level of contaminants in the nation's drinking water. These standards are part of the SDWAct's "multiple barrier" approach to drinking water protection, which includes assessing and protecting drinking water sources, protecting wells and collection systems, making sure water is treated by qualified operators, ensuring the integrity of distribution systems, and making information available to the public on the quality of their drinking water. According to the EPA, these multiple barriers, along with the involvement of the EPA, states, tribal nations, drinking water utilities, communities, and citizens, ensure that tap water in the U.S. and its territories is safe to drink. In most cases, the EPA delegates responsibility for implementing drinking water standards to states and tribal nations.

> The Safe Drinking Water Act establishes primary drinking water standards, regulates underground injection disposal practices, and establishes a groundwater control program [49].

* The "Safe Drinking Water Act" consists of Title XIV of the Public Health Service Act (42 U.S.C. 300f-300j-D) as added by Public Law 93-523 (December 16, 1974) and subsequent amendments [112].

There are two categories of drinking water standards [49]:

- A *National Primary Drinking Water Regulation* (NPDWR or primary standard) is a legally enforceable standard that applies to PWS. Primary standards protect drinking water quality by limiting the levels of specific contaminants that are known or anticipated to occur in water and can adversely affect public health. They take the form of Maximum Contaminant Levels (MCLs) or Treatment Techniques (TTs), which are described below.
- A *National Secondary Drinking Water Regulation* (NSDWR or secondary standard) is a nonenforceable guideline about contaminants that may cause cosmetic effects (such as skin or tooth discoloration) or aesthetic effects (such as taste, odor, or color) in drinking water. The EPA recommends secondary standards to water systems but does not require systems to comply. However, states may choose to adopt them as enforceable standards.

Drinking water standards apply to those Public Water Supplies (PWS) that provide water for human consumption through at least 15 service connections, or regularly serve at least 25 individuals. PWS include municipal water companies, homeowner associations, schools, businesses, campgrounds, and shopping malls. The EPA estimates there are approximately 170,000 PWS in the U.S. They are classified by the EPA according to the number of people the systems serve, the source of their water, and whether they serve the same customers year-round or on an occasional basis. The three classifications (and the number of people each served in 1999) are as follows: Community Water System (53 923 systems serving 253 million), Non-Transient Non-Community Water System (20,082 systems serving 6.3 million), and Transient Non-Community Water System (93,729 systems serving 16.8 million) [50]. Community Water Systems, which are PWS that supply water to the same population all year, constitute the vast majority of systems that supply water to the nation's population. Approximately 11,000 of the Community Water Systems relied on surface water as its source, serving 167 million people, and the remainder relied on groundwater, serving approximately 86 million people [50]. Because of the large numbers of people serviced by these water systems, it is sound environmental health policy to protect them from contamination in order to prevent waterborne illnesses.

9.4.2.2 SDWAct Amendments

As indicated in Table 9.5, the SDWAct has been amended several times since the original act of 1974. "The first major amendments, enacted in 1986, were largely intended to increase the pace at which EPA regulated contaminants. These amendments required EPA to (1) issue regulations for 83 specified contaminants by June 1989 and for 25 more contaminants every three years thereafter, (2) promulgate requirements for disinfection and filtration of public water

TABLE 9.5
Safe Drinking Water Act and Major Amendments

Year	Act	Purpose
1974	Safe Drinking Water Act	
1977	Amendments	Authorized continuation of a the agreement with the National Academy of Sciences to conduct a study of drinking water quality
1979	Amendments	Authorizes states regarding: underground injection control, extension/exemption of public water systems,
1980	Amendments	permits grants to states for water filtration systems
1986	Amendments	Creates a demonstration program to protect aquifers from pollutants, mandates state-developed critical wellhead protection programs, requires the development of drinking water standards for many contaminants now unregulated, and imposes a ban on lead-content plumbing materials
1988	Lead Contamination Control Act	Deals with the recall of lead-lined drinking water coolers
1996	Amendments	Consumer confidence reports, cost-benefit analysis, drinking water state revolving fund, microbial contaminants and DBPs, operator certification, public information and consultation, small water systems
2002	Public Health Security and Bioterrorism Preparedness and Response Act	Large water system emergency response plan
2005	Amendments	2005 Energy Policy Act exempts hydraulic fracturing and oil and gas drilling from certain sections of the Safe Drinking Water Act of 1974 and the Clean Water Act of 1972
2011	Reduction of Lead in Drinking Water Act (RLDWA)	Reduction of Lead in Drinking Water Act (RLDWA)
2013	Community Fire Safety Act	Evaluation of sources of lead in water distribution systems and alternate routing systems
2015	Amendments	Directs EPA to develop and submit to Congress a strategic plan for assessing and managing risks associated with algal toxins in drinking water provided by public water systems

Source: Tiemann, M., Safe Drinking Water Act. Summaries of Environmental Laws Administered by the EPA, Congressional Research Service, Washington, DC, 1999.

supplies, (3) ban the use of lead pipes and lead solder in new drinking water systems, (4) establish an elective wellhead protection program around public wells, (5) establish a demonstration grant program for state and local authorities having designated sole-source aquifers to develop groundwater protection programs, and (6) issue rules for monitoring injection wells that inject wastes below a drinking water source. The amendments also increased EPA's enforcement authority" [51].

The Lead Contamination Control Act of 1988 added a new part F to the SDWAct. It was intended to reduce exposure to lead in drinking water by requiring the recall of lead-lined water coolers, and required the EPA to issue a guidance document and testing protocol to help schools and day care centers to identify and correct lead contamination in their drinking water [51]. The primary impetus for the act was a report to Congress that identified water coolers in schools as a potential source of children's exposure to lead in drinking water [52].

In 1996, Congress again made sweeping changes to the SDWAct. Originally, the SDWAct primarily focused on treatment as the means of providing safe drinking water at the tap. The 1996 amendments modified the existing law by recognizing source water protection, operator training, funding for water system improvements, and public information as important components of safe drinking water programs [53]. Implementation of the 1986 provisions had brought to the fore widespread dissatisfaction among states and communities. These concerns included inadequate regulatory flexibility and unfunded mandates. "As over-arching themes, the 1996 Amendments target resources to address the greatest health risks, increase regulatory and compliance flexibility under the Act, and provide funding for federal drinking water mandates. Specific provisions revoked the requirement that EPA regulate 25 contaminants every 3 years, increased EPA's authority to consider costs when setting standards, authorized EPA to consider overall risk reduction, established a state revolving loan program to help communities meet compliance costs, and expanded the Act's focus on pollution prevention through a new source water protection program" [53]. A cost-benefit analysis and a risk assessment are required before a standard can be set. The standards are initially based on health protection and the availability of technology. They are called *Maximum Contaminant Levels* (MCLs). The amendments required the EPA to promulgate standards that maximize health risk reduction benefits at costs that are justified by the benefits.

The 1996 SDWAct amendments required that the EPA establish criteria for a program to monitor unregulated contaminates found in drinking water supplies. Further, every 5 years the EPA must publish a list of contaminants to be monitored in public drinking water supplies. One way to approach the requirement to regularly update a regulatory action is to establish a regulatory platform that first establishes criteria for updating—in this case a list of substances—then applying the criteria at specified intervals—in this instance, every 5 years. To develop such a platform is a policy decision. The EPA released its Unregulated Contamination Monitoring Rule (UCMR) in September 1999, which covered 25 chemicals and one microorganism [54]. This was in response to the 1996 SDWAct amendments that provided for monitoring of no more than 30 contaminants over 5 year period, monitoring only a representative sample of PWS that serve fewer than 10,000 people, and storing analytical results in a National Contaminated Occurrence Database. The second list, UCMR 1, was proposed in August 2005 and contained 26 unregulated drinking water contaminants that must be monitored by U.S. water suppliers that exceed EPA designated minimum number of customers [55]. The data collected will help the EPA determine whether to regulate the contaminants, their occurrence in drinking water, the potential population exposed to each contaminant, and the levels of exposure.

9.4.2.3 Key Provisions of the SDWAct, as Amended, Relevant to Public Health

There are five parts to the SDWAct, as amended. The parts establish various responsibilities and authorities for the EPA and the states. Parts A, B, C, and F are the most germane for public health concerns.

Part A—Definitions, §1401(1) "The term '*primary drinking water regulation*' means a regulation which—A) applies to PWS; B) specifies contaminants which, in the judgment of the Administrator, may have any adverse effect on the health of persons; C) specifies for each such contaminant, either—(i) a MCL, if, in the judgment of the Administrator, it is economically and technologically feasible to ascertain the level of such contaminants in water in PWS, or (ii) if, in the judgment of the Administrator, it is not economically or technologically feasible to so ascertain the level of such contaminant, [...]; and D) contains criteria and procedures to assure a supply of drinking water which dependably complies with such MCLs, […]. (2) The term '*secondary drinking water regulation*' means a regulation which applies to PWS and which specifies the MCLs which, in the judgment of the Administrator, are required to protect the public welfare. Such regulations may apply to any contaminant in drinking water A) which may adversely affect the odor or appearance of such [...] or B) which may otherwise adversely affect the public welfare. Such regulations may vary according to geographic and other considerations." §1412(b)(4) "Each maximum contaminant level goal established under this subsection shall be set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety. [...]" §1412(b)(5) "For the purpose of this subjection, the term 'feasible' means feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration). […]"

The preceding definitions are important not only for forming a foundation for regulatory actions under the SDWAct, but also for their richness in policy implications. Noteworthy among the policy implications are the following: (a) water quality regulations apply only to PWS (how

to provide any services to private entities must be determined by health providers); (b) MCLs goals are based on no known or anticipated human health effects (regulators must therefore decide what constitutes an adverse health effect for each contaminant); (c) MCLs must include considerations of economic and technology feasibility (this policy is contentious because national water quality standards will lead to more costly technologies in some states, particularly in some Western states, where there are large numbers of small water suppliers who lack financial resources to implement new water treatment technologies); and (d) secondary drinking water regulations are based on "public welfare," such as odor or aesthetic properties (this policy of secondary water regulations provides state regulators with authority to consider water properties in addition to toxicological properties).

Part B covers PWS. It requires the EPA to set minimum national standards to protect public health from drinking water contaminants. The EPA was directed to develop, publish, and promulgate National Primary Drinking Water Regulations (NPDWRs) on 83 substances within 36 months following enactment of the 1986 amendments. In addition, the 1986 amendments required the EPA to devise a priority list of additional contaminants for regulation and, every 3 years thereafter, issue MCLs and Maximum Contaminant Level Goals (MCLGs) for another 25 contaminants. The MCL is the National Primary Drinking Water Standard; the MCLG is the desired standard if technology permits its achievement. For carcinogens, the MCLG is zero. Part B authorizes EPA to grant a state primary enforcement responsibility for PWS under conditions specified in the statute and requires states to develop their plans to protect wellhead areas from contaminants.

In addition to establishing MCLs and MCLGs for specific contaminants in drinking water, the EPA has established National Safe Drinking Water Regulations (NSDWRs) that set non-mandatory water quality standards for 15 contaminants [56]. The EPA does not enforce these "secondary maximum contaminant levels" or "SMCLs"; they serve only as guidelines to assist PWS in managing their drinking water quality. The SMCLs are based on cosmetic effects, technical effects, and aesthetic considerations, such as taste, color, and odor. The EPA considers these contaminants not to present a risk to human health at the SMCL. The NSDWRs were adopted in July 1979 and have been amended several times since then. Two states, California and Florida, have adopted the Secondary Standards as mandatory or required [57].

The EPA notes that a variety of problems are addressed by their SMCLs. These include aesthetic effects (undesirable taste or odor), cosmetic effects (effects that do not damage the body but are still undesirable, e.g., skin discoloration, and technical effects (damage to water equipment or reduced effectiveness of treatment for other contaminants). EPA guidance implies that SMCLs were established as an aid to drinking water providers who were experiencing problems with customers' decreased use of unaesthetic drinking water. EPA guidance suggests methods to treat contaminants that exceed SMCLs.

In December 2005, the EPA announced the finalization of two new drinking water protection rules. Both rules represent the last phase of a congressionally required rulemaking strategy required by the 1996 amendments to the SDWAct [58]. The Long Term 2 Enhanced Surface Water Treatment Rule requires that PWS that are supplied by surface water sources must monitor for *Cryptosporidia*. Those water systems that measure higher levels of *Cryptosporidia* or do not filter their water must provide additional protection by using EPA approved options for microbial control. The second rule, the Stage 2 Disinfection Byproducts Rule, requires PWS that have high risks of disinfection byproducts (DBPs) to take corrective action when DBPs exceed drinking water standards.

Part C governs protection of underground sources of drinking water. It directs the EPA to regulate underground injection, which is the subsurface emplacement of fluid through a well or dug-hole [48]. Emplacements of fluid could occur, for instance, through a septic tank, a cesspool, a dry well, or a fissure. The EPA is directed by the SDWAct to regulate state programs that in turn, were to regulate underground injection.

Part F is concerned with prohibiting the use of lead solder, pipes, or flux in drinking water systems and removal from schools of drinking fountains fabricated with lead-lined tanks and lead-containing solder. It required EPA to identify such coolers by brand name and provide this information to states, which in turn, are to develop programs of public education, water testing, and removal actions to replace lead-lined water coolers in schools.

The SDWAct and its amendments are important not only for their establishment of standards for contaminants in drinking water systems, but for the use of these standards in other federal regulatory contexts. For instance, drinking water standards are used for some CERCLAct sites to establish groundwater cleanup levels. Regarding hazardous waste issues, the 1984 amendments to the RCRAct, described later in Chapter 12, contain several provisions directly applicable to hazardous waste injection wells. In particular, under these provisions, the EPA must review all RCRAct-listed hazardous wastes to determine whether injection or other land disposal of those wastes may continue [48].

* * *

It is important to understand how the EPA sets drinking water standards. "The 1996 Amendments to SDWAct require EPA to go through several steps to determine, first, whether setting a standard is appropriate for a particular contaminant, and if so, what the standard should be. Peer-reviewed science and data support an intensive technological evaluation, which includes many factors: occurrence in the environment; human exposure and risks of adverse health effects in the general population and sensitive subpopulations; analytical methods of detection; technical feasibility; and impacts of regulation on water systems, the economy and public health.

Considering public input throughout the process, EPA must (1) identify drinking water problems; (2) establish priorities; and (3) set standards" [49].

1. Identify drinking water problems—the EPA makes these determinations based on health risks and the likelihood that the contaminant occurs in PWS at levels of concern. The National Drinking Water Contaminant List (CCL) lists contaminants that (a) are not already regulated under the SDWAct, (b) may have adverse health effects, (c) are known or anticipated to occur in PWS, and (d) may require regulations under the SDWAct.
2. Establish priorities—According to the EPA, contaminants on the CCL are divided into priorities for regulation, health research and occurrence data collection. To support any regulatory decisions, the EPA must determine that regulating the contaminants would present a meaningful opportunity to reduce human health risk.
3. Propose and finalize an NPDWR—After reviewing health effects studies, EPA sets a MCLG, the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. MCLGs are non-enforceable public health goals. Since MCLGs consider only public health and not the limits of detection and treatment technology, sometimes they are set at a level which water systems cannot meet. When determining an MCLG, the EPA considers the risk to sensitive subpopulations (infants, children, the elderly, and those with compromised immune systems) of experiencing a variety of adverse health effects. Three broad categories of contaminants are considered:

- Non-Carcinogens (not including microbial contaminants): For chemicals that can cause adverse non-cancer health effects, the MCLG is based on the reference dose (RFD). An RFD is an estimate of the amount of a chemical that a person can be exposed to on a daily basis that is not anticipated to cause adverse health effects over a person's lifetime. In RFD calculations, sensitive subgroups are included, and uncertainty may span an order of magnitude.
- Chemical Contaminants—Carcinogens: If there is evidence that a chemical may cause cancer, and there is no dose below which the chemical is considered safe, the MCLG is set at zero. If a chemical is carcinogenic and a safe dose can be determined, the MCLG is set at a level above zero that is considered safe.
- Microbial Contaminants: For microbial contaminants that may present public health risk, the MCLG is set at zero because ingesting one protozoa, virus, or bacterium may cause adverse health effects. EPA is conducting studies to determine whether there is a safe level above zero for some microbial contaminants. So far, however, this has not been established.

Once the MCLG is determined, the EPA sets an enforceable standard. In most cases, the standard is a MCL, the maximum permissible level of a contaminant in water which is delivered to any user of a PWS. The MCL is set as close to the MCLG as feasible, which the SDWAct defines as the level that may be achieved with the use of the BAT, TTs, and other means which the EPA finds are available (after examination for efficiency under field conditions and not solely under laboratory conditions), taking cost into consideration [49].

"When there is no reliable method that is economically and technically feasible to measure a contaminant at particularly low concentrations, a Treatment Technique (TT) is set rather than an MCL. A TT is an enforceable procedure or level of technological performance which public water systems must follow to ensure control of a contaminant. Examples of TT rules are the Surface Water Treatment Rule (disinfection and filtration) and the Lead and Copper Rule (optimized corrosion control).

After determining an MCL or TT based on affordable technology for large systems, the EPA must complete an economic analysis to determine whether the benefits of that standard justify the costs. If not, the EPA may adjust the MCL for a particular class or group of systems to a level that 'maximizes health risk reduction benefits at a cost that is justified by the benefits. The EPA may not adjust the MCL if the benefits justify the costs to large systems, and small systems are unlikely to receive variances.

States are authorized to grant variances from standards for systems serving up to 3300 people if the system cannot afford to comply with a rule (through treatment, an alternative source of water, or other restructuring) and the system installs EPA-approved variance technology. With EPA approval, states can grant variances to systems serving 3301–10,000 people. The SDWAct does not allow small systems to have variances for microbial contaminants" [49].

Under certain circumstances, *exemptions* from standards may be granted to allow extra time to seek other compliance options or financial assistance. After the exemption period expires, the PWS must be in compliance. The terms of variances and exemptions must ensure no unreasonable risk to public health.

Primary standards go into effect 3 years after they are finalized. If capital improvements are required, the EPA's administrator or a state may allow this period to be extended for up to two additional years.

Small systems receive special consideration from the EPA and states. According to the EPA, more than 90% of all PWSs are small, and these systems face the greatest challenge in providing safe water at affordable rates. The 1996 SDWAct

amendments provide states with tools to help small systems affordably comply with standards. When setting new primary standards, the EPA must identify technologies that achieve compliance and are affordable for systems serving fewer than 10,000 people. These may include packaged or modular systems and point-of-entry/point-of-use treatment devices under the control of the water supplier. When such technologies cannot be identified, the EPA must identify affordable technologies that maximize contaminant reduction and protect public health. Small systems are considered in three categories: serving 10,000 to 3301 people; 3300 to 501 people; and 500 to 25 people.

As of January 2006, the EPA has promulgated MCLs or TTs for 87 water contaminants [59]. Of this number, 11 are specific to microorganisms (e.g., *Legionella*), 3 for disinfectants (e.g., chlorine dioxide), 16 for inorganic chemicals (e.g., arsenic), 53 for organic chemicals (e.g., benzene), and 4 for radionuclides (e.g., ^{226}radium). As previously stated, this list is periodically updated based on requirements in the 1996 amendments to the SDWAct.

9.4.2.4 EPA Drinking Water Requirements for States and PWS

The SDWAct of 1974 and its amendments establish the basic framework for protecting the drinking water used by PWS in the U.S. This law contains requirements for ensuring the safety of the nation's public drinking water supplies. Public drinking water supplies include water systems, which regularly serve 25 or more people per day or which have at least 15 service connections. The EPA sets national standards for drinking water to protect against health risks, considering available technology and cost. Each standard also includes monitoring and reporting requirements. The act allows states to take over the implementation of the program by obtaining "primacy."

In 2002, the EPA promulgated The Lead and Copper Rule (LCR), 40 C.F.R., which provided monitoring and reporting guidance for PWS. § 141.80 to § 141.91 require monitoring at consumer taps to identify levels of lead in drinking water that may result from corrosion of lead-bearing components in a PWS's distribution system or in household plumbing. These samples help assess the need for, or the effectiveness of, corrosion control treatment. In 2016, perhaps due to the Flint, Michigan, drinking water crisis, the EPA issued a memorandum to provide recommendations on how PWS should address the removal and cleaning of aerators, prestagnation flushing, and bottle configuration for the purpose of LCR sampling. The memorandum provides details on how to implement each recommendation [59a].

On February 29, 2016, the EPA sent letters to governors, state environment and public health commissioners, and tribal leaders outlining specific steps to enhance implementation of the EPA's LCR. The EPA letters were in reaction to the Flint, Michigan, water crisis (see subsequent case study) and states and tribes were expected to reaffirm programs in place that complied with the LCR. The overall impact of the letter seems to be a reaffirmation of the importance of monitoring of lead in the water of PWS.

9.4.2.5 Associations between Nonpotable Water and Human Health

Providing drinking water free of biological or chemical disease-causing agents is the primary goal of all water supply systems. During the first half of the twentieth century, the causes for most waterborne disease outbreaks were bacteria, whereas beginning in the 1970s, protozoa and chemicals became the dominant causes [60]. Most outbreaks involve only a few individuals. However, failures in water treatment systems have occasionally led to instances of widespread waterborne disease. For example, more than 400,000 people were affected in 1993 when the Milwaukee, Wisconsin, water supply became contaminated with *Cryptosporidia* [61]. An example of a public water supply contaminated by a bacterium (*Escherichia coli)* occurred in Walkerton, Ontario, Canada in May 2000. *E. coli* is an intestinal bacterium that causes muscle cramps, fever, nausea, and severe diarrhea, and can cause kidney failure in extreme cases. The outbreak may have caused more than 2000 cases of illness, including seven deaths [62].

Drinking water contaminated with microbial or chemical contaminants can cause human disease. According to CDC sources of drinking water (and the percentage of waterborne disease outbreaks) are wells (70.5%), springs (5.9%), surface water (11.8%), and a combination of wells and springs (11.8%) [63]. Since 1971, CDC, EPA, and the Council of State and Territorial Epidemiologists have maintained a collaborative surveillance system for collecting and periodically reporting data related to occurrences and causes of Water Borne Disease Outbreaks (WBDOs). This surveillance system is the primary source of data concerning the scope and effects of waterborne disease outbreaks on persons in the U.S. [64]. Public health agencies in the U.S. states and territories report information on waterborne disease outbreaks to the CDC Waterborne Disease and Outbreak Surveillance System. For 2011–2012, 32 drinking water-associated *outbreaks* were reported, accounting for at least 431 *cases* of illness, 102 hospitalizations, and 14 deaths. For 2011–2012, public health officials from 14 states reported 32 outbreaks associated with drinking water during that time period. For an event to be defined as a waterborne disease outbreak, two or more persons must be epidemiologically linked by time, location of water exposure, and case illness characteristics; and the epidemiologic evidence must implicate water as the probable source of illness [64].

During 2011–2012, these outbreaks resulted in at least 431 illness cases, 102 hospitalizations (24% of cases), and 14 deaths. At least one etiologic agent was identified in 30 (94%) outbreaks. *Legionella* was implicated in 21 (66%) outbreaks, 111 (26%) cases, 91 (89%) hospitalizations, and all 14 deaths. *Norovirus* was implicated in two single-etiology outbreaks involving 138 cases, with no hospitalizations or deaths. Three outbreaks caused by non-*Legionella* bacteria resulted in 90

(21%) cases, among which 56 (62%) were caused by Shiga toxin-producing *E. coli*, 22 (24%) by *Shigella sonnei*, and 12 (13%) by *Pantoea agglomerans* (hospital-acquired bloodstream infection) [64].

Common exposure settings among drinking water-associated outbreaks were hospitals or health-care facilities ($n=16$, 50%), hotels ($n=4$, 13%), and camps/cabins ($n=3$, 9%). *Legionella* was responsible for 66% of outbreaks and 26% of illnesses, and viruses and non-*Legionella* bacteria together accounted for 16% of outbreaks and 53% of illnesses. The two most commonly identified deficiencies† leading to drinking water-associated outbreaks were *Legionella* in building plumbing systems (66%) and untreated groundwater (13%).

Legionella was the most frequently reported outbreak etiology (65.6%); thus, acute respiratory illness was the most commonly reported illness type. Outbreaks associated with community water systems (78.1%) outnumbered those associated with noncommunity systems and bottled water. Outbreaks associated with water systems that used surface water sources (56.3%) were more frequently reported than outbreaks associated with all other sources. The deficiency that led to most drinking water-associated outbreaks ($n=21$, 65.6%) was the presence of *Legionella* in drinking water systems. The second most common deficiency was untreated groundwater (i.e., groundwater contamination at the source), both alone ($n=4$, 12.5%) and in combination with untreated surface water ($n=1$, 3.1%). All five drinking water-associated outbreaks with groundwater deficiencies (including one outbreak with multiple deficiencies) occurred in noncommunity water systems; four occurred in camps or outdoor workplaces and one occurred in a meeting facility. No reported outbreaks occurred in individual water systems (e.g., private wells) [64].

Among 431 cases of illness attributed to drinking water-associated outbreaks, the etiologies, illnesses, water sources and systems, and deficiencies were distributed differently than among the related outbreaks. As shown in Figure 9.2, viruses caused 32.0% of cases, followed by *Legionella* (25.8%), and non-*Legionella* bacteria (20.9%). More than half of cases (51.5%) were linked to noncommunity water systems, and cases linked to groundwater (60.6%) were more frequently reported than all other reported sources. Most cases involved acute gastrointestinal illness (71.5%). Together, deficiencies of untreated groundwater and *Legionella* in drinking water systems accounted for 72.4% of all outbreak-associated cases.

As recommended by the CDC, continued vigilance by public health, regulatory, and industry professionals to identify and correct deficiencies associated with building plumbing systems and groundwater systems could prevent most reported outbreaks and illnesses associated with drinking water systems [64].

Drinking water supplies can also become contaminated by chemical contaminants (Figure 9.2). The classes of contaminants include DBPs (from chlorination of water), metals (lead, arsenic), nitrates (from fertilizers, septic tanks), radon (naturally occurring), and pesticides/synthetic organic chemicals. The human health effects caused by specific contaminants will vary according to each substance's toxicity, population at risk, and dose. For example, DBPs are formed when chlorine is added to water supplies for disinfection purposes and then combines with organic materials. The EPA has estimated that an upper bound estimate of 2%–17% of human bladder cancer cases is attributable to DBP exposure [cited in 65]. Young children are at elevated health risk from exposure to lead, pesticides, and nitrates. Lead exposure *in utero* is associated with developmental effects in infants; low-level, chronic exposure to pesticides has been associated with neurotoxic and behavioral effects in children; and ingestion of high concentrations of nitrates in infants under 4 months of age can result in methemoglobinemia, a condition that is fatal in 7%–8% of cases [cited in 65].

Private wells are generally exempt from meeting water quality standards, unless local authorities require otherwise, which is rarely the case. Given that about 20% of drinking water comes from private wells, a potential public health problem exists. Local health departments often have information available about the potential health hazard of uninspected private wells and make that available to local residents.

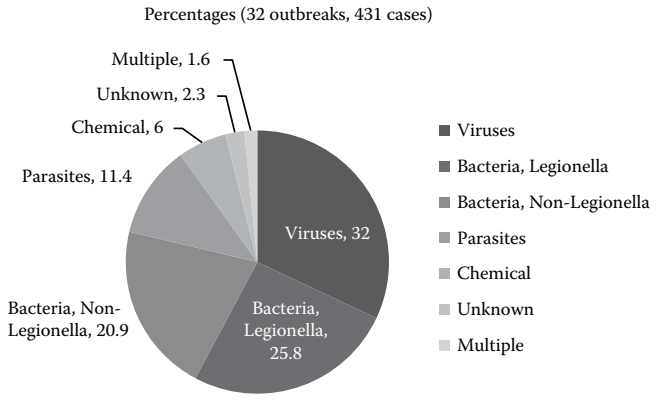

FIGURE 9.2 Etiologic agents and U.S. waterborne disease outbreaks caused by impure drinking water, 2011–2012. (From, Beer, K. D. et al. *Mort. Morb. Wkly. Rep*., 64, 842–8, 2015.)

9.4.2.6 Associations between Nonpotable Water and Ecosystem Health

WHO warms that poor access to sufficient quantities of water can be a key factor in water-related disease and is closely related to ecosystem conditions. The agency observes that about one-third of the world's population lives in countries with moderate to high water stress, and problems of water scarcity are increasing, partly due to ecosystem depletion and contamination. If present global consumption patterns continue, by 2025 two out of every three persons on the globe may be living in water-stressed conditions [66].

Further, WHO and others observe that the sustainability of many water ecosystems has been impacted by development and land use changes involving elimination of marshes and wetlands; the diversion of surface water or alteration of flows; increased exploitation of underground aquifers; and

contamination of water by waste and discharges from industry and transport, as well as from household and human waste [67]. The absolute quantity and the diversity of pollutants reaching freshwater systems have increased since the 1970s. These include not only biological contaminants, e.g., microorganisms responsible for traditional waterborne diseases, but also heavy metals and synthetic chemicals, including fertilizers and pesticides.

WHO advises that water ecosystems should be valued for their protection of water supplies and suggests protection should include the following: (a) An "ecosystem approach" that recognizes and ascribes value, including economic value, to the "services" natural ecosystems provide in terms of water filtration and purification, and ensures their sustainability, through modern management regimes; (b) integrated water resource management; and (c) protecting water from contamination from household to global level—careful disposal of waste and protection of health from contaminated water sources is a vital principle [67].

9.4.2.7 Bottled Drinking Water

Globally, bottled water is big business. Rising concern for health and wellness, distrust of local drinking water sources, and evolution of new packaging initiatives are the major factors driving the global growth of the bottled water market. According to a market report, bottled water (neat, carbonated, flavored, and functional) was valued at $157.27 billion in 2013, and is expected to reach $279.65 billion by 2020, growing at a compound annual growth rate (CAGR) of 8.7% from 2014 to 2020. By volume, the global bottled water market is expected to grow at a CAGR of 8.3% during the forecast period from 2014 to 2020 to reach a market size of 465.12 billion liters by 2020. In 2013, the volume of the market was 267.91 billion liters [68].

According to industry sources, in 2014 the total volume of bottled water consumed in the U.S. was 11 billion gallons, a 7.4% increase from 2013. That translates into an annual average of 34 gallons per person. While that may sound like a lot, it actually puts the U.S. in 10th place for global per capita consumption. Sales revenues for the U.S. bottled water market in 2014 were $13 billion in wholesale dollars, a 6.1% increase over the previous year [69].

In the U.S., tap water and bottled water are regulated by two different federal agencies, the EPA and FDA. As described, the EPA regulates tap water under its SDWAct authorities. Bottled drinking water is regulated as a food product, and as such, has been regulated by the FDA since 1938 under the Food, Drug, and Cosmetic Act (FDCAct). The FDA has established specific regulations for bottled water, including a standard of identity regulations that define different types of bottled water, such as spring water and mineral water. The agency has also established standard of quality regulations that establish allowable levels for contaminants (chemical, physical, microbial, and radiological) in bottled water.

Relevant to this chapter, §305 of the SDWAct amendments of 1996 include language that amends §410 of the FDCAct as follows:

"(b)(1) Not later than 180 days before the effective date of a national primary drinking water regulation promulgated by the Administrator of the Environmental Protection Agency for a contaminant under §1412 of the SDWAct, [t]he Secretary [of DHHS] shall promulgate a standard for that contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems [b]ut not in water used for bottled drinking water.[...] 4(A) If the Secretary does not promulgate a regulation under this subsection within the period described in paragraph (1), the national primary drinking water regulation referred to in paragraph (1) shall be considered [a]s the regulation applicable under this subsection to bottled water." Stated more simply, the FDA must adopt the EPA's MCLs if the contaminants appear in bottled water.

According to industry sources, in 2014 the total volume of bottled water consumed in the U.S. was 11 billion gallons, which translates into an average of 34 gallons per person.

In addition to the FDA, state and local governments also regulate bottled water. The FDA relies on state and local government agencies to approve water sources for safety and sanitary quality, as specified in §129.3 of the FDCAct. Additionally, states also regulate the bottled water industry as well as the industry itself [70].

It is clear from the preceding language that congressional intent was to yoke bottled drinking water quality with that of tap water as a means to ensure bottled water quality. Has the intent been realized? According to one national environmental group, the Natural Resources Defense Council (NRDC), "[b]ottled water sold in the U.S. is not necessarily cleaner or safer than most tap water" [71]. This conclusion was predicated on findings from their study of 103 brands of bottled water. Approximately one-third of the waters tested contained levels of contamination that exceeded allowable limits under either state or bottled water industry standards or guidelines in at least one sample. Moreover, the NRDC concluded that bottled water regulations are inadequate because the FDA's rules exempt waters that are packaged and sold within the same state, which is 60%–70% of all bottled water sales, and approximately 20% of states don't regulate bottled water.

Setting aside issues related to the source of bottled water, the product as a consumer item has brought considerable environmental impacts predicated on the massive volume of used plastic bottles that contained the water. This matter of plastic waste, which will be discussed in Chapter 12, challenges waste disposal agencies. In order to reduce the cost of waste disposal of plastic water bottles, some commercial entities have discontinued selling bottled water. For example, in 2015 the Detroit Zoo ceased selling water sold in plastic bottle and also installed 20 filtered water refill stations [72]. Similarly, in 2011 the U.S. National Park Service announced a policy that permitted directors of the 408 national parks, monuments, and historical sites to eliminate sales of disposable plastic water bottles, as long as refilling stations and reusable bottles

replaced them [73]. In April 2012 Concord, Massachusetts, residents voted to ban the sale of single-serving plastic water bottles; the measure went into effect in January 2013. The ban was challenged by the water industry, but a decision by the state's attorney general upheld Concord's ban [74].

9.4.2.8 Case Study: Flint, Michigan, Water Crisis, 2014–2016

Many examples exist of major environmental disasters that have given resonance to the public's attention. Some examples include eruptions of volcanoes, nuclear power meltdowns, hazardous waste seeping into homes, effects of climate change, and unsafe drinking water in communities. These kinds of events instill fear in members of the public as they visualize themselves placed in harm's way. An environmental crisis that caught the attention of an international audience occurred in Flint, Michigan, where events led to lead-contaminated water being supplied to the city. The Flint crisis was the product of failures by government at all levels, inept planning by city officials, and misconduct by policymakers and some of their subordinates. The residents of Flint, especially the children, became the victims of this mix of misconduct and ineptness.

Flint, Michigan was a once vibrant city that thrived on American automobile manufacturing; in the 1970s, it had a population numbering 200,000. As the American automobile manufacturers floundered in global vigor, assembly plants were closed, including some in Flint. By the early twenty-first century, the city's population had shrunk to about 99,000, with a demographic of 57% African-American, 37% white, and 5% other. The economic base of the city shrank as its population decreased.

In 2011, the Michigan Legislature enacted Public Act No. 4, signed into law by the state's governor, that in effect gave the state authority to supplant the local government of a city assessed by the state to be in financial crisis. In particular, the law states "Upon the confirmation of a finding of a financial emergency, the governor shall declare the local government in receivership and shall appoint an emergency manager to act for and in the place and stead of the governing body and the office of chief administrative officer of the local government" [75]. In 2014, following an assessment by the state of Michigan of Flint's school and city government finances, Public Act No. 4 was applied to the city. On March 14, 2013, Michigan's governor appointed an emergency manager for Flint, setting into motion a series of events that culminated in children's exposure to lead in drinking water, inept decisions by government, emergency response and aid, a visit by President Obama, dismissal of some public employees, and litigation, including potential charges of criminal behavior.

A financial decision by Flint's appointed emergency manager to change water suppliers was the precipitating event of the city's crisis. Flint was a customer of the Detroit water system, but for cost reduction reasons decided to subscript to a source of water in the planning stage, the Karegnondi Water Authority, which would draw water from Lake Huron. This goal of the switch was to "save" the city approximately $13 million annually. In June 2013, for the 1 year interim prior to connecting with the new water supplier, Flint's emergency manager, in consultation with Michigan's Department of Environmental Quality (DEQ), selected the Flint River as Flint's public water source. This decision was made despite available data showing the Flint River's water was contaminated with some hazardous chemicals, due to the river having been polluted for many years by industrial sources along the river. The following is an abbreviated timeline of key events surrounding the Flint water crisis [76]:

- April 2014: Michigan's DEQ and Flint's Department of Public Works gear up to start treating water from the Flint River. Corrosion control is proposed in the city's operating plan, but DEQ officials later tell the city it's not necessary. Later in the month officials toast glasses of Flint River water in celebration. In spring/summer 2014, there are immediate concerns about the taste and color of the treated Flint River water. By September, there were already two boil water advisories because of signs of bacteria.
- October 2014: General Motors announce Flint's water is too corrosive for manufacturing at its engine plant in Flint.
- January 2015: Flint notifies water customers it is in violation of the Safe Water Drinking Act due to elevated levels of total trihalomethanes (TTHM). Despite reassurances from Michigan's DEQ that the water is safe, the state office building in Flint starts using bottled water.
- February 2015: Michigan's governor approves $2 million for Flint water projects. In an email exchange with the DEQ about a Flint home with high lead levels, an EPA employee warns that it may be a sign of systemic lead contamination. A Department of Community Health official sends email to Flint preschools and daycares giving them an alert about high TTHM levels in Flint water and suggests they use bottled water.
- March 2015: Although lacking legal authority, the Flint City Council votes to forego use of the Flint River, an action discredited by the city's emergency manager.
- Spring/summer 2015: Questions increasingly surface over water testing methods and rising levels of lead in Flint water. The EPA's regional lead expert issues a report that questions why corrosion control isn't being used and says lead and copper poisoning is a threat.
- July–August 2015: Michigan's DEQ works to discredit the EPA staffer and publicly avers there is no lead problem in Flint. A Virginia Tech professor begins testing water from Flint.
- September 2–8, 2015: Water testing by Virginia Tech reveals high lead levels in Flint's water, beyond the federal threshold that requires action. However, the Michigan DEQ stands by their Flint tests that show rising, but allowable levels of lead in city water.

- September 24, 2015: A Flint medical doctor holds a press conference at the Hurley Medical Center saying she has found elevated blood lead levels in Flint children.
- September 25, 2015: The City of Flint issues a health advisory about the potential of lead-contaminated water.
- September 29, 2015: Genesee County issues a health advisory about Flint's drinking water.
- October 8, 2015: Michigan's governor announces that Flint will reconnect with the Detroit water system.
- December 14, 2015: Flint's mayor declares a state of emergency, saying the city needs federal help to deal with its lead-in-water crisis.
- December 30, 2015: Michigan's DEQ Director and the Director of Communications resign.
- January 16, 2016: President Barack Obama signs an emergency declaration to assist Flint, an action that authorizes the Federal Emergency Manage Agency to assist Flint.
- January 21, 2016: The EPA's Region 5 Administrator, whose area of responsibility includes Flint, resigns.
- February 5, 2016: The Michigan DEQ's head of the office of municipal drinking water for the state is fired.
- March 3, 2016: The Obama administration extends Medicaid coverage to 15,000 children and pregnant women in Flint affected by lead in tap water. The arrangement provides recipients with a variety of free health services, including monitoring for the level of lead in their blood and behavioral health treatment [77].
- March 23, 2016: The Flint water task force, appointed by the governor, finds the state primarily responsible for the water crisis.
- May 4, 2016. President Obama visits Flint for purpose of observing first-hand the city's problems.
- April 20, 2016: Michigan Attorney General announces charges against two DEQ employees and one Flint employee.
- August 8, 2016: According to a university analysis, the social costs stemming from dangerous levels of lead in the drinking water, such as the effect on children's health, amount to $395 million [78].
- June 14, 2017: Michigan's Attorney general brought criminal charges against five michigant state officials. The charges include invouluntary man slaughter [78a].

In October 2014 General Motors announces Flint′s drinking water supply was too corrosive for manufacturing at its engine plant in Flint [66].

Perspective: There are many lessons to be learned from the Flint water crisis; but this effort in education must not take precedence over the public health imperative of providing care for the city's children who were exposed to lead. Whether it's medical monitoring or some kind of health surveillance, Flint's children must be part of the city's follow up. Moreover, although a full analysis of the Flint, Michigan water crisis will be the conducted by future historians, some observations are already evident. A signal finding is failure of government at all levels, most significantly at the state level. The state appears to have had data about the poor water quality of the Flint River, but failed to act on the data. The regional EPA senior administrators also appear to have given a deaf ear to warnings from the agency's technical staff in regard to the river's water quality. Further, Flint's appointed emergency managers failed to understand the consequences of their decision to switch public water sources. An application of "critical thinking" (Chapter 1) might have prevented the water crisis. Also, some critics of how the Flint water crisis emerged have pointed to the efficacy of Michigan's Public Act No. 4, questioning whether local government should be supplanted by unelected policy managers who are not responsible to local citizenry.

9.5 GLOBAL WATER POLLUTION POLICIES

Water quality and its security are global essentials and policies to protect water resources are cornerstones of environmental policies globally. The previous sections have presented and discussed the two key U.S. water policies. This section will present water quality policies of the EU and two countries with emerging global economies, China and India.

9.5.1 EU Water Pollution Policies

EU legislation provides for measures against chemical pollution of surface waters. There are two components—the selection and regulation of substances of EU-wide concern (the priority substances) and the selection by Member States of substances of national or local concern (river basin specific pollutants) for control at the relevant level.

The first component constitutes the major part of the Union's strategy against the chemical pollution of surface waters. It is set out in Article 16 of the Water Framework Directive 2000/60/EC. This requires the establishment of a list of priority substances to be selected from among those presenting a significant risk to or via the aquatic environment at EU level. It also requires the designation of a subset of priority hazardous substances, and proposals for controls to reduce the emissions, discharges, and losses of all the substances and to phase out the emissions, discharges, and losses of the subset of priority hazardous substances.

In order to improve the quality of the monitoring data obtained under the Water Framework Directive, the Commission adopted Directive 2009/90/EC which provided technical specifications for chemical analysis and monitoring of water status. The regulation of chemical pollutants in water began with Directive 76/464/EEC. The introduction of provisions under the Water Framework Directive includes transitional elements such that parts of the earlier legislation

are applicable until the end of 2012 [79]. The features of the Water Framework have been summarized by the European commission in a set of 12 notes herein abridged [80]:

- Note 1: The EU is a land of shared waters. About 60% of the EU's surface area lies in river basins that cross at least one national border, and all Member States except Cyprus and Malta contain sections of at least one international river basin district (IRBD). Under the Water Framework Directive, each Member State is responsible for implementation in the portion of an IRBD lying within its territory and should coordinate these actions with the other Member States in the district.
- Note 2: The Water Framework Directive sets the goal of achieving a "good status" for all of Europe's surface waters and groundwater by 2015. This is a major challenge, as recent assessments estimate that at least 40% of the EU's surface waterbodies are at risk of not meeting the 2015 objective.
- Note 3: The Water Framework Directive protects clean water across Europe. It highlights the importance of groundwater bodies: Member States must designate separate bodies and ensure that each one achieves "good status" by 2015. This mirrors the requirements for surface waterbodies.
- Note 4: One of the aims of the European Union's Water Framework Directive is to ensure that by 2015 all of Europe's waterbodies are of good ecological quality.
- Note 5: The Water Framework Directive introduces two key economic principles. First, it calls on water users—such as industries, farmers, and households—to pay for the full costs of the water services they receive. Second, the directive calls on Member States to use economic analysis in the management of their water resources and to assess both the cost-effectiveness and overall costs of alternatives when making key decisions.
- Note 6: Monitoring is the main tool used by Member States to classify the status of each waterbody. The directive sets a five-class scale (high, good, moderate, poor, and bad) for surface waters and two classes (good, poor) for groundwater, and it requires Member States to achieve good status in all waters by 2015.
- Note 7: Clean water is vital for public health and ecosystems. The Water Framework Directive aims to ensure the good chemical status of both surface water and groundwater bodies across Europe. For surface waters this goal is defined by limits on the concentration of specific pollutants of EU relevance, known as priority substances. To date, 33 priority substances have been identified. A new Directive, published in December 2008, establishes limits, known as Environmental Quality Standards, for these 33 substances and for an additional 8 substances regulated under previous legislation. The Water Framework Directive also calls for surface waters to meet good ecological status, which provides a measure of healthy ecosystems. To achieve this objective, Member States may need to ensure that additional pollutants of national relevance are controlled. The Water Framework Directive also requires good chemical status for groundwater. It is reinforced by the 2006 Groundwater Directive, which specifies measures to assess monitor and control groundwater pollution.
- Note 8: The Water Framework Directive also requires good chemical status for groundwater. It is reinforced by the 2006 Groundwater Directive, which specifies measures to assess monitor and control groundwater pollution.
- Note 9: However, the quality standard approach proved insufficient for protecting Europe's polluted waters. When eutrophication became a major problem in the North and Baltic seas and parts of the Mediterranean in the late 1980s, the EU started to focus on the sources of pollutants. This led to the Directive on Urban Wastewater Treatment, which requires Member States to invest in infrastructure for collecting and treating sewage in urban areas while the Nitrates Directive requires farmers to control the amounts of nitrogen fertilizers applied to fields. The Directive on Integrated Pollution Prevention and Control adopted a few years later aims to minimize pollutants discharged from large industrial installations.
- Note 10: The Water Framework Directive provides European countries with a common basis to address these problems. In particular, the directive's river basin approach to water management—centered on the review of river basin management plans every 6 years—establishes a mechanism to prepare for and adapt to climate change. Planning for droughts and floods will also be an integral part of this system.
- Note 11: The new Marine Strategy Framework Directive extends EU water legislation to the marine environment and constitutes the environmental component of Europe's new cross-sector Integrated Maritime Policy. The new directive follows an approach similar to that of the Water Framework Directive.
- Note 12: The Water Framework Directive acknowledges that its success relies on close cooperation with the public and stakeholders at local level and their involvement in key decisions.

Perspective: The EU Water Framework is unique in that its policies must acknowledge the cross-boundary nature of many of Europe's waterways. No other set of national or regional water policies reflect this kind of water reality. For this reason, the Water Framework emphasizes the importance of Member States' cooperation on implementing the provisions of the Framework.

9.5.2 China's Water Pollution Policies

China is a country rich in culture, tradition, and natural resources that have sustained a large population over several millennia. The country has become the world's second largest national economy and the manufacturing center for much of the global community. Unfortunately, China faces water depletion and pollution. While China is home to 20% of the world's population, it has only 7% of its fresh water sources. Overuse and contamination have produced severe shortages, with nearly 70% of the country's water supplies dedicated to agriculture and 20% of supplies used in the coal industry. Approximately two-thirds of China's approximately 660 cities suffer from water shortages [81].

In response to these challenges, China has announced an action plan that includes a list of measures to tackle water pollution, with the aim of improving the quality of the water environment around the country by 2030 [82]. The action plan, as issued by the State Council on April 16, 2015, requires that by 2020, China's water environment quality will gradually improve; the percentage of severely polluted waterbodies will be greatly reduced; and the quality of drinking water will be improved. Also by 2020, the Council states that groundwater overdraft will be reduced; the aggravated pollution of groundwater will be preliminarily controlled; and the environmental quality of offshore areas, and the aquatic ecosystem in areas such as the Beijing–Tianjin–Hebei Region, will be improved. The plan includes specific indicators, including that by 2020, the quality of over 70% of the water in seven key river basins, such as the Yangtze River and Yellow River, will reach Level III or above, and the amount of foul water in urban built-up areas will be controlled, thus not exceeding 10%.

A list of ten measures that were adopted in order to realize the targets of the action plan are as follows:

1. The discharge of pollutants will be controlled and emission reduction measures will aim to tackle pollution caused by industries, urban living, agriculture and the rural sector, and ships and ports.
2. Economic restructuring and upgrading will be further boosted. Industrial water and reclaimed water and seawater will be used to promote cyclic development.
3. Measures will aim to continue saving and protecting water resources. A strict management system of water resources will be implemented so as to control the overall use of water, improve water-use efficiency, and protect the ecological flows of key rivers.
4. Scientific and technological support will be further improved. Advanced technologies will be promoted and fundamental research is set to be strengthened. The environmental protection industry will be regulated and the authorities will accelerate the development of the environmental protection service industry.
5. Markets will play a bigger role. The authorities will make efforts to step up water price reform, improve taxation policies, facilitate diversified investment, and establish an incentive mechanism that promotes water environment treatment.
6. Relevant law enforcement and supervision will be stricter, and environmental violations and illegal construction projects will be severely punished.
7. The management of the water environment will be further strengthened. The authorities will strictly control the amount of pollutants and various environmental risks, and give authorization, whenever appropriate, to discharge pollutants.
8. The authorities will also make efforts to ensure the safety of aquatic ecosystem, including ensuring the safety of drinking water sources, treating underground water pollution and pollution in major river basins, and strengthening the protection of waterbodies and the ocean environment. By the end of 2017, foul water in urban built-up areas will be basically eliminated.
9. The duties of all parties will be clarified and implemented. Local governments should be more responsible for the protection of the water environment and pollutant discharge units should be made accountable. The central government will check the implementation of the action plan in different basins, regions, and sea areas every year.
10. Public participation and community supervision will be improved, and the government will regularly publish a list of cities and provinces that have the best and worst water environment.

An indication of China's commitment to improving its water security occurred in 2015 when the government imposed a record-high penalty of 160 million yuan (US$26 million) on six companies from the city of Taizhou in eastern Jiangsu Province for discharging waste acids into two rivers. Some analysts called this an unprecedented example for businesses in China to better manage industrial waste [83]. A second indicator is the government's announcement in 2016 of plans to spend a total of 430 billion yuan (US$65 billion) on about 4800 separate projects aimed at improving the quality of its water supplies [84].

9.5.3 India's Water Pollution Policies

Like China, India is also a country rich in culture, tradition, and natural resources that has sustained a large population over several millennia. It is the second most populous country worldwide, second only to China. India is also a major world economic power. Notwithstanding these assets and prominence, India faces major environmental challenges due to population growth, economic development, and insufficient attention to use of natural resources. India's air pollution challenges were described in Chapter 8 (Air Quality). Herein are described the country's water pollution problems and policies intended to mitigate them.

According to Water Aid, an international NGO, India has the world's highest number of people without access to clean water, which imposes a major financial burden for some of the country's poorest people [85]. Further, there are 75.8 million people in India (5% of the country's population)

who are forced to purchase 50 L of water daily (nearly 20% of their daily income) or use supplies that are contaminated with sewage and chemicals. Use of non-potable water brings health consequences. Global data indicate that there are about 315,000 children who die from diarrheal diseases each year, 140,000 of which occur in India [86]. The NGO's report cites poor management of water resources as the biggest problem. India already faces chronic water shortages and drought, as rivers become increasingly polluted and groundwater reserves rapidly decline due to the unchecked use of water pumps by farmers and villagers. The problem will worsen as global temperatures rise and rain becomes more erratic with climate change. Within 15 years, the country is expected to have only half the water it needs to meet competing demands from cities, agriculture, and industry [86]. These challenges will require policies that other countries have found to be efficacious in addressing problems of water quality and quantity.

India's central policy on water pollution is the Water (Prevention and Control of Pollution) Act of 1974 [87]. The act's objectives are stated as "provide for the prevention and control of water pollution and the maintenance or restoration of the wholesomeness of water for the establishment, with a view to carrying out the purposes aforesaid, of Boards for the prevention and control of water pollution, for conferring on and assigning to such Boards powers and functions relating thereto and for matters connected therewith [87]."

As with India's air pollution law (Chapter 8), the water pollution law is framed around the responsibilities and authorities of a Central Board and State Boards. Following are excerpts from the 1974 law that are germane to public health [87]:

"1. Subject to the provisions of this Act, the main function of the Central Board shall be to promote cleanliness of streams and wells in different areas of the States. 2. In particular and without prejudice to the generality of the foregoing function, the Central Board may perform all or any of the following functions, namely: a) Advise the Central Government on any matter concerning the prevention and control of water pollution, b) Co-ordinate the activities of the State Boards and resolve disputes among them, c) Provide technical assistance and guidance to the State Boards, carry out and sponsor investigations and research […], d) Plan and organize the training of persons engaged or to be engaged in programmes for the prevention, control or abatement of water pollution […], e) Organize through mass media a comprehensive programme regarding the prevention and control of water pollution […], f) Collect, compile and publish technical and statistical data relating to water pollution […], g) Lay down, modify or annul, in consultation with the State Government concerned, the standards for a stream or well, h) Plan and cause to be executed a nation-wide programme for the prevention, control or abatement of water pollution, […].

Subject to the provisions of this Act, the functions of a State Board shall be: a) To plan a comprehensive programme for the prevention, control or abatement of pollution of streams and wells in the State […], b) To advise the State Government on any matter concerning the prevention, control or abatement of water pollution, c) To collect and disseminate information relating to water pollution […], d) To encourage, conduct and participate in investigations and research […], e) To collaborate with the Central Board in organizing the training of persons engaged or to be engaged in programs […], f) To inspect sewage or trade effluents, works and plants for the treatment of sewage and trade effluents and to review plans, specifications or other data relating to plants set up for the treatment of water, works for the purification thereof and the system for the disposal of sewage or trade effluents or in connection with the grant of any consent as required by this Act, g) To lay down, modify or annul effluent standards for the sewage and trade effluents and for the quality of receiving waters […], h) To evolve economical and reliable methods of treatment of sewage and trade effluents, […], i) To evolve methods of utilization of sewage and suitable trade effluents in agriculture)[…], j) To lay down standards of treatment of sewage and trade effluents to be discharged into any particular stream […] k) for the prevention, control or abatement of discharges of waste into streams or wells […]" [87].

According to § 24 of the Water Act, 1974: "a) No person should knowingly cause or permit any poisonous, noxious or polluting matter determined in accordance with such standards as may be laid down by the State Board to enter (whether directly or indirectly) into any stream or well or sewer or on land; or b) No person shall knowingly cause or permit to enter into any stream any other matter which may tend, either directly or in combination with similar matters, to impede the proper flow of the water of the stream in a manner leading or likely to lead to a substantial aggravation of pollution due to other causes or of its consequences […]. Whoever contravenes the provisions of § 24 shall be punishable with imprisonment for a term which shall not be less than one year and six months but which may extend to six years and with fine" [87].

"Section 47. Offences by companies: 1. Where an offence under this Act has been committed by a company every person who at the time the offence was committed was in charge of, and was responsible to the company for the conduct, of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly […].

The powers given to Central/State Boards to make application to courts for restraining apprehended pollution of water in streams or wells: 1. Where it is apprehended by a Board that the water in any stream or well is likely to be polluted by reason of the disposal or likely disposal of any matter in such stream or well or in any sewer or on any land, or otherwise, the Board may make an application to a court, not inferior to that of a Metropolitan Magistrate or a Judicial Magistrate of the first class, for restraining the person who is likely to cause such pollution from so causing" […] [87].

9.6 GLOBAL WATER SECURITY POLICIES

While the quality of drinking water is generally good in the U.S. and other developed countries, that is not the case globally. In particular, developing countries struggle to build the environmental health infrastructure necessary to drastically reduce the horrible toll of waterborne diseases. The diseases

are caused by ingestion of water contaminated by human or animal feces or urine containing pathogenic bacteria or viruses. Waterborne diseases include cholera, typhoid, dysentery, and other diarrheal diseases. These diseases can be prevented through disinfection of drinking water supplies and sanitary disposal of animal and human bodily wastes.

WHO collects data from individual countries in order to estimate the access of human populations to potable water and adequate sanitation. According to their data (which currently cover 89% of the world's population) 1.1 billion people lacked access to "improved water supply" and more than 2.4 billion lacked access to "improved sanitation," primarily in developing countries [88]. Given the world's population of more than six billion people in the year 2000, approximately 20% lacked access to potable water and 40% lacked access to proper sanitation. Using the WHO data, Gleick [89] in 2002 estimated that as many as 135 million people will die from "unmet human needs for water" by year 2020, assuming the lack of sustained public health interventions. To put this figure into perspective, 135 million people exceeded the combined populations of France (60 million), Spain (40 million), and Canada (31 million) in 2002 [90]. Imagine the hue and cry should these three countries disappear over the next 20 years. The same anxiety and fear should be mobilized to prevent the same number of deaths from occurring in developing countries.

Using WHO data, one source estimated that as many as 135 million people will die from "unmet human needs for water" by year 2020, assuming the lack of sustained public health interventions.

As a matter of international environmental health policy, should the developed countries provide the resources necessary to prevent the global loss of life and illnesses attributable to waterborne diseases? The answer is, obviously, yes. Altruistic reasons include children's welfare, improved quality of life, decreased disabilities, and increased longevity. Prevention of waterborne diseases would also improve national economic development by increased workforces, lower health care costs, improved social stability, and larger tax bases from employed workers and from the products they would produce.

9.6.1 Climate Change's Impact on Water Security

In part due to climate change, fresh water is expected to become increasingly scarce in the future. Water on the planet is approximately 98% salty and only 2% is fresh. Of that 2%, almost 70% is snow and ice, 30% is groundwater, less than 0.5% is surface water (lakes, rivers, etc.), and less than 0.05% is in the atmosphere [91].

Climate change has several effects on these proportions on a global scale. The main effect is warming, which causes polar ice to melt into the sea, turning fresh water into sea water, with little direct effect on water supply (illustrated in Figure 6.1). Another effect of warming is to increase the amount of water that the atmosphere can hold, which in turn can lead to more and heavier rainfall when the air cools. Although more rainfall can add to fresh water resources, heavier rainfall leads to more rapid movement of water from the atmosphere back to the oceans, reducing our ability to store and use it. Warmer air also means that snowfall is replaced by rainfall and evaporation rates tend to increase.

Yet another impact of higher temperatures is the melting of inland glaciers. This will increase water supply to rivers and lakes in the short to medium term; however, this will cease once these glaciers have melted. In the sub-tropics, climate change is likely to lead to reduced rainfall in what are already dry regions. The overall effect is an intensification of the water cycle that causes more extreme floods and droughts globally [91].

The Intergovernmental Panel on Climate Change (IPCC) cautions that the global picture is less important than the effect of warming on fresh water availability in individual regions and in individual seasons. An IPCC technical report on climate change and water concludes that, despite global increases in rainfall, many dry regions including the Mediterranean and southern Africa will badly suffer from reduced rainfall and increased evaporation [91]. As a result, the IPCC special report on climate change adaptation estimates that around one billion people in dry regions may face increasing water scarcity. Of special import, a report from UNICEF in 2017 forecasts that one in four of the world's children will be living in areas with extremely limited water resources by 2040. The agency estimates that 600 million children will reside in regions enduring extreme water stress as a consequence of climate change [92].

9.6.2 State of California's Drought Policies

California has experienced a severe drought for several years, ending in 2017. In response the government of California implemented policies that are intended to lessen the burden of water shortage. In April 2015, following 4 years of drought conditions, California's governor issued an executive order that cut urban potable water use by 25% statewide. Implementing the executive order became the responsibility of the State Water Resources Control Board. In the board's first proposal, a community was placed in one of four tiers based on how much water it used in September 2014, which was later based on how much water communities used during July, August, and September 2014. Further, the original set of four tiers, with cuts ranging from 10% to 35%, was expanded to nine tiers, with cuts ranging from 4% to 36%.

Failure to meet water conservation goals would incur a penalty of up to $100,000 per day, although most water agencies were reluctant to impose fines, preferring educational outreach and warnings [93]. In October 2015 California state officials commenced imposing fines on water systems that failed to meet water conservation goals. While announcing that the state overall met its monthly conservation goals in September 2014, officials said Beverly Hills, Indio, Redlands, and the Coachella Valley Water District had missed their mandates by wide margins. Each was fined $61,000 [94].

In November 2015, California's governor extended his executive order that mandated a 25% reduction in water usage across the state. The original order, issued in April, could now be extended until October 2016 if the drought persisted through January 2016. Although the 25% state goal was not achieved, some water conservation did occur during 2015. The state's experience revealed that some policy elements were more effective than others. For example, asking homeowners to voluntary conserve water was ineffective, but one of the state's most successful water-reduction efforts was rebates to encourage homeowners to tear out their grass lawns, in favor of artificial turf or desert-friendly native plants [95].

Due to a welcome wet winter in 2015, the state's governor revised his water conservation executive order. On May 9, 2016 he ordered state water regulators to extend some drought protections, such as a prohibition on irrigating lawns and landscape so intensely that water runs down the sidewalk or into the street. He also demanded a new plan for making conservation a way of life over the long term. But the governor's order did not include an extension of the mandatory 25% water use cutback he ordered in 2015 [96]. In early 2016, a strong series of storms left parts of Northern California rehydrated, with reservoirs brimming with water. But for Southern California no drought relief has arrived. To deal with the dichotomy, the State Water Resources Control Board ruled on May 18, 2016 that local water districts will be allowed to set their own savings targets based on water supply and demand forecasts tailored to their areas [97].

9.6.3 Water Security and Produced Water

Increased human population, climate change, and economic development are among several factors that have resulted in strained supplies of water. This need translates into using some nontraditional sources of water. One such source is *produced water*, which is water trapped in underground formations that is brought to the surface during oil and gas exploration and production. Because the water has been in contact with the hydrocarbon-bearing formation for centuries, it has some of the chemical characteristics of the formation and the hydrocarbon itself. It may include water from the reservoir, water injected into the formation, and any chemicals added during the drilling, production, and treatment processes. Produced water can also be called "brine," "saltwater," or "formation water."

The physical and chemical properties of produced water vary considerably depending on the geographic location of the field, the geological formation from which it comes, and the type of hydrocarbon product being produced. Produced water properties and volume can even vary throughout the lifetime of a reservoir. The major constituents of interest in produced water are salt, oil and grease, various inorganic and organic chemicals, and naturally occurring radioactive material. Generally, the radiation levels in produced water are very low and pose no risk. Most produced water needs some form of treatment before it can be used. The levels of specific constituents found in a particular produced water sample and the desired type of reuse will determine the types of treatment that are necessary.

Produced water is by far the largest volume byproduct stream associated with oil and gas exploration and production. Approximately 21 billion barrels (1 bbl = 42 U.S. gallons) of produced water are generated annually in the U.S. from about 900,000 wells. This is equivalent to a volume of 2.4 billion gallons per day. For perspective, the Denver Water agency, which supplies drinking water to 1.3 million customers, has a combined total capacity of approximately 745 million gallons per day. Several western U.S. states are using treated produced water for beneficial purposes. Some of these uses include domestic, livestock watering, industrial, and commercial, agriculture irrigation, mining, fire protection, and dust suppression. The determination of a specific beneficial use depends on federal and state jurisdiction, and the circumstances of each case. As an example, five states (Colorado, Montana, New Mexico, Utah, Wyoming) use treated produced water for various domestic purposes [98].

9.6.4 Water Security and Gray Water

The reuse of gray water is an emerging environmental policy issue. Gray water is generally defined as all wastewater generated from household activities except that produced from toilets, which is called "blackwater." Gray water includes water from dish washers, clothes washers, household wash basins, showers, and bathtubs. Such "waste" can be collected and used for outdoor watering of plants, trees, lawns, and irrigation of crops. The average amount of gray water produced in the U.S. is 40 gallons per day per person, which equates to about 65% of a household's daily water consumption [99]. This is a significant amount of water that is potentially available for recycling. Gray water is important because several U.S. states are considering its use as a component of water conservation programs. These programs are largely nascent and are in response to shortages of water supplies needed to meet the needs of households, industry, and agriculture. The causes of the shortages vary, but factors include increased human populations, fragile groundwater supplies, greater water demand by industry, and drought conditions. Making maximum use of existing water supplies is an environmental policy that will become increasingly important in many countries including the U.S. as climate changes due to greenhouse GHG emissions continue to appear.

Colorado—a state with a pending water shortfall—is considering gray water as part of a state plan for water security. More specifically, Colorado water providers, facing a shortfall of 163 billion gallons, are developing the first statewide water plan to sustain population and industrial growth. State water planners hypothesize that if even the worst sewage could be cleaned to the point where it is potable—filtered through super-fine membranes or constructed wetlands, treated with chemicals, zapped with ultraviolet rays—then the state's dwindling aquifers and rivers could be saved [100].

Similar to Colorado, California water managers are incorporating recycled water into their water security plans.

In the last couple of decades, some coastal water managers have attempted to recycle some of this water for human use. The so-called purple pipe systems take sewage that has been filtered and cleansed and use it to irrigate crops, parks, and golf courses. This water, however, is not currently used as drinking water. The Metropolitan Water District of Southern California is considering developing what could be one of the largest recycled water programs in the world [101].

For areas short of water, use of recycled water (gray water) will predictably become more common, even given the $1 billion cost to build wastewater treatment plants that are adequate to produce potable water [101].

9.6.5 Water Security and Desalination

Desalination of ocean water for conversion into drinking water supplies is another method for water security in some geographic areas where fresh water is limited. According to a MIT report in 2014, some 700 million people worldwide already suffer from water scarcity; that number is expected to swell to 1.8 billion in just 10 years. Some countries, like Israel, already heavily rely on desalination; more will follow suit [102]. The current costs of constructing a desalinization plant are enormous, as is the huge amount of energy used for desalination. For example, in 2015 the Western Hemisphere's largest ocean desalination plant opened in Carlsbad, San Diego County, California [103]. The plant is capable of producing 50 million gallons of fresh water daily, about 10% of the county's total water use. The plant's cost was approximately $1 billion, with annual operating costs to be determined. The State of California is considering the construction of an additional 15 desalination plants, given the state's water shortage and dependence. The costs of construction and operation of desalination plants are forecast to decrease as improved technology and more energy-efficient equipment is developed.

As noted by UNESCO, in 2014 there were more than 14,000 desalination plants in more than 150 countries—exemplifying the growing reliance on this technology. In 2008 about 50% of this capacity exists in the West Asia Gulf region, while North America has about 17%, Asia (apart from the Gulf) about 10%, and North Africa and Europe about 8% and 7%, respectively [104].

On a much smaller scale than desalination plants, research is ongoing for the purpose of developing less expensive methods for producing potable water. For example, researchers at Alexandria University in Egypt have developed a procedure called pervaporation to remove the salt from sea water and make it potable. Specially made synthetic membranes are used to filter out large salt particles and impurities so they can be evaporated away, and then the rest is heated, vaporized, and condensed back into clean water. Crucially, the membranes are easily fabricated from inexpensive materials that are available locally, and the vaporization part of the process doesn't require any electricity. This means the new method is both inexpensive and suitable for areas without a regular power supply—both factors that are very important for developing countries [105].

Perspective: Inadequate water security has become a reality for areas afflicted because of climate change and other factors, including unwise use of fresh water sources, population increase, and irrigation of farms. Water security policies will need to be implemented for both afflicted and non-impacted areas, as a matter of current and future urgency. For example, water restrictions in areas of protracted drought, development of recycled water treatment resources, use of produced water, and construction of desalination plants are examples of policies being contemplated or in actual practice.

UNESCO: In 2014 there were more than 14,000 desalination plants in more than 150 countries. About 50% of this capacity exists in the West Asia Gulf region [104].

9.7 IMPROVED WATER EFFICIENCY AND OTHER SUCCESSES

As data in this chapter establish, supplies of fresh water are not meeting human and ecological demands. Climate change, population growth, agriculture irrigation, and wasteful individual behaviors are factors contributing to this shortage. Individual households wasting water is another factor. For example, the EPA estimated in 2015 that the U.S. population needlessly wastes 1 trillion gallons of water annually. The waste is due to leaky kitchen and bathroom faucets, malfunctioning toilets, errant sprinkler systems, and such. The loss equals the annual household water use of more than 11 million U.S. homes, according to the EPA [106].

Responsibly responding to the shortage will require water security policies, as well as making the most of available supplies of water. Regarding the latter, water efficiency must be practiced. The EPA advocates water management plans, noting "The U.S. population has doubled over the past 50 years, while our thirst for water has tripled. With at least 40 states anticipating water shortages by 2024, the need to conserve water is critical. EPA strives to integrate water management best practices at all of its facilities" [107].

The EPA has implemented its own best water practices that apply to its programs. Figure 9.3 illustrates a typical office building's water use. It is noteworthy that about two-thirds of water is used for sanitary and heating/cooling purposes. The following are the top 10 water best management practices that the EPA has implemented to reduce water use at its office buildings and laboratories: (1) meter/measure/manage, (2) optimize cooling towers, (3) replace restroom fixtures, (4) eliminate single-pass cooling, (5) use water-smart landscaping and irrigation, (6) reduce steam sterilizer tempering water use, (7) reuse culture water, (8) control reverse osmosis system operation, (9) recover rainwater, and (10) recover air handler condensate [107]. In fiscal year (FY) 2014, the EPA reduced its water use by 40.4% compared to an FY 2007 baseline, exceeding the water intensity reductions required by Executive Order (EO) 13514. This is an example of water conservation achieved by a large user of water resources.

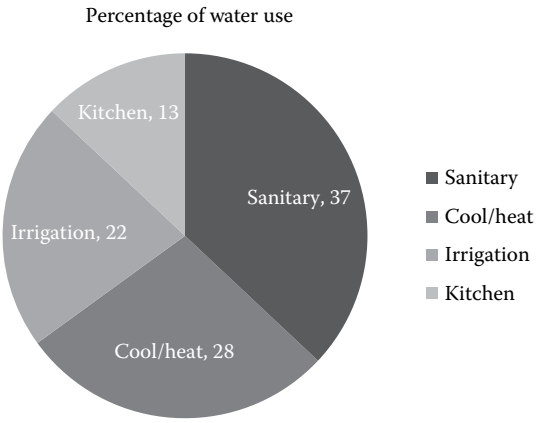

FIGURE 9.3 End uses of water for a typical office building. (From EPA, Stevens, M., California seeks to build one of world's largest recycled water programs, *Los Angeles Times*, September 22, 2015.)

An example of a federal policy on water conservation is found in President Obama's Executive Order 13514 issued in 2009, which sets sustainability goals for U.S. federal agencies and focuses on making improvements in their environmental, energy, and economic performance. One goal is a 26% improvement in water efficiency by 2020 [108]. U.S. state policies on water efficiency are nascent, but the foregoing discussion of California's water security policies that responded to the state's drought is an example of water efficiency policies at a state level of government.

Although the image of water insecurity is grim, there are other images of successful outcomes in water management and security. For example, agriculture has emerged as the biggest threat to water quality in many parts of the U.S. The nutrients phosphorus and nitrogen from manure and synthetic fertilizers are causing problems in the Midwest and elsewhere. A Midwest farm association is promoting new conservation strategies, such as building artificial wetlands and underground "bioreactors" to capture nutrients in drainage systems. One farmer uses rapeseed and rye plants in his corn fields to absorb nutrients that might otherwise find their way into a local river, a runoff that would contribute to algal contamination in adjacent lakes. These and similar agriculture strategies will lessen water pollution attributable to agricultural runoff of fertilizers and nutrients that in turn contribute to water pollution [109].

An example illustrates that polluted waterways can be renewed to as secure water sources. The Harbor Raritan Estuary between New York and New Jersey is the most densely developed urban estuary in the U.S. Since 2009 more than $1 billion of federal, state, and local funds have been invested in projects of conservation, restoration, and development of publicly-accessible waterfront spaces. To date, this effort has resulted in more than 80 habitat restoration and land conservation projects. The improvements through 2015 include the restoration of more than 200 acres of wetlands and creation or enhancement of more than 500 acres of new parks and public spaces [110].

In another example, Medford, Oregon's wastewater treatment plant was discharging warm water into the Rogue River in violation of EPA regulations. But instead of spending millions on expensive machinery to cool the water to federal standards, the city is planting trees. Shade trees cool rivers, and the end goal is 10–15 miles of new native vegetation along the Rogue River [111].

These examples suggest that policies of water quality protection and/or restoration can help in reducing the magnitude of water insecurity, but are costly and require time and support from the public and policymakers alike.

9.8 HAZARD INTERVENTIONS

As described in this chapter, water quality and security are threatened in many parts of the globe, and unabated climate change will exacerbate the problem. Interventions to reduce or interdict the hazard of inadequate water quality will be required. These include global, regional, national, local, and individual policies for protection of water security. Environmental health water policies such as those described for the U.S. and the EU are examples. Other examples are water polices being set in place in countries with emerging national economies, such as China and India. But any of these water protective polices are only as effective as their implementation. Strong policies require strong implementation and follow-through.

Water conservation policies and use of unconventional sources of water, for example, produced or recycled water, must be made part of the water security calculus. More efficient uses of water in agriculture and industrial operations must also be part of the calculus, as exemplified by some examples cited in this chapter.

Individuals must assume their responsibilities for personal policies of water quality protection. Persons should know and keep track of their water expenditures. In the industrialized countries, how much water is used for household purposes, for example, laundry, kitchen, baths, and lawn care should be subject to water conservation. Eschewing water service at restaurants is another policy. And most importantly, controlling the amount of water used for toilet flushing can be achieved by reducing the frequency of flushes. In geographic areas where water security is an extant problem, individuals should be educated on the important of water conservation and application of some innovative methods (e.g., rain collection devices) for water conservation.

9.9 SUMMARY

Water is the fluid of and for life. This chapter has presented the global consequences of inadequate water quality and security. As a reminder, the global state of water security has been characterized by the UN as follows:

- Worldwide, infectious diseases such as waterborne diseases are the number one killer of children under 5 years old and more people die from unsafe water annually than from all forms of violence, including war.

- Unsafe water causes 4 billion cases of diarrhea annually, and results in 2.2 million deaths, mostly of children less than 5 years old.
- Two-thirds of the global populations (4.0 billion people) are estimated to live under conditions of severe water scarcity at least 1 month of the year. Nearly half live in India and China. Half a billion people in the world face severe water scarcity all year round.
- Worldwide, 2.5 billion people live without improved sanitation; more than 70% of these people who lack sanitation, or 1.8 billion people, live in Asia.
- Every day, two million tons of sewage and industrial and agricultural waste are discharged into the world's water.
- Reflection on U.S. water quality data provides a troubling characterization, given that 44% of U.S. rivers, 64% of lakes, and 30% of estuaries are assessed as "impaired." The leading causes of impairment are viruses and bacteria. However, public drinking water supplies are generally safe, given available water treatment resources.

Policies to protect water quality and security were described. For the U.S., just as the CAAct controls the emissions of contaminants released into outdoor air, the CWAct, as amended, controls the emissions of contaminants into U.S. bodies of water. As with the CAAct, the CWAct contains a number of policies of importance to public health. One of the earliest provisions, continuing today, is the awarding of grants to states for construction of sewage treatment plants, an example of federalism. The public health benefits of treating raw sewage in order to achieve sanitary and healthful conditions are obvious. As another important policy, the CWAct requires U.S. states, or the EPA where states choose to defer to the EPA, to issue permits that limit the amount of contaminants discharged into bodies of water. These emission standards are for purpose of meeting water quality standards established under the SDWAct. The CWAct also adopts the policy that the regulated community (i.e., those entities that release contaminants into water) must use the BAT in their waste management operations. This policy leads to updates and improvements in waste management as technology changes. The policy also moves the regulated community toward a uniform technology.

The SDWAct, as amended, is the complement of the CWAct. The act establishes water quality standards that forge emission standards under the CWAct. The SDWAct contains policies of import to public health practice. The act creates the policy of dual drinking water regulations. Primary regulations are intended to protect human health and are enforceable under law. Secondary regulations, which are voluntary unless adopted as law by individual states, pertain to welfare considerations such as odor, appearance, and taste of water. The SDWAct also contains a second set of dual standards. Specifically, EPA must establish MCLs for individual water contaminants, which are legally enforceable by states, unless individual states have promulgated more stringent standards. MCLs, as policy, must consider the availability of technology necessary to achieve desired contaminant levels. Where technology is lacking, MCLGs are established. The policy of having both MCLs and MCLGs marries the present to the future. The public health's benefits when water quality standards shift when new or improved water treatment technologies are adopted.

Also described in this chapter is EU legislation that provides for measures against chemical pollution of surface waters. There are two components—the selection and regulation of substances of EU-wide concern (the priority substances) and the selection by Member States of substances of national or local concern (river basin specific pollutants) for control at the relevant level. The first component constitutes the major part of the Union's strategy against the chemical pollution of surface waters. It is set out in Article 16 of the Water Framework Directive 2000/60/EC, which is the primary EU policy on water quality and security.

As the world's human population continues to expand, with corresponding demands for food and water security, evolving policies on water conservation and water reinforcement will become increasing important.

9.10 POLICY QUESTIONS

1. The CWAct requires states and tribes to establish ambient water quality standards for bodies of water. Select a lake within your state's borders and determine the applicable water quality standards. Discuss the public health implications of the lake's water quality standards.
2. In the context of public health, discuss the significant differences between a primary drinking water regulation and a secondary drinking water regulation, as found in the SDWAct.
3. If climate change models are correct, changes in global rainfall patterns are likely, making water conservation a necessary environmental policy. Discuss 10 ways that you personally can conserve water, now and in the future. List the ways in descending order of effectiveness in terms of water conservation.
4. For pollution control purposes, several federal environmental statutes include the embedded policy of granting permits to those who pollute, which is a kind of command and control policy. Select one such statute and discuss two alternatives to a permit policy. Using critical thinking, discuss the likely effectiveness of each alternative.
5. Do you purchase bottled water? If so, explain why. If not, explain why not. If you purchase bottled water, what do you do with the empty plastic bottles?
6. Using Internet resources, locate your state's TDML report. What are the key features of the plan? In your opinion, does the plan adequately respond to the provisions of the CWAct?
7. Your community has many residences that have private wells for household use. As a senior member of the local health department you have been asked to

advise the county commission on whether mandatory water quality inspection should occur. Describe your response.

8. The Flint, Michigan water crisis resulted in the revelation that many schools in the U.S. have drinking water contaminated with lead. Using the EPA SWDIS, conduct a survey of your community's schools regarding the quality of school drinking water. Describe the findings in a two page report.
9. Using Internet resources, research the quality of surface and groundwater water supplies in your state. Prepare a two page report of your findings.
10. What department or agency in your state has responsibility for water quality? Describe the agency's principal responsibilities for protecting water quality.
11. Waterborne diseases can be common in geographic areas that lack potable drinking water and/or where water pollution is inadequately controlled. List three waterborne diseases and describe the consequences to public health, the prevalence of each disease, and actions that can prevent each disease.
12. Rate the adequacy of your local public water supply, using a scale of 0–5, where 0 represents unacceptable quality and 5 represents water of impeccable quality. Using this scale, ask three persons who reside in your community about their perception of local water quality. Using the rating from all three persons, discuss the implications of your survey.
13. Identify the source of your community's drinking water. Identify any threats to the source as to pollution sources. Describe each threat and suggest methods to interdict them.
14. Research using internet resources, the geographic global areas that are experiencing drought. Select two areas and describe the effects of drought and policies being implementing in response to drought.
15. A primary feature of the CWAct, as amended, is to provide grants to states for construction or upgrade of wastewater treatment plants. Research the amount of grant money that has been supplied by EPA to your state for wastewater treatment purposes. In your opinion, should the federal government be financing what is a state's responsibility?
16. Algal contamination of water sources has become a significant problem globally. Prepare a two page paper that details the extent of the problem in the U.S. and discuss recommendations as how to counteract the contamination.
17. Assume your community is suffering through a prolonged summer drought and that local water restrictions have been announced. Your neighbor continues to water his/her lawn, using sprinklers that thoroughly soak the lawn. Do you feel compelled to take action? If so, what would you do? If not, why not? Be specific and elaborative.
18. An international NGO has announced a humanitarian program to provide low-cost water pumps to an African population that lacks water security. As a charitable person, you are impressed with the purpose of the NGO's proposal. Describe what research you would conduct prior to providing financial assistance to the NGO.
19. Discuss the procedures and steps that the EPA uses for ranking priority chemical pollutants under provisions of the SDWA, as amended.
20. After swallowing the material in this chapter, discuss the three most important lessons you learned. Was your personal environmental health behavior changed by the content of this chapter? If so, how? If not, why not?

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10 Food Safety and Security

10.1 INTRODUCTION

This chapter is about the third of humankind's three basic needs, food. Prior chapters have presented the other two survival needs: air quality and water quality/security. This chapter addresses food safety and food security as companion challenges to the well-being of global populations, for both are required for human survival. The World Food Summit of 1996 defined food security as existing "when all people at all times have access to sufficient, safe, nutritious food to maintain a healthy and active life" [1]. One can observe that safe food is integral to this definition, suggesting that the definition of food security could embody safe food. However, this chapter will consider safe food and food security as separate concepts, since existing policies historically have made this distinction. Therefore, for the purposes of this chapter, safe food will refer to food that when consumed will cause no ill effects to the consumer. And food security will refer to the availability of safe food. In support of this distinction, one can have safe food within a food supply, but if it is not accessible (i.e., insecure), one would experience hunger.

This chapter describes the salient food safety and securities policies in the U.S., EU, China, and India. The effects of unsafe food and insecure food supplies on human and ecological health are presented, as well as hazard interventions to prevent the development of unsafe food supplies. The global consequences and implications of food insecurity are described, along with several factors that confound food security.

As a reminder, we humans have evolved from ancestors who hunted feral animals for food, later learning to cultivate grains, vegetables, and fruits. Food grown and prepared before the invention of refrigeration became commonplace in America was generally consumed soon after its acquisition. This was in order to avoid contact with pathogens found in deteriorating food. Decay of food is caused by microorganisms that parasitize dead plant or animal tissue and thereby render food unsafe for human consumption (shown in Figure 10.1). To preserve food, meat was salted or exposed to dense smoke from hardwood fires. Vegetables and fruits were canned or stored in root cellars. With refrigeration came the ability to chill or freeze food and safely store it for short to long periods of time. In modern times, irradiation has been used to preserve food; but due to concerns that irradiation might allegedly cause harmful changes in food, which then could affect consumers of irradiated food, this method has not gained widespread acceptance. The problem of pathogens in deteriorating food was theoretically overcome though refrigeration. However, the equally important health consequence of how food is prepared remained a problem. Fresh, or properly preserved, food that is contaminated with pathogens from human contact during growing, transporting, preparing, or serving has the potential to cause human illnesses.

Government's involvement in protecting the public against adulterated or impure food is a relatively recent occurrence in the U.S. Until the early twentieth century, food safety was deemed to be the responsibility of individual consumers and therefore not a matter for government intervention. As will be described in the following sections, states had the primary authority over issues of food safety—an arrangement that still prevails. However, the federal government gradually assumed a strong role in food safety as a matter of interstate commerce. Federal involvement in food safety brought together the public health triad of federal, state, and local governments directed to a common purpose—in this case, prevention of foodborne illnesses.

> In the U.S., an estimated 48 million foodborne illnesses occur annually, causing 3000 deaths [19]. Globally, 600 million people contract a foodborne illness, causing 420,000 deaths annually [17].

Foodborne illnesses are a serious environmental health problem, although the U.S. food supply is relatively safe overall. However, how food is grown, transported, prepared, and served can introduce pathogens and other hazards of potential harm to human health. In the U.S. there are three federal statutes that concern food safety. To be described are the Food, Drug, and Cosmetic Act (FDCAct), the Federal Meat Inspection Act (FMIAct) (and analogous laws for poultry and eggs), and the FDA Food Safety Modernization Act (FSMAct).

10.2 FOOD SAFETY AND SECURITY POLICIES

Many national governments and one regional government, the EU, have implemented food safety and security policies. These will be summarized in the following sections. In the U.S. there exist three primary federal statutes bearing on *food safety*, as administered by the U.S. Food and Drug Administration (FDA) and the Department of Agriculture (USDA). *Food security* policies lie primarily with the USDA, as will be highlighted herein. Also described are food safety policies implemented by EU directives and food policies established by China and India, the world's two most populous countries.

FIGURE 10.1 Decaying moldy food unsafe for human consumption. (From The Wooden Spoon Archives, The Jefferson Chronicles, Oak Ridge, NJ, 2012.)

10.3 U.S. FOOD SAFETY AND SECURITY POLICIES

The three principal federal food safety statutes are the FDCAct, the FMIAct, and the FSMAct. As will be related, two of these statutes date from the early years of the twentieth century, and have been amended over the years. The third statute, the FSMAct of 2011, is a recent statute. Regarding food security in the U.S. the USDA has significant responsibilities and authorities that will be summarized in this section.

10.3.1 U.S. Food, Drug, and Cosmetic Act, 1906

This act is a powerful statement by the U.S. federal government of the value of protecting the nation's food security, therapeutic drugs, and cosmetics. The FDA is the principal federal agency with regulatory authorities to administer the provisions of the act. Given the purpose of this chapter, the act's provisions specific to food safety are presented. Other provisions (e.g., drugs and medical devices) while important, lie outside the focus of this chapter.

10.3.1.1 History

Americans of the twenty-first century expect not to be harmed by the food and medicinal drugs and therapeutic devices with which they come into contact. The expectation is the product of personal experience (e.g., few of us have had protracted illnesses from eating impure food) and there is general trust in public health systems (e.g., restaurant inspections). While episodes of illness occur as the result of impure food (e.g., undercooked meat in hamburgers), the current situation is vastly different from that of our ancestors.

In the nineteenth and early twentieth centuries, any government control of food and drugs was the responsibility of states. State laws, if enacted, greatly varied between states. In that era, use of chemical preservatives and toxic colors added to food was virtually uncontrolled [2]. Instances of morbidity surely occurred, given current bacteriological and toxicological knowledge, but no health reporting system was in place then to record the extent of morbidity. As public concern grew in the late nineteenth century about unsanitary conditions in the meatpacking industry, a similar concern arose about the harm caused by drugs, medications, and concoctions sold for alleged medicinal purposes. "Medicines" containing opium, morphine, heroin, and cocaine were sold without any restriction [2]. Moreover, labels gave no indication about the ingredients of over-the-counter drugs and medications. The policy of "buyer beware" prevailed during this period.

During the 1870s, the grassroots Pure Food Movement arose and soon became the principal source of political support for federal food and drugs legislation [2]. In 1903, Dr. Harvey W. Wiley became the director of the USDA's Division of Chemistry and soon thereafter aroused public opinion against impure consumer products that his staff had identified. In a sense, Dr. Wiley was serving as a surrogate surgeon general, informing the public and advocating for public health legislation. Strenuous opposition to Wiley's campaign for a federal food and drug law came from whiskey distillers and the patent medicine firms, many of which thought they would be put out of business by federal authorities and regulation of their industries. Supporting the need for federal legislation were agricultural organizations, some food processors, public health professionals, and state food and drug officials. The political scale was tipped toward legislative action through the intercession of club women who rallied behind the pure food cause [2]. Remarkably, Congress enacted both the Pure Food and Drug Act and the FMIAct on the same day, June 30, 1906.

The Pure Food and Drugs Act of 1906 prohibited the manufacture and interstate shipment of adulterated and mislabeled foods and drugs. The law enabled the federal government to initiate litigation against alleged illegal products, but lacked affirmative requirements to guide compliance with the law. The 1906 law also lacked key provisions necessary to make it effective in identifying harmful food and drug products. For example, food adulteration continued to flourish because judges could find no authority in the law for any standards of purity and content established by the FDA [3]. The 1906 law eventually became obsolete due to both lack of enforcement authorities and technological changes in how food and drugs were produced. The provisions of the 1906 Pure Food and Drugs Act simply were not sufficiently robust to keep up with technology changes in the food and drug industries. Thirty-two years passed before the act was updated.

In June 1938, President Franklin D. Roosevelt signed into law the Federal FDCAct, which replaced the Pure Food and Drug Act of 1906. The 1938 law contained many significant changes, including those shown in Table 10.1 [3]. Even the 1938 law was found to be in need of further improvements. For instance, the 1938 law prohibited poisonous substances, but required no evidence that food ingredients were safe for human consumption.

In 1949, Congress began lengthy hearings on the FDCAct, resulting in three substantive amendments: the Pesticide Amendment of 1954, the Food Additives Amendment of 1958, and the Color Additive Amendments of 1960 [3]. These amendments effectuated an environmental health policy that no substance legally can be introduced into the U.S. food supply unless there has been a prior determination that it is safe. Moreover, these amendments required manufacturers to conduct the

TABLE 10.1
Chapters of the Food, Drug, and Cosmetic Act

Chapter	Title
I and II	Short Title and Definitions
III	Prohibited Acts and Penalties
IV	Food
V	Drugs and Devices
VI	Cosmetics
VII	General Authority
VIII	Imports and Exports
IX	Tobacco Products
X	Miscellaneous

Source: FDA (Food and Drug Administration), Federal Food, Drug, and Cosmetic Act (FD&C Act), Office of Food and Veterinary Medicine, Silver Spring, MD, 2015.

research necessary to establish their products' safety. The FDA became a reviewer of manufacturers' data, with the authority to reject products or to request more data from manufacturers.

The FDCAct has been amended several times since 1960. In particular, Congress added products to the list of items regulated by FDA. The key product amendments are listed in Table 10.2. Noteworthy is that FDA was given regulatory coverage over medical devices, devices that radiate energy, and dietary food supplements.

10.3.1.2 Key Provisions of the FDCAct Relevant to Public Health

The scope of the FDA's regulatory authority is very broad. The agency's responsibilities are closely related to those of several other government agencies. The following is a list of traditionally recognized product categories that fall under the FDA's regulatory jurisdiction; however, this is not an exhaustive list. In general, FDA regulates the following [4]:

- "Foods, including: dietary supplements, bottled water, food additives, infant formulas, and other food products (although the USDA plays a lead role in regulating aspects of some meat, poultry, and egg products)
- Drugs, including: prescription drugs (both brand-name and generic) and nonprescription (over-the-counter) drugs
- Biologics, including: vaccines, blood and blood products, cellular and gene therapy products, tissue and tissue products, and allergenics
- Medical Devices, including: simple items like tongue depressors and bedpans, complex technologies such as heart pacemakers, dental devices, and surgical implants and prosthetics
- Electronic Products that give off radiation, including: microwave ovens, x-ray equipment, laser products, ultrasonic therapy equipment, mercury vapor lamps, and sunlamps
- Cosmetics, including: color additives found in makeup and other personal care products, skin moisturizers and cleansers, nail polish, and perfume
- Veterinary Products, including: livestock feeds, pet foods, and veterinary drugs and devices
- Tobacco Products, including: cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco" [4].

PRODUCT CATEGORIES REGULATED BY FDA [4]

Biologics
Cosmetics
Drugs
Foods
Medical Devices
Radiating Electronics
Tobacco Products
Veterinary Products

TABLE 10.2
Congressional Amendments Adding to FDA's Regulatory Authority

Year	Title	Public Law
1968	Radiation Control for Safety and Health Act	PL 90-602, 82 Stat 1173
1976	Medical Device Regulation Act	PL 94-295, 90 Stat 539
1990	Nutrition Labeling and Education Act	PL 101-535, 104 Stat 2353
1990	Safe Medical Device Amendments	PL 101-629, 104 Stat 4511
1994	Dietary Supplement Health and Education Act	PL 103-417, 108 Stat 4332
1997	Food and Drug Administration Modernization Act	PL 105-115, 111 Stat 2296

Source: FDA (Food and Drug Administration), Federal Food, Drug, and Cosmetic Act (FD&C Act), Office of Food and Veterinary Medicine, Silver Spring, MD, 2015.

10.3.1.3 Public Health Implications of the FDCAct, as Amended

The FDCAct, with its amendments, has resulted in removal of unsafe food additives from the U.S. food supply, tighter pesticide regulations on levels of these substances in food sources, and review of therapeutic drugs intended for medical use. These actions benefit the public's health, and represent primary prevention measures.

Of note for prevention of foodborne illness, is FDA's *Food Code*, which is a set of guidelines that represent best practices for the retail and food service industries [5]. The *Food Code* was first issued by the FDA in 1993 and is currently updated every 4 years. According to the FDA, more than 1 million retail and food service establishments use the *Food Code's* provisions as a model to develop or update their own food safety rules. While following the *Food Code* is not mandated

ENFORCEMENT EXAMPLE

(Washington, DC—May 7, 2012)—Global health care company Abbott Laboratories plead guilty and agreed to pay $1.5 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of the prescription drug Depakote for uses not approved as safe and effective by the FDA. The resolution is the second largest payment by a drug company. The settlement included a criminal fine and forfeiture totaling $700 million and civil settlements with the federal government and the U.S. states totaling $800 million [25].

of states, a survey found that 48 of the 56 U.S. states and territories, which cover 79% of the U.S. population, have adopted food safety codes modeled after the *Food Code* [6]. As environmental health policy, the widespread voluntary adoption of the *Food Code* by states, territories, and the food industry is an example of how prevention of foodborne illness can be reduced by adoption of a common set of food safety practices.

The removal or reduction of antibiotics in the American food chain addresses a long-standing concern of medical and public health agencies that excessive use of antibiotics is a problem. In particular, a too frequent reliance on antibiotics has led to pathogens' developing drug resistance. The FDA had initiated work in 1977 under its FDCAct authorities on how to limit antibiotics in livestock food. But the agency's efforts languished until litigated by environmental and public health groups. The plaintiffs argued that using common antibiotics in livestock feed has contributed to the rapid growth of antibiotic-resistant bacteria in both animals and humans. Further, plaintiffs cited data that indicated antibiotic-resistant infections cost Americans more than $20 billion annually. The litigation led a federal judge on March 22, 2012 to order the FDA to start proceedings to withdraw approval for the use of common antibiotics in animal feed, unless makers of the drugs could produce evidence that their use is safe. The court cited concerns that overuse is endangering human health by creating antibiotic-resistant "superbugs" [7].

In response to the aforementioned court decision, the agency chose a strategy to work with industry to protect public health by providing documents to help phase out the use of medically important antimicrobials in food animals for production purposes (e.g., to enhance growth or improve feed efficiency), and to bring the therapeutic uses of such drugs (to treat, control, or prevent specific diseases) under the oversight of licensed veterinarians. In particular, the 2012 document, *New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI* #209 (Guidance #213), provides guidance for drug companies to voluntarily revise the FDA-approved labeled use conditions to (a) remove the use of antimicrobial drugs for production purposes; (b) add, where appropriate, scientifically-supported disease treatment, control, or prevention uses; and (c) change the marketing status from over-the-counter to Veterinary Feed Directive for drugs administered through feed or to prescription status for drugs administered through water in order to provide for veterinary oversight or consultation [8]. In brief, the FDA chose to work with the drug and livestock industries for their voluntary phase-out of some antibiotics used in livestock production [9].

This FDA strategy of voluntary action by industrial sources has seemed ineffective. For example, the FDA announced in 2015 that U.S. sales of medically important antibiotics approved for use in livestock rose by 23% between 2009 and 2014, again raising concerns about risks to humans from antibiotic-resistant bacteria [10].

In contrast to the federal strategy, California has enacted the strictest law on antibiotic use in farms. The state enacted a law to sharply limit the use of antibiotics in farm animals, making it the first state to ban the routine use of the drugs in animal agriculture. The law bans the use of medically important antibiotics to promote growth in cows, chickens, pigs, and other animals raised for profit. Meat producers are only able to administer the drugs with the approval of a veterinarian when animals are sick, or to prevent infections when there is an "elevated risk" [11].

In departure from the FDA's stance on antibiotics in livestock, the agency has taken action on removal of trans fats from the U.S. food supply and, separately, acted to prohibit three chemicals used in food packaging. Regarding the former, in June 2015 the FDA finalized its determination that partially hydrogenated oils (PHOs), the primary dietary source of artificial trans fat in processed foods, are not "generally recognized as safe" for use in human food. Food manufacturers have 3 years to remove PHOs from products [12]. Trans fat is associated with clogging of arteries and its removal contributes to improved public health.

In another action, in January 2016 the FDA announced that it will withdraw its approval for three chemicals used to make grease, stain, and water-repelling food packaging. The banned chemicals are all perfluorinated compounds (PFCs), a class of chemicals used to coat products like pizza boxes, pastry wrappers, take-out food containers, paper plates, and nonstick cookware. In lab studies, PFCs have been linked to adverse effects on hormones, reproductive, developmental, neurological, and immune systems, and to certain cancers [13]. In 2016 the FDA also announced that it had begun reviewing certain food additives for possible restrictions.

Regarding food additives, some environmental groups, supplemented by social media campaigns, have questioned the safety of some food additives. In response, in advance of any FDA regulatory action, several food companies have begun to voluntarily remove some food additives. In particular, in 2015 Taco Bell and Pizza Hut committed to remove artificial flavorings and coloring from their food products [14]. Similarly, cereal manufacturers Kellogg and General Mills both plan to stop using artificial colors and flavors in their cereal and other food products by the end of 2018 [15]. Further, Kraft is removing artificial preservatives from its most popular individually

wrapped cheese slices [16]. Some of this voluntary action by food manufacturers may be influenced by their anticipation of food labeling revisions by the FDA, perhaps leading to closer scrutiny by consumers of food products.

10.3.1.4 Associations between Unsafe Food and Human Health

Estimates of the public health burden of foodborne disease are persuasive as to the gravity of unsafe food as an environmental hazard. In 2015 WHO released its first report on the global prevalence of foodborne diseases. The report *Estimates of the Global-Burden of Foodborne Diseases* provides the most comprehensive report available on the impact of contaminated food on health and well-being. WHO's methodology estimated the burden of foodborne diseases caused by 31 agents—bacteria, viruses, parasites, toxins, and chemicals. Their findings indicate that annually as many as 600 million, or almost 10% of the world's human population, fall ill after consuming contaminated food. Of these, 420,000 people die, including 125,000 children under the age of 5 years, despite the fact that children comprise only 9% of the global population [17].

ENFORCEMENT EXAMPLE

Washington, DC—October 1, 2015: Three former officials of the Peanut Corporation of America (PCA) were sentenced to prison for their roles in shipping salmonella-positive peanut products. On September 21, 2015, PCA's former president received 28 years in federal prison, the largest criminal sentence ever given in a food safety case. The trial established that known tainted food led to a salmonella outbreak in 2009 with more than 700 reported cases of salmonella poisoning in 46 states, including 9 deaths [18].

Data for foodborne illness in the U.S. come from the Center for Disease Control and Prevention (CDC), which reported, "Food safety is an important public health priority. Foodborne illness (sometimes called 'foodborne disease', 'foodborne infection', or 'food poisoning') is a common, costly—yet preventable—public health problem. CDC estimates that annually about 1 in 6 Americans (or 48 million people) get sick, 128,000 are hospitalized, and 3000 die of foodborne diseases" [19].

The CDC collects foodborne illness reports from states and other sources in order to assess etiologic agents. To evaluate progress toward prevention of enteric and foodborne illnesses in the U.S., the Foodborne Diseases Active Surveillance Network (FoodNet) monitors the incidence of laboratory-confirmed infections caused by nine pathogens commonly transmitted through food in 10 U.S. sites. In 2015, FoodNet reported 20,107 confirmed cases, 4531 hospitalizations, and 77 deaths [20]. The number and incidence of confirmed infections per 100,000 population were reported for *Salmonella* (n=7728 [incidence=15.89]), Campylobacter (6309 [12.97]), Shigella (2688 [5.53]), Cryptosporidium (1612 [3.31]), STEC non-O157 (796 [1.64]), STEC O157 (463 [0.95]), Vibrio (192 [0.39]), Yersinia (139 [0.29]), Listeria (116 [0.24]), and Cyclospora (64 [0.13]).

Compared with incidence in 2012–2014, the 2015 incidence of confirmed infections was significantly higher for STEC non-O157 (40% increase; CI=21%–62%), and Cryptosporidium (57% increase; CI=20%–106%). No significant changes were observed in 2015 for other pathogens compared with the previous 3 year averages.

FoodNet also received 3112 positive Culture-Independent Diagnostic Tests (CIDT) reports. The number of positive CIDT reports, by pathogen, was Campylobacter (2021), Shigella (454), *Salmonella* (361), and STEC (254). These numbers represent an increase in positive CIDT reports in 2015 of 92% for Campylobacter, 284% for Shigella, 247% for *Salmonella*, and 120% for STEC, when compared with the 2012–2014 averages; the overall increase in CIDT reports for these four pathogens was 122%. Adding positive CIDT reports to confirmed cases resulted in the following incidence rates per 100,000 population: 17.12 for Campylobacter, 16.63 for *Salmonella*, 6.46 for Shigella, and 3.12 for STEC. Compared with 2012–2014, the 2015 incidence of confirmed infections plus positive CIDT reports was significantly higher for STEC but not for any other pathogen [20].

10.3.1.5 Associations between Unsafe Food and Ecosystem Health

Data are lacking on the impact of unsafe food on ecosystem health. However, an important aspect of food security is food wastage, which does impact ecosystem health. The seminal study on this subject was conducted in 2013 by the Food and Agriculture Organization of the United Nations (FAO) [21]. The FAO estimated that each year, approximately one-third of all food produced for human consumption in the world is lost or wasted. This food wastage represents a missed opportunity to improve global food security, but also to mitigate environmental impacts.

The FAO study provided a global account of the environmental footprint of food wastage (i.e., both food loss and food waste) along the food supply chain, focusing on impacts on climate, water, land, and biodiversity. A model was developed to answer two key questions: what is the magnitude of food wastage impacts on the environment; and what are the main sources of these impacts, in terms of regions, commodities, and phases of the food supply chain involved—with a view to identify "environmental hotspots" related to food wastage.

The scope of the FAO study was global: the world was divided into seven regions and a wide range of agricultural products—representing eight major food commodity groups—was considered.

From the study, FAO estimated the global volume of food wastage to be 1.6 Gtons of "primary product equivalents," while the total wastage for the edible part of food was 1.3 Gtons. This amount can be weighed

FAO estimates that approximately one-third of all food produced for human consumption in the world is lost or wasted. Further, food wastage ranks as the third top emitter of greenhouse gases (GHGs) after the U.S. and China [21].

against total agricultural production (for food and nonfood uses), which is about 6 Gtons.

The FAO also studied food wastage's impact on climate change. Without accounting for GHG emissions from land use change, the carbon footprint of food produced and not eaten was estimated to be 3.3 Gtons of CO_2 equivalent: as such, food wastage ranks as the third top emitter of GHGs after the U.S. and China. Globally, the blue water footprint (i.e., the consumption of surface and groundwater resources) of food wastage was about 250 km^3, which is equivalent to the annual water discharge of the Volga River, or three times the volume of Lake Geneva. Finally, produced but uneaten food vainly occupies almost 1.4 billion hectares of land, which represents about 30% of the world's agricultural land area. While it was difficult for the FAO to estimate impacts on biodiversity at a global level, food wastage unduly compounds the negative externalities that mono-cropping and agriculture expansion into wild areas create on biodiversity loss, including mammals, birds, fish, and amphibians.

The FAO observed that the loss of land, water, and biodiversity, as well as the negative impacts of climate change, represent huge costs to society that are yet to be quantified. The direct economic cost of food wastage of agricultural products (excluding fish and seafood), based on producer prices only, is about $750 billion, equivalent to the GDP of Switzerland in 2013.

The FAO study highlighted global environmental hotspots related to food wastage at regional and sub-sectoral levels, for consideration by policy-makers engaged in waste reduction:

- "Wastage of cereals in Asia emerges as a significant problem for the environment, with major impacts on carbon, blue water, and arable land. Rice represents a significant share of these impacts, given the high carbon-intensity of rice production methods (e.g., paddies are major emitters of methane), combined with high quantities of rice wastage.
- Wastage of meat, even though wastage volumes in all regions are comparatively low, generates a substantial impact on the environment in terms of land occupation and carbon footprint, especially in high income regions (which waste about 67% of meat) and Latin America.
- Fruit wastage emerges as a blue water hotspot in Asia, Latin America, and Europe because of food wastage volumes.
- Vegetables wastage in industrialized Asia, Europe, and South and Southeast Asia constitutes a high carbon footprint, mainly due to large wastage volumes" [21].

The FAO opined that by highlighting the magnitude of the environmental footprint of food wastage, the results of their study—by regions, commodities, or phases of the food supply chain—allows prioritizing actions and defining opportunities for various actors' contributions to resolving this global challenge [21].

10.3.2 U.S. Federal Meat Inspection Act, 1906

The U.S. diet has always contained animal-derived protein in the form of hunted animals or farmed livestock. Meat as a food source is the subject of the Federal Meat Inspection Act (FMIAct) of 1906. The act's provisions of meat inspection by government or private sources and removal of contaminated meat from the food chain have brought public health benefits.

10.3.2.1 History

Consumption of meat and meat products has long been part of the human diet, although debate continues about the ethics of raising animals as a food source. Our ancestors—whether indigenous people or colonists—hunted the forests, plains, and bodies of water for birds, mammals, fish, and shellfish to use as food sources. With the passage of time, rural Americans grew their own food in gardens and processed domesticated animals into meat and meat products. Farmers slaughtered animals in the fall and winter, when temperatures were cool, diminishing the deterioration of meat products. Salt rubbed into the meat and smoke from wood fires was used to preserve meats so that consumption of the meat could occur during warmer seasons. A family's meat quality and personal health protection were therefore at the mercy of a farmer's skill and resources in food preservation. Government had no role to play in what were essentially personal matters of family diet and health.

As villages and cities grew in numbers and population, meat was supplied by butchers and sold in butcher shops. In the nineteenth century, cities such as Chicago and Cincinnati became renowned as centers of the meatpacking industry. The U.S. public was indifferent to how animals were slaughtered and under what conditions. During this period until 1906, states had the primary responsibility for protecting the public against impure food, including meat products. Needless to say, food inspection programs varied considerably between states.

The public's ignorance of the conditions in the meatpacking industry began to change in the early years of the twentieth century. In particular, Upton Sinclair's 1906 book, *The Jungle*, which graphically described unsanitary conditions and inhumane slaughter of animals in the Chicago meatpacking industry, had a major influence on public opinion. Sinclair's book, much like Rachael Carson's book *Silent Spring* 56 years later, served to turn a spotlight on a major environmental health problem. On June 30, 1906, Congress enacted the FMIAct; it was substantially amended by the Wholesome Meat Act of 1967. The FMIAct was the first federal government involvement in the food safety of meat and meat products.

The primary goals of the FMIAct, as amended, are to prevent adulterated or misbranded livestock and products from being sold as food, and to ensure that meat and meat products are slaughtered and processed under humane and sanitary conditions. These requirements apply to animals and their products produced and sold within states as well as to imports, which must be inspected under equivalent foreign standards [22]. Excerpted key provisions of the FMIAct follow. "Secretary" refers to the Secretary of the USDA [23]:

§602. Congressional Statement of Findings: "Meat and meat food products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. […]"

§603. Inspection of Meat and Meat Food Products: (a) Examination of animals before slaughtering; diseased animals slaughtered separately and carcasses examined. "For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all cattle, sheep, swine, goats, horses, mules, and other equines before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce […]."

The primary goals of the FMIAct, as amended, are to prevent adulterated or misbranded livestock and products from being sold as food and to ensure that meat and meat products are slaughtered and processed under humane and sanitary conditions.

(b) Humane Methods of Slaughter: "For the purpose of preventing the inhumane slaughtering of livestock, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of the method by which cattle, sheep, swine, goats, horses, mules, and other equines are slaughtered and handled in connection with slaughter in the slaughtering establishments inspected under this chapter." […]

ENFORCEMENT EXAMPLE

An Omaha, Nebraska, company recalled nearly 84 tons of ground beef after USDA inspectors traced *E. coli* to the company. *E. coli* is deadly and can cause dehydration, bloody diarrhea, and abdominal cramps. All 167,427 pounds were produced by All American Meats, Inc. on October 16, 2015 for sale in 60- and 80-pound boxes and shipped to retailers nationwide. The USDA published online a list of retailers selling the contaminated meat [24].

§604. Post Mortem Examination of Carcasses and Marking or Labeling; Destruction of Carcasses Condemned; Reinspection: "For the purposes herein before set forth the Secretary shall cause to be made by inspectors appointed for that purpose a post mortem examination and […] found to be not adulterated shall be marked, stamped, tagged, or labeled as 'Inspected and passed'; and said inspectors shall label, mark, stamp, or tag as 'Inspected and condemned' all carcasses and parts thereof of animals found to be adulterated; and all carcasses and parts thereof thus inspected and condemned shall be destroyed for food purposes by the said establishment in the presence of an inspector […]."

§606. Inspectors of Meat Food Products; Marks of Inspection; Destruction of Condemned Products; Products for Export: "For the purposes herein before set forth the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all meat food products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, and for the purposes of any examination and inspection and inspectors shall have access at all times, by day or night, whether the establishment be operated or not, to every part of said establishment; […]."

In summary, the FMIAct, as amended, provides a framework to inspect, label, and enforce standards of meat and meat products and humane slaughter. Inspections include both a visual examination of carcasses as well as tests for microbacterial contamination. Federal meat inspectors bear the public health responsibility for approving or condemning meat or meat products intended for human consumption. As an issue of environmental health policy, some of the inspection work has been delegated to company inspectors, with USDA meat inspectors performing related, but different duties. This change in policy will be described subsequently.

10.3.2.2 Public Health Implications of the FMIAct

Pathogens in meat and meat products have the potential to cause human illness. There are, however, few data on the incidence of foodborne illnesses specific to meat and meat products and humane slaughter. That does not mean that foodborne illnesses from meat and other foods are inconsequential. One source examined 3500 foodborne food outbreaks, representing 115,700 individual illnesses between the years 1990 and 2003, and found that beef and beef dishes were associated with 338 outbreaks and 10,795 cases, which represented about 9% of the total cases [25]. Moreover, it is known that contaminated meat has been associated with individual outbreaks of illness. For example, in 1996 the CDC investigated an outbreak of *Salmonella* serotype Thompson infections that were associated with a restaurant in Sioux Falls, South Dakota. Fifty-two infections were found in persons who had eaten food prepared by the restaurant. Results of the investigation revealed that cooking times and storage temperatures for roast beef were inadequate to prevent *Salmonella* proliferation [26].

In 2002, the USDA announced more stringent regulations that are intended to reduce *E. coli* contamination of meat and meat products, particularly ground beef. In support of the revised regulations, the USDA noted that 43% of animal carcasses were contaminated with *E. coli* [27]. Moreover, the department referenced CDC data showing foodborne transmission of *E. coli* annually causes more than 62,000 illnesses and 52 deaths. Under the proposed regulations, no slaughter plants would be exempt from random *E. coli* testing (some small production meat processors previously were exempt). Further, the new regulations would require meat processors to add microbiological testing to actions required of them.

Under the FMIAct, the USDA must regulate the operations of meatpackers for purposes of preventing contaminants in meat from reaching consumers. However, how the USDA develops and enforces its meat inspection authorities has historically been subject to policy challenges. The meatpacking industry has argued that federal meat inspectors should have less authority to inspect meat and meat products, asserting that such inspections impede a plant's productivity. The industry preferred an inspection system whereby meat inspections would be conducted by a plant's personnel, but overseen by federal meat inspectors. To date, the industry's proposal has not been fully implemented.

In 2014 the USDA revised its chicken slaughter inspection rule to allow greater involvement by company inspectors [20]. Specifically, USDA states, "the new rule establishes a New Poultry Inspection System (NPIS) for young chicken and all turkey slaughter establishments. The NPIS does not replace the current Streamlined Inspection System (SIS), the New Line Speed Inspection System (NELS), or the New Turkey Inspection System (NTIS). As such, young chicken and turkey slaughter establishments may choose to operate under the NPIS or may continue to operate under their current inspection system, i.e., SIS, NELS, NTIS, or Traditional Inspection, as modified by this final rule. The NPIS is designed to facilitate pathogen reduction in poultry products by shifting Agency resources to allow Food Safety and Inspection Service (FSIS) inspectors to perform more offline inspection activities that are more effective in ensuring food safety, while providing for a more efficient and effective online carcass-by-carcass inspection. […]"

"Key elements of the NPIS include: (1) Requiring that establishment personnel sort carcasses and remove unacceptable carcasses and parts before the birds are presented to the FSIS carcass inspector; (2) shifting Agency resources to conduct more offline inspection activities that are more effective in ensuring food safety, which will allow for one offline verification inspector per line per shift and will reduce the number of online inspectors to one; (3) replacing the Finished Product Standards (FPS), which will apply to establishments that continue operating under SIS, NELS, and NTIS, with a requirement that establishments that operate under the NPIS maintain records to document that the products resulting from their slaughter operations meet the definition of ready-to-cook (RTC) poultry; and (4) authorizing young chicken slaughter establishments to operate at a maximum line speed of 140 birds per minute (bpm), provided that they maintain process control" [28]. Reaction to this revised rule was mixed. Some consumer groups disavowed the increased role of company inspectors, which lessened the inspection by USDA food inspectors. In contrast, some public health groups supported USDA's increased attention to assays of poultry products for presence of pathogens.

In addition to the FMIAct, analogous acts pertain to poultry and egg products [29]. The Poultry Products Inspection Act and the Egg Products Inspection Act mandate inspections of producers of those products and authorize the USDA to take actions similar to those in the FMIAct in order to prevent contaminated poultry and eggs from causing foodborne illnesses. The Food Safety and Inspection Service of the USDA is the administrative unit that bears the responsibility for enforcing the provisions of the FMIAct, the Poultry Products Inspection Act, and the Egg Products Inspection Act. All three acts require states to cooperate with the USDA and require the states to establish their own statutes that comply with the three federal statutes. This is another example of federalism in action, a characteristic of the main body of federal environmental health legislation.

10.3.2.3 Associations between Unsafe Meat and Human Health

Episodes of meat-associated foodborne disease can occur because of failures in meat production, preparation, or delivery to and preparation by consumers. A significant provision of the FMIAct gives the USDA authority to take action against producers of meat or meat products that are found to be unsafe for human consumption. Specifically, §673 of the act states, "…[a]ny carcass, part of a carcass, meat or meat product… is capable of use as human food and is adulterated or misbranded… shall be liable to be proceeded against and seized and condemned, at any time, on a libel of information in any United States district court or other proper court…" States with their own food safety statutes can also suspend operations or close facilities found to be producing meat or meat products contaminated with pathogens.

Preventing contaminated meat from reaching consumers is, in public health terms, an act of primary prevention, i.e., hazard interdiction. Two examples will suffice to illustrate the interdiction of contaminated ground beef from reaching consumers. In October 2002, the USDA recalled 27.4 million pounds of poultry found contaminated with Listeria, which had been made into delicatessen products and produced at a Pennsylvania processing plant—largest recall at that time in U.S. history. In July 2002, the department recalled 19 million pounds of *E. coli* contaminated ground beef produced by a Colorado beef products plant, following illnesses in 19 persons who had consumed ground beef produced by the plant [30].

10.3.2.4 Associations between Unsafe Meat and Ecosystem Health

Although unsafe meat that is discarded into environmental media can potentially harm ecosystems as water pollutants (pathogens of tissue decay) or air emissions (fetid odors), the primary ecosystem health problem derives from the farming of livestock. In particular, waste from large commercial livestock operations can be a hazard to ecosystem health if not properly managed by farmers. As commented by the USDA, "Animal production has the potential to negatively affect surface water quality (from pathogens, phosphorus, ammonia, and organic matter); groundwater quality (from nitrate); soil quality (from soluble salts, copper, arsenic, and zinc); and air quality (from odors, dust, pests, and aerial pathogens). Manure and other byproducts of animal production, if not carefully managed, will have a significant

negative impact on the environment. Agricultural production has been identified by the Environmental Protection Agency (EPA) as the largest single contributor to water quality impairment for rivers and lakes" [31].

As a potential contributor to water pollution, the EPA has regulations specific to large animal production facilities. In particular, "Animal Feeding Operations (AFOs) are agricultural operations where animals are kept and raised in confined situations. An AFO is a lot or facility (other than an aquatic animal production facility) where the following conditions are met: animals have been, are, or will be stabled or confined and fed or maintained for a total of 45 days or more in any 12-month period, […]. AFOs that meet the regulatory definition of a concentrated animal feeding operation (CAFO) are regulated under EPA's National Pollutant Discharge Elimination System (NPDES) permitting program. The NPDES program regulates the discharge of pollutants from point sources to waters of the U.S. Confirmed Animal Feeding Operations (CAFOs) are point sources, as defined by the CWAct [Section 502(14)]). To be considered a CAFO, a facility must first be defined as an AFO, and meet the criteria established in the CAFO regulation" [32].

In addition, AFOs that qualify are subject to EPA's regulations on emissions of GHGs. Specifically, in response in 2008 the EPA issued the Mandatory Reporting of Greenhouse Gases Rule (74 FR 56260), which requires reporting of GHG data and other relevant information from large sources and suppliers in the U.S. In general, the rule is referred to as 40 CFR Part 98 (Part 98). Implementation of Part 98 is referred to as the Greenhouse Gas Reporting Program (GHGRP).

The USDA, states, territories, and tribes all have responsibilities for providing advice and counsel to AFOs, with some states implementing EPA's regulatory authorities.

10.3.3 Nutrition Labeling and Education Act, 1990

For several years, members of Congress were aware of consumer and industry interest in nutrition labeling, leading to various legislative acts that addressed some of the nutrition labeling issues. These preliminary congressional efforts culminated in November 1990 with passage of the Nutrition Labeling and Education Act (NLEA) of 1990. As described by the Nutrition Labeling Committee of the Institute of Medicine, this was the most significant food labeling legislation in 50 years [33]. The NLEA amended the FDCAct to give the FDA explicit authority to require nutrition labeling on most food packages and specified the nutrients to be listed in the nutrition label.

The NLEA also required that nutrients be presented in the context of a consumer's daily diet; specified that serving sizes should represent "an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food"; and provided for a voluntary nutrition labeling program for raw fruits, vegetables, and fish. The NLEA also required standard definitions to be developed by the FDA that characterized the level of nutrients and required that the FDA approve health claims.

The NLEA's requirements for the content of the nutrition label were very similar to those in the FDA's 1990 proposal except that the NLEA included complex carbohydrates and sugars in the list of required nutrients. It also permitted the agency to add or delete nutrients based on a determination that such a change would "assist consumers in maintaining healthy dietary practices" [33]. General principles for nutrient content claims and the definition of terms for claims to be allowed were also proposed, as were general principles for health claims.

The NLEA pertains only to labels of food products regulated by FDA, is the majority of foods. However, meat and poultry product labels are under the authority of the USDA, and alcoholic beverage product labels are under the authority of the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury [33].

10.3.4 FDA Food Safety Modernization Act, 2011

The Food Safety Modernization Act (FSMAct) was signed into law by President Obama on January 4, 2011 [34]. This law is the most sweeping reform of U.S. food safety laws in more than 70 years. The FSMAct aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it. Prevention of disease and disability is the cornerstone of public health and is the focus of the FSMAct.

The FSMAct provides the FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention-and risk-based food safety standards and to better respond to and contain problems when they do occur. The law also gives the FDA important new tools to hold imported foods to the same standards as domestic foods and directs the FDA to build an integrated national food safety system in partnership with state and local authorities.

The following are among the FDA's key new authorities and mandates. Specific implementation dates specified in the law are noted in parentheses [34]:

Prevention: For the first time, the FDA will have a legislative mandate to require comprehensive, science-based preventive controls across the food supply. This mandate includes:

- Mandatory preventive controls for food facilities: Food facilities are required to implement a written preventive controls plan. This involves: (1) evaluating the hazards that could affect food safety, (2) specifying what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards, (3) specifying how the facility will monitor these controls to ensure they are working, (4) maintaining routine records of the monitoring, and (5) specifying what actions the facility will take to correct problems that arise. (Final rule due 18 months following enactment)
- Mandatory produce safety standards: the FDA must establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables. Those standards must consider naturally occurring hazards, as well as those that may be

introduced either unintentionally or intentionally, and must address soil amendments (materials added to the soil such as compost), hygiene, packaging, temperature controls, animals in the growing area, and water. (Final regulation due about 2 years following enactment)

- Authority to prevent intentional contamination: the FDA must issue regulations to protect against the intentional adulteration of food, including the establishment of science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points. (Final rule due 18 months following enactment)

The FSMAct is the most sweeping reform of U.S. food safety laws in more than 70 years. The act aims to ensure the U.S. food supply is safe by shifting the focus from responding to food contamination to preventing it. The FSMAct therefore adopted the core principle of public health: prevention of disease and disability [34].

Inspection and compliance: The FSMAct recognizes that preventive control standards improve food safety only to the extent that producers and processors comply with them. Therefore, it will be necessary for the FDA to provide oversight, ensure compliance with requirements and respond effectively when problems emerge. The FSMAct provides the FDA with important new tools for inspection and compliance, including the following excerpts of greatest relevance to public health:

- *Mandated inspection frequency*: The FSMAct establishes a mandated inspection frequency, based on risk, for food facilities and requires the frequency of inspection to increase immediately. All high-risk domestic facilities must be inspected within 5 years of enactment and no less than every 3 years thereafter. Within 1 year of enactment, the law directs FDA to inspect at least 600 foreign facilities and double those inspections every year for the next 5 years.
- *Records access*: The FDA will have access to records, including industry food safety plans and the records firms will be required to keep documenting implementation of their plans.
- *Testing by accredited laboratories*: The FSMAct requires certain food testing to be performed by accredited laboratories and directs the FDA to establish a program for laboratory accreditation to ensure that U.S. food testing laboratories meet high quality standards. (Establishment of accreditation program due 2 years after enactment).
- *Response*: The FSMAct recognizes that the FDA must have the tools to respond effectively when problems emerge despite preventive controls. New authorities include:
- *Mandatory recall*: The FSMAct provides the FDA with authority to issue a mandatory recall when a company fails to voluntarily recall unsafe food after being asked to by the FDA.
- *Expanded administrative detention*: The FSMAct provides the FDA with a more flexible standard for administratively detaining products that are potentially in violation of the law (administrative detention is the procedure FDA uses to keep suspect food from being moved).
- *Suspension of registration*: FDA can suspend registration of a facility if it determines that the food poses a reasonable probability of serious adverse health consequences or death. A facility that is under suspension is prohibited from distributing food. (Effective 6 months after enactment)
- *Enhanced product tracing abilities*: The FDA is directed to establish a system that will enhance its ability to track and trace both domestic and imported foods. In addition, the FDA is directed to establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or control a foodborne illness outbreak. (Implementation of pilots due 9 months after enactment)
- *Additional Recordkeeping for High Risk Foods*: The FDA is directed to issue proposed rulemaking to establish recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that the Secretary designates as high-risk foods. (Implementation is due 2 years after enactment).
- *Imports*: The FSMA gives the FDA unprecedented authority to better ensure that imported products meet U.S. standards and are safe for U.S. consumers. New authorities include:
- *Importer accountability*: For the first time, importers have an explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe. (Final regulation and guidance due 1 year following enactment)
- *Third party certification*: The FSMAct establishes a program through which qualified third parties can certify that foreign food facilities comply with U.S. food safety standards. This certification may be used to facilitate the entry of imports. (Establishment of a system for the FDA to recognize accreditation bodies is due 2 years after enactment)
- *Voluntary qualified importer program*: The FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. Eligibility is limited to, among other things, importers offering food from certified facilities. (Implementation due 18 months after enactment)
- *Authority to deny entry*: The FDA can refuse entry into the U.S. of food from a foreign facility if the FDA is denied access by the facility or the country in which the facility is located.

- *Enhanced Partnerships*: The FSMAct builds a formal system of collaboration with other government agencies, both domestic and foreign. In doing so, the statute explicitly recognizes that all food safety agencies need to work together in an integrated way to achieve our public health goals. The following are examples of enhanced collaboration:
- *State and local capacity building*: The FDA must develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies. The FSMAct provides the FDA with a new multi-year grant mechanism to facilitate investment in State capacity to more efficiently achieve national food safety goals.

Foreign capacity building: The law directs the FDA to develop a comprehensive plan to expand the capacity of foreign governments and their industries. One component of the plan is to address training of foreign governments and food producers on U.S. food safety requirements.

Reliance on inspections by other agencies: The FDA is explicitly authorized to rely on inspections of other federal, state, and local agencies to meet its increased inspection mandate for domestic facilities. The FSMAct also allows the FDA to enter into interagency agreements to leverage resources with respect to the inspection of seafood facilities, both domestic and foreign, as well as seafood imports.

* * *

Under the provision of the FSMAct, in 2016 the FDA updated the requirements for food labeling under the terms of the NLEA of 1990. The new Nutrition Facts label will include the following [35]:

- "An updated design to highlight "calories" and "servings," two important elements in making informed food choices.
- Requirements for serving sizes that more closely reflect the amounts of food that people currently eat. By law, the NLEA requires that serving sizes be based on what people actually eat.
- Declaration of grams and a percent daily value (%DV) for "added sugars."
- Dual column labels to indicate both "per serving" and "per package" calorie and nutrition information for certain multi-serving food products that could be consumed in one sitting or multiple sittings.
- Updated daily values for nutrients like sodium, dietary fiber, and vitamin D, consistent with Institute of Medicine recommendations and the 2015–2020 Dietary Guidelines for Americans.
- Declaration of Vitamin D and potassium that will include the actual gram amount, in addition to the %DV. The %DV for calcium and iron will continue to be required, along with the actual gram amount.
- "Calories from Fat" will be removed because research shows the type of fat is more important than the amount. "Total Fat," "Saturated Fat," and "Trans Fat" will continue to be required.
- An abbreviated footnote to better explain the %DV" [35].

The FDA asserts that it is also making minor changes to the Supplement Facts label found on dietary supplements to make it consistent with the Nutrition Facts label. Most food manufacturers will be required to use the new label by July 26, 2018. Manufacturers with less than $10 million in annual food sales will have an additional year to comply with the new rules. The FDA plans to conduct outreach and education efforts on the new requirements.

In an additional action under the FSMAct, the FDA announced in 2015 a final rule to add selenium (Se) to the list of required nutrients for infant formula, and to establish both minimum and maximum levels of Se in infant formula. By amending regulations to add Se to the list of required nutrients for infant formula and establish a safe range for this use, the FDA is able to require manufacturers currently marketing infant formula in the U.S. to add Se within this safe range, and to require any new manufacturer entering the U.S. market to adopt this practice as well [36].

10.3.5 USDA Food Security Policies

The USDA has responsibilities under various federal statutes to provide food assistance to both domestic and global groups in need of improved food security. Domestic programs of agriculture involve conducting research and providing services to the U.S. agriculture programs and businesses. Additionally, the department has responsibilities for providing the following food assistance programs via its Food and Nutrition Service [37]:

- Supplemental Nutrition Assistance Program: benefits for eligible low-income families.
- Special Supplemental Nutrition Program for Women, Infants, and Children" low-income women, infants, and children up to age five through nutritious foods, information on healthy eating, and healthcare referrals.
- Child Nutrition Programs: nutrition assistance for children
- Nutrition Programs for Seniors: programs that focus on the needs of older Americans.
- USDA commodity distribution programs, including Commodity Supplemental Food Program for low-income elderly people at least 60 years.

In addition to these domestic programs of food assistance, the USDA supports global food security through in-country capacity building, basic and applied research, and support for improved market information, statistics, and analysis. USDA is strategically placed in over 80 countries, constantly

monitoring agricultural matters globally. Since 2010, USDA has aligned appropriate programs to Feed the Future plans to support agriculture development in target countries and regions: Ghana, Kenya, East Africa, Bangladesh, Haiti, Guatemala, and Central America. USDA international food aid programs benefited about 34 million individuals globally with assistance valued at nearly $1.6 billion [38].

10.3.6 U.S. State and Local Food Safety Policies

State and local governments have the primary responsibility for enforcing food safety regulations. The authorities of states vary, as do the degrees of local government involvement. States typically establish standards for the transportation, storage, preparation, and serving of food by food service establishments. Local health departments conduct inspections of restaurants and commercial food processors, typically under authorities in state laws. Issuance of permits to food service establishments is at the heart of state food safety laws. Without approved permits, food service establishments cannot legally operate. As an illustration of one state's approach to food safety, consider the state of Georgia. In Georgia, two state agencies have the primary responsibilities for protecting the public against foodborne illness. One agency, the Division of Public Health, has the state's primary authority for illness attributable to food services. The other state agency, the Georgia Department of Agriculture, has authority to regulate and inspect food supplies.

Excerpts from the key public health food safety provisions administered by the Georgia Division of Public Health include the following [39]:

§ II 290-5-14-02: "Selected Provisions: (1)(a): It shall be unlawful for any person to operate a food service establishment, or mobile food unit, a temporary food service operation or a restricted food service operation without having first obtained a valid food service permit from the health authority pursuant to this Chapter. […] (d): The permit shall be prominently displayed at all times, as near the main entrance as practicable. (e) The permit shall be the property of the health authority and shall be returned within 7 days to the local health authority when the food service establishment ceases to operate or is moved to another location or when the permit is revoked."

§ III 290-5-14-03: "Selected Provisions: Food Care: (1) Food Supplies: (a): Food shall be in sound condition, free from spoilage, filth, or other contamination and shall be safe for human consumption. (b) Food shall be obtained from approved sources that comply with all laws relating to food processing and shall have no information on the label that is false or misleading. […] (d) Fluid milk and fluid milk products used or served shall be pasteurized and shall meet the Grade A quality standards as established by law. Dry milk and dry milk products shall be made from pasteurized milk and milk products… (g) Only clean whole eggs, with shell intact and without cracks or checks, or pasteurized liquid, frozen, or dry eggs or pasteurized dry egg products shall be used, except that hard-boiled, peeled eggs, commercially prepared and packaged, may be used. (2) Food Protection: (a) At all times, including while being stored, prepared, displayed, served, or transported, food shall be protected from potential contamination, […] (3) Food Storage: (a) Food, whether raw or prepared, if removed from the container or package in which it was obtained, shall be stored in an approved, clean, and covered container except during necessary periods of preparation of service… (g) Enough conveniently located refrigeration facilities or effectively insulated facilities shall be provided to assure the maintenance of perishable and potentially hazardous food at required temperatures during storage. (4) Food Preparation: (a) Food shall be prepared with the least possible manual contact with suitable utensils, and on surfaces that prior to use have been cleaned, rinsed and sanitized to prevent cross-contamination. (b) Raw fruits and vegetables shall be thoroughly washed with potable water under pressure before being cooked or served. A separate sink shall be provided for this purpose. (5) Food Display and Service: (g) Food on display shall be protected from consumer contamination by the use of packaging or by the use of easily cleanable counter, serving line or salad bar protective devices, display cases, or by other effective means. (6) Food Transportation: (a) During transportation, food and food utensils shall be kept in covered containers or completely wrapped or packaged so as to be protected from contamination and spoilage."

§ XI 290-5-14-11: "Selected Provisions: Compliance Procedures: (1) Permits: (a) Issuance: Permits shall be issued by the health authority. Such permits shall be valid until suspended or revoked. (2) Inspections: (a) Inspection Frequency: An inspection of a food service establishment shall be performed at least twice annually. Additional inspections of the food service establishment shall be performed as often as necessary […] (b) Access: Representatives of the health authority, after proper identification, shall be permitted to enter any food service establishment or operation at any reasonable time for the purpose of making inspections to determine compliance with this Chapter" [39].

Reflection on Georgia's food safety law and regulations shows a program centered on permits issued to food service establishments. Without a permit from the state's public health department (or county health department, if delegated by the state), no food service operations are allowed to operate. Moreover, the state can revoke a permit if sufficient unsanitary conditions are found by local health department inspectors. Of particular note are *critical violations* found by health inspectors, as distinguished from *minor violations*. Critical violations are those findings that have direct implications for the public's health, e.g., service personnel not wearing protective gloves or food stored at temperatures that permit the growth of bacteria.

The state's regulations provide detailed specifications on food transportation, storage, preparation, and service. While the regulations and public health systems of inspections and reporting are generally impressive, they are only as effective as available budgets and personnel permit.

* * *

The Georgia Department of Agriculture's food safety authorities complement those of the Georgia Division of Public

Health. The department's primary food safety authorities derive from several Georgia state laws, and include the following [40]:

- Enforce state laws, rules, and regulations by conducting sanitation inspection of retail food stores, salvage food operations, mobile meat trucks, and rolling stores.
- Inspect food storage warehouses, wholesale bakeries, bottled water, and flavored drink processors, seafood processors, and wholesale fish dealers, and sanitation in establishments where food is handled and manufactured.
- Enforce federally mandated programs of inspection and sampling of dairy farms and dairy processing plants. This authority extends to the inspection of out-of-state milk products shipped to Georgia, along with authority to inspect tanker trucks, route trucks, and warehouses that are used to transport or store dairy products.
- Respond to consumers' inquiries about sanitary conditions relative to food and foodborne illness.

* * *

A comparison of the food safety authorities administered by the two Georgia state agencies shows both similarities and differences. As to similarities, both the Division of Public Health and the Department of Agriculture derive their food safety authorities from state laws. Without authorizing statutes, the agencies would have no specific food safety authority. Also, the prevention of foodborne illness is at the heart of both agencies' authorities and programs. This prevention focus is primarily achieved by requiring food supplies and food service establishments to be registered under state control; and, second, to conduct inspections of food producers, transporters of food products, storage facilities where food products are stored, and food service establishments.

Regarding differences between the two agencies' food safety authorities, the Division of Public Health focuses on the registration and inspection of food service establishments; whereas the Department of Agriculture focuses on registration and inspection of food producers, transporters, and those who store food, such as warehouse operators. As a policy observation, this kind of sharing of public health responsibility for food safety is much like the duality of responsibility found throughout environmental health. For example, on matters of toxic substances, the EPA has primacy in controlling the release into the environment of substances that can harm human and ecological health; whereas the U.S. Public Health Service agencies conduct research on the toxicity and human health implications of toxic substances and work with states to collect surveillance health data and exposure data that can be used to help determine regulatory standards developed by the EPA or other regulatory agencies.

In addition to the state of Georgia's responsibilities in food protection, city and county health departments play a critical role as well. For example, Georgia's DeKalb County Department of Health's food protection unit reviews and approves plans for new food service establishments, issues permits, and conducts ongoing inspections. Approximately 1800 food establishments and services are inspected by the county each year. The results from restaurant inspections are made available to the public by: (1) posting a copy of the inspection report in a prominent place in each restaurant inspected and (2) placing the inspection reports on the county's website. As environmental health policy, providing the public with information with which to make personal health decisions is a matter of right-to-know.

In addition, the department evaluates and issues temporary event food service permits for festivals, carnivals, and fairs. Hotels and motels are evaluated and inspected for food safety. The unit also investigates all foodborne illness complaints and refers for follow-up any significant findings to disease surveillance programs operated by the state of Georgia's Division of Public Health.

* * *

Several environmental health policy issues pertain to food safety. Federalism is one such issue. The entry in 1906 of the federal government into the areas of meat inspection, food, drugs, and cosmetics, somewhat diminished the food safety role of free enterprise in the food industry. Heretofore, food safety was largely a matter of "let the buyer beware," supported by state food safety laws. Outbreaks of foodborne illnesses were considered then as a matter of personal health and consumer consequence. While individual consumer choice and an informed public remain essential for preventing foodborne illnesses, stronger federal and state laws, girded with local health departments' inspections, are essential for food safety.

Another policy issue is how to inform the public about food service establishments that fail to meet standards of food safety. Some local health departments place current and past results of restaurant inspections on their websites. How these are presented to the public is a challenge. The inspection report must be factually accurate, but should not create unrealistic fears in the public. This difficult balance in health communication has led some food safety authorities to suggest that Internet posting of individual food service scores is inappropriate, possibly raising unreasonable fears in the public.

There are several arguments against posting food establishment's inspection reports on the Internet or giving them to local news media. Some inspectors have expressed concern that the public could be misled by unabridged inspection scores, citing problems in inspection procedures that do not clearly distinguish between critical and noncritical findings [41]. They note, depending on the kind of inspection system used, that a restaurant with a score of 95, based on a critical health finding like prepared food left unrefrigerated, would be seen as preferable to a restaurant with a score of 88, based primarily on administrative failures, such as inappropriate placement of the food inspection score within the food service establishment. Further, some food inspectors have expressed their concern that their professional relationship with food

service managers can be hindered when inspection scores are made available to the public [41].

On the other hand, in support of communicating food service inspection reports to the public is the acceptance by many health departments that posted reports help improves food safety. In a study of foodborne-disease hospitalizations in Los Angeles County, California, it was found that restaurant hygiene grading with public posting of results was an effective means for reducing the incidence of foodborne disease [42]. Investigators reported a 13% decrease in the number of foodborne-diseases in the year following implementation of a public posting program for restaurant inspections. As this study suggests, public perception can be a powerful motivator for change. Much like how the Toxics Release Inventory data have led to voluntary reductions of emission from industrial facilities, food establishments fear a poor rating of their services. Therefore some argue that public availability of inspection scores help reinforce food quality standards and practices [42].

Regardless of which side one takes on the argument about the public's access to food inspection reports, the trend seems clear. The U.S. public will continue to want access to government information that has health and safety relevance to them. This trend has been accelerated because of the rapid growth of social media and the public's access to it. Moreover, the well-publicized news media reports of occasional food poisonings have compounded the public's concerns and personal interests. The challenge is therefore not whether to report food establishment ratings, but how to do it in a responsible manner.

10.4 GLOBAL FOOD SAFETY AND SECURITY POLICIES

The previous sections of this chapter have dealt with U.S. food safety and security policies. This section describes parallel food polices established by the EU, China, and India. Each of these three entities face challenges to their populations' food safety and security similar to the ones the U.S. faces. All three have taken policy approaches that are both similar, as well as disparate from those of the U.S.

10.4.1 EU Food Safety Policies

As stated by the European Commission (EC), a series of food incidents in Europe during the late 1990s drew attention to the need to establish general principles and requirements concerning food and feed law at the Union level [44]. Accordingly, in 2002 the EC developed an integrated approach to food safety "from farm to table." This approach was primarily set out in its *White Paper on Food Safety*. The policy covers all sectors of the food chain, including feed production, primary production, food processing, storage, transport, and retail sale.

Later in 2002, the European Parliament and the Council adopted Regulation (EC) No 178/2002 establishing the general principles and requirements of food law (General Food Law Regulation). The General Food Law Regulation is the foundation of food and feed law in the EU. It establishes an overarching and coherent framework for the development of food and feed legislation both at Union and Member State levels. To this end, it states general principles, requirements, and procedures that underpin decision-making in matters of food and feed safety, covering all stages of food and feed production and distribution.

The General Food Law Regulation is the foundation of food and feed law in the EU. It establishes an overarching and coherent framework for the development of food and feed legislation both at Union and Member State levels.

The General Food Law also established an independent agency responsible for scientific advice and support, the European Food Safety Authority. Moreover, the law created the main procedures and tools for the management of emergencies and crises, as well as the Rapid Alert System for Food and Feed. The General Food Law Regulation ensures a high level of protection of human life and consumers' interests in relation to food, while ensuring the effective functioning of the internal market [44]. The key provisions of the Regulation follow:

Safety requirements: The safety of food is of critical importance. Consumers must have confidence and assurance that the food they buy will do them no harm or have an adverse effect. The General Food Law Regulation establishes that only safe food and feed can be placed on the Union market or fed to food-producing animals. It also establishes basic criteria for establishing whether a food or feed is safe.

Traceability: Tracing food and feed throughout the food chain is very important for the protection of consumers, particularly when food and feed are found to be faulty. The General Food Law Regulation defines traceability as the ability to trace and follow food, feed, and ingredients through all stages of production, processing and distribution.

Traceability:

- Facilitates withdrawal of faulty food/feed from the market
- Provides consumers with targeted and accurate information on specific products
- Covers all food and feed, all food and feed business operators, without prejudice to existing legislation on specific sectors
- Affects importers who are required to be able to identify from whom the product was exported in the country of origin
- Obliges businesses to be able to identify at least the immediate supplier of the product in question and the immediate subsequent recipient, with the exemption of retailers to final consumers-one step back-one step forward (unless specific provisions for further traceability exist) […]

Operators' responsibilities: Primary responsibility for ensuring compliance with food law—and in particular the safety of the food—rests with the food (or feed) business operators. To complement and support this principle, the competent

authorities of the Member States must assure adequate and effective controls. When food or feed is unsafe, business operators are obliged to withdraw or recall it. […].

Implementation guidance: A guidance document aims to assist all players in the food chain to better understand the Regulation and to apply it correctly and in a uniform way. […] As a rule, the guidelines do not address specific issues faced by particular types of businesses [45]. There are other implementing documents that give more details to the food management community on their responsibilities under the provisions of the General Food Law.

10.4.2 Food Safety Policies in China

China updated its food safety policy in 2015. As summarized by Sim and Yang, on April 24, 2015, the Standing Committee of China's National People's Congress revised the 2009 Food Safety Law of the People's Republic of China (Food Safety Law) [46]. "The revised law came into effect on October 1, 2015. The revisions to the Food Safety Law are wide-ranging, imposing stricter controls and supervision on food production and management. On December 9, 2015, the China Food and Drug Administration (CFDA) published draft amendments to the Implementing Regulations of the Food Safety Law (Implementing Regulations) for public consultation. Highlights of the changes are summarized below.

1. Record-keeping and registration mechanisms for food producers and importers: The primary enforcement powers for food safety used to be divided among different agencies. Since 2013, the State Council has commenced a structural adjustment for the purpose of establishing a more centralized system, with CFDA under the State Council responsible for the supervision of food production, distribution and restaurant/catering services.[…]

Food producers must maintain a record system to record the supply and examination of food ingredients, food additives, and food-related products. Such record must be kept for a period of 6 months after the expiration date of the relevant food products, or 2 years if the expiration date is not specified. Food importers and importing agents must be recorded with the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). Manufacturers of imported food products must also be registered with the AQSIQ.

2. Online food platforms: Ordering food online is now a global trend and the safety of food purchased over the Internet has raised issues. Under the new law, providers of third-party online food trading platforms must review a trader's permit and register the real identity of the trader. If a platform provider becomes aware of food safety violations, the provider must immediately stop the trader from such illegal activities and report the same to local FDAs. […]
3. Health foods: Health foods that contain ingredients outside the approved list of health food ingredients must be registered with CFDA. CFDA registration is required for health foods that are imported for the first time and serve to supplement vitamins, minerals, and other nutrients. Other health foods must be recorded with provincial level FDAs. […] Consistent with existing regulations for health foods, the new law prohibits labels and instructions of health foods from referring to any preventive or therapeutic function. They should also contain the statement "this product cannot replace medicine." […]
4. Baby food: A key revision under the new law is stricter regulation of baby formula food. The ingredients, food additives, formula, and labels of baby formula food must be recorded with provincial level FDAs. Formulas for baby milk must be registered with CFDA. Reports and other materials showing the development process and safety of the formula must be submitted for formula registration. […]
5. Genetically modified foods: The new law introduces rules on genetically modified foods and provides that packages of genetically modified foods must be labeled as such, and the information on the labels must be accurate. […]
6. Foods for special medical purposes: Formula foods for special medical purposes must be registered with CFDA. The product formula, production technology, labels, instructions, and materials showing the safety and nutritional adequacy of the product and clinical effects of special medical use must be submitted for product registration. The new law stipulates that relevant regulations for pharmaceutical advertising apply to advertisements of foods for special medical purpose. […]
7. Increased sanctions: […] For food traders, engaging in the production of foods or food additives without proper permit will be subject to an administrative fine up to 20 times the products' value. Likewise, failure to register health foods, formula foods for special medical use, or baby milk formulas is subject to an administrative fine up to 20 times the products' value and the food permit may be revoked in serious cases. […]

The new law places more emphasis on the supervision and control of every step of food production, distribution, sale and recall. Special provisions are set out for food products that have been a focus in food safety incidents in recent years, especially health foods and infant milk formulas. Meanwhile, the new law has also taken into account new types of food trading activities, including food sold on a third-party trading platform and food imported through e-commerce channels. With respect to the latter, the draft Implementing Regulations propose that food imported through e-commerce channels are subject to the same regulations as those applicable to food products imported through traditional channels" [46].

10.4.3 Food Safety Policies in India

On August 23, 2006 the Parliament of India consolidated a number of existing provincial food safety policies into the Food Safety and Standards Act of 2006. As summarized by Arora, in India the Food Safety and Standards Authority of India (FSSAI) is the country's apex food regulator [47]. "It is empowered by and functions under the Ministry of Health and Family Welfare, Government of India. The FSSAI implements and enforces food regulations as prescribed in the Food Safety and Standards Act, 2006 (FSS Act). The FSS Act is an act of Parliament, popularly known as the Food Act. […] The regulations of the FSS Act became effective in 2011 with FSSAI as its regulatory body. Though the act continues to evolve it needs to be further harmonized with standards of international agencies for global parity.

In the FSSAI regulations, food products fall into two categories—standardized and non-standardized. The standardized food products are those for which standards are prescribed and do not require product approval prior to manufacture, sale, distribution, or import. The first time manufacturer or importer of standardized foods only requires an FSSAI license to begin a food business" [47]. Key excerpts from the FSSAI regulations follow:

"Non-standardized food products do not have standards as their safety parameters are either not known or not yet ascertained. Presently FSSAI has standardized only 380 articles of food in 16 categories so all other foods require product approval if they are not listed among these 380 food items. FSSAI is working to standardize another 12,000 more foods […].

Traditional foods also do not require product approval as they are being consumed for centuries in India. The ingredients and preparation methods are well known and this guarantees their safety. If, however, traditional foods use any new ingredients or food additive or new technologies in preparation, they need product approval.

Foods Imported into India have to follow the FSS Act, Rules and Regulations. If the food articles are standardized, the importer only needs a FSSAI license to import them. The importer also needs to comply with FSSAI regulations for sale and distribution of the food products. If a new or unknown food article is introduced for import, it is considered non-standardized and requires product approval under the §22 of the FSS Act, 2006. The FSS Act, 2006 does not apply to foods being exported out of India. Exporters do not require FSSAI product approval as these food products are not sold to Indian consumers.

Non-standardized food products, awaiting product approval, are assessed for safety in four categories. To expedite product approval, a 90-day outer limit is now in place for completion of the application review process. However, if the product is referred to the Scientific Panel for further scrutiny, the time limit could be extended. The 90-day time limit has three, 30-day cycles that constitute the various application review stages. […]

New Draft Regulations have been formulated by FSSAI. Of special interest is §22 of the FSS Act, which deals with 'Nutraceuticals, Functional Foods, Novel Foods, and Health Supplements.' For the first time regulations have been proposed for this category of foods. If these products propound nutritional or medicinal benefits they need to have sound scientific evidence. The products must not contain either steroids or psychotropic drugs. Ingredients like vitamins and minerals must conform to the recommended dietary allowances for Indians, as proposed by the Indian Council of Medical Research" [47].

10.4.4 U.S. Global Food Security Act, 2016

In a bipartisan action between the U.S. Congress and the Obama administration, the Global Food Security Act of 2016 (H.R. 1567) was enacted and signed into law by President Obama. This bill requires the President to develop and implement a Global Food Security Strategy to promote global food security, resilience, and nutrition. The key sections of the statute are as follows [48]:

(Sec. 2) This section specifies that it is in the U.S. national security interest to promote global food security, resilience, and nutrition, consistent with national food security investment plans through programs and activities that:

- Accelerate inclusive, agricultural-led economic growth that reduces global poverty, hunger, and malnutrition;
- Increase the productivity, incomes, and livelihoods of small-scale producers;
- Build resilience to food shocks among vulnerable populations and households while reducing reliance upon emergency food assistance;
- Create an environment for agricultural growth and investment;
- Improve the nutritional status of women and children;
- Align with and leverage U.S. strategies and investments in trade, economic growth, science and technology, agricultural research and extension, maternal and child health, nutrition, and water, sanitation, and hygiene;
- Strengthen partnerships between U.S. and foreign universities that build agricultural capacity; and
- Ensure the effective use of taxpayer dollars in achieving these objectives.

(Sec. 3) This section sets forth definitions that apply to this bill.

(Sec. 4) The President must coordinate a whole-of-government strategy to promote global food security, resilience, and nutrition, consistent with national food security investment plans. This section specifies required goals and criteria for the strategy. The President must coordinate the efforts of federal departments and agencies to implement the strategy by establishing: (1) monitoring and evaluation systems, coherence, and coordination across federal departments and agencies; and (2) platforms for regular consultation and collaboration with key stakeholders and congressional committees [48].

The USDA will have major responsibilities for implementation of this law, with the law's impacts to be assessed in subsequent years.

Perspective: The food safety policies of the EU, China, and India all illustrate the importance that is given to preventing the distribution of unsafe food to populations within their borders. While this section has provided summaries of the operative food safety laws and regulations, the actual implementation of these policies is a matter for performance by designated authorities. These three sets of food safety policies share sub-policies of registration of foods imported into the respective countries, reviews of new food products, labeling of foods, and reporting of adverse effects to food authorities.

10.5 STATE OF FOOD SECURITY IN THE U.S.

Even though the U.S. is an affluent country in many respects, including food production, the country's disparities in income and cultural structure have manifested in food insecurity for a portion of the country's population. Put simply, hunger exists in the U.S. The USDA conducts surveys of food patterns in the U.S. From these surveys, the USDA reports that most U.S. households have consistent, dependable access to enough food for active, healthy living—they are food secure. But a minority of American households experience food insecurity at times during the year, meaning that their access to adequate food is limited by a lack of money and other resources. USDA's food and nutrition assistance programs increase food security by providing low-income households access to food, a healthful diet, and nutrition education.

The USDA also monitors the extent and severity of food insecurity in U.S. households through an annual, nationally representative survey. Reliable monitoring of food security contributes to the effective operation of the federal food assistance programs, as well as that of private food assistance programs and other government initiatives aimed at reducing food insecurity. The survey report presents statistics covering households' food security, food expenditures, and use of federal food and nutrition assistance [38]. Key findings in the report for 2014 include:

- The estimated percentage of U.S. households that were food insecure remained essentially unchanged from 2013 to 2014; however, food insecurity was down from a high of 14.9% in 2011. The percentage of households with food insecurity in the severe range—described as very low food security—was unchanged.
- In 2014, 86.0% of U.S. households were food secure throughout the year. The remaining 14.0% (17.4 million households) were food insecure. Food-insecure households (those with low and very low food security) had difficulty at some time during the year providing enough food for all their members due to a lack of resources. The changes from 2013 (14.3%) and 2012 (14.5%) to 2014 were not statistically significant; however, the cumulative decline from 14.9% in 2011 was statistically significant.
- In 2014, 5.6% of U.S. households (6.9 million households) had very low food security, unchanged from 5.6% in 2013. In this more severe range of food insecurity, the food intake of some household members was reduced and normal eating patterns were disrupted at times during the year due to limited resources.
- Children were food insecure at times during the year in 9.4% of U.S. households with children (3.7 million households), essentially unchanged from 9.9% in 2013. These households were unable at times during the year to provide adequate, nutritious food for their children [38].

Children were food insecure at times during 2014 in 9.4% of U.S. households with children (3.7 million households). These households were unable at times during the year to provide adequate, nutritious food for their children.

Food insecurity in the U.S. has healthcare consequences. A study by researchers at the Boston University School of Medicine used data from the USDA, Census Bureau, and research on food security journal publications between 2005 and 2015 to estimate these health care costs [49]. The investigators examined the costs of treating diseases and health conditions associated with household food insecurity. They included earnings lost when people took time off work because of these illnesses or to care for family members with illnesses related to food insecurity. The investigators estimated that the absence of food security in the U.S. carries enormous healthcare costs, more than $160 billion in 2014. In comparison, this figure is about five times the whole year 2016 budget request of the U.S. National Institutes of Health, the country's foremost federal health research agency.

10.6 GLOBAL STATE OF FOOD SECURITY

In 2015 the FAO released its annual summary of global food security [50]. The FAO reported "About 793 million people are undernourished globally, down 167 million over the last decade, and 216 million less than in 1990–1992. The decline is more pronounced in developing regions, despite significant population growth. In recent years, progress has been hindered by slower and less inclusive economic growth as well as political instability in some developing regions, such as Central Africa and western Asia.

The year 2015 marked the end of the monitoring period for the Millennium Development Goal (MDG)

In 2015 FAO reported "About 793 million people are undernourished globally, down 167 million over the last decade, and 216 million less than in 1990–1992. The decline is more pronounced in developing regions" [50].

targets (Chapter 2, Section 2.6.4). For the developing regions as a whole, the share of undernourished people in the total population has decreased from 23.3% in 1990–1992 to 12.9%. Some regions, such as Latin America, the east and south-eastern regions of Asia, the Caucasus and Central Asia, and the northern and western regions of Africa have made fast progress. Progress was also recorded in southern Asia, Oceania, the Caribbean, and southern and eastern Africa, but at too slow a pace to reach the MDG 1c target of halving the proportion of the chronically undernourished.

A total of 72 developing countries out of 129 have reached the MDG 1c hunger target. Most enjoyed stable political conditions and economic growth, often accompanied by social protection policies targeted at vulnerable population groups. For the developing regions as a whole, the two indicators of MDG 1c—the prevalence of undernourishment and the proportion of underweight children under 5 years of age—have both declined" [50].

Perspective: These FAO data are encouraging in the sense that global progress is occurring in nations' providing levels of food security. But the report also is discouraging because the FAO estimates that 793 million people still lack adequate food nourishment. For sake of perspective, this number is approximately the 2016 combined populations of the U.S., Indonesia, and Brazil [51]. As will be described in this section, several factors are contributing to food insecurity in areas of the world.

10.6.1 Threats to Food Security

As noted in the prior section, according to FAO data global progress has been made in achieving food security, especially in developing nations. Further encouraging data about global production of food came from a study conducted by researchers at the Potsdam Institute for Climate Impact Research in Germany [60]. The researchers were interested in the relationship between food waste and the waste's generation of GHGs. This study provides a systematic approach to estimate consumer level food waste on a country scale and globally, based on food availability and requirements. The study revealed that in the year 2010, food availability was 20% higher than was required on a global scale. Surplus between food availability and requirements of a given country was considered as food waste. The global food requirement changed from 2300 kcal/cap/day to 2400 kcal/cap/day during the last 50 years, while food surplus grew from 310 kcal/cap/day to 510 kcal/cap/day. Similarly, GHG emissions related to the food surplus increased from 130 Mt CO_2eq/year to 530 Mt CO_2eq/year, an increase of more than 300%. Moreover, the global food surplus may increase up to 850 kcal/cap/day, while the total food requirement will increase only by 2%–20% by 2050. Consequently, GHG emissions associated with the food waste may also increase tremendously to 1.9–2.5 Gt CO_2eq/year.

Reflection on the FAO report and the Potsdam study leads to the conclusion that food security is greatly influenced by food distribution systems. Put into different words, surplus food isn't getting to those in need. Moreover, there are many factors that contribute to lack of food security domestically and globally. Six of these factors will be discussed herein. As will be evident, all six are factors derivative of anthropogenic causes.

10.6.1.1 Human Population Growth and Food Security

The human population continues to increase, both in numbers and complexity of social structures. Although some disagreement exists regarding population forecasts, there is no disagreement that the 2016 world human population of approximately 7.3 billion will increase by billions during the twenty-first century. For the purposes of this book, population estimates developed by the UN will be utilized, "Currently, the world population continues to grow though more slowly than in the recent past. Ten years ago, world population was growing by 1.24% per year. Today, it is growing by 1.18% per year or approximately an additional 83 million people annually. The world population is projected to increase by more than one billion people within the next 15 years, reaching 8.5 billion in 2030, and to increase further to 9.7 billion in 2050 and 11.2 billion by 2100" [52]. Further, nine countries are expected to make up half of the world's population growth between now and 2050: India, Nigeria, Pakistan, Congo, Ethiopia, Tanzania, the U.S., Indonesia, and Ghana. Africa has the world's highest rate of population growth [52].

This projected increase in population presents numerous sociopolitical questions, not the least of which is, "Will there be enough food?" In consideration of this question, FAO concluded in 2009, "Political turmoil, social unrest, civil war and terrorism could all be on the table unless the world boosts its food production by 60% come mid-century, the UN's main hunger fighting agency has warned. The world's population is expected to hit 9 billion people by 2050, which, coupled with the higher caloric intake of increasingly wealthy people, is likely to drastically increase food demand over the coming decades. […]. Exacerbating this problem is a convergence in diets worldwide, with reliance on an ever smaller group of crops leaving global food supplies increasingly vulnerable to inflationary pressure, insects and disease" [53].

The FAO notes that progress has been made in the battle against global hunger, with vegetable production in Asia and the Pacific—where more than three-quarters of the world's vegetables are grown—increasing by 25% over the last decade. However, FAO estimates that 842 million people in the world remain undernourished, with nearly two-thirds of them living in the Asia-Pacific region. One in four children under the age of 5 years is stunted due to malnutrition.

To combat the problem, FAO has outlined two primary options: increasing arable land areas as well as productivity rates. A lack of available arable land and more sluggish growth rates in staple crops have complicated efforts to bolster these two pillars of food security. Over the past 2 years, productivity rates for rice and wheat have hovered around 0.6%–0.8%. Those rates would have to stabilize around 1% in order to offset serious shortages [53].

"Environmentalists have also urged better food distribution methods. In February, the FAO, World Bank and World Resources Institute estimated that the world is losing 25%–33% of the food it produces—nearly 4 billion metric tons.

More efficient agricultural production, better means of storing food and biologically diverse, local food systems less susceptible to global changes have also been proposed as solutions to help tackle the growing threat of food insecurity" [54].

Increased human population has contributed to greater interconnectivity between food-importing and food-exporting nations. This interconnectivity has been investigated by researchers interested in the effects of disruptions (e.g., climate change) on food security. In one investigation, by Columbia University researchers annual staple food production and trade data from 1992 to 2009 were used to analyze the changing properties of the global food system. "Over the 18-year study period, we show that the global food system is relatively homogeneous (85% of countries have low or marginal food self-sufficiency) and increases in complexity, with the number of global wheat and rice trade connections doubling and trade flows increasing by 42% and 90%, respectively. The increased connectivity and flows within these global trade networks suggest that the global food system is vulnerable to systemic disruptions […]. To test this hypothesis, we superimpose continental-scale disruptions on the wheat and rice trade networks. We find greater absolute reductions in global wheat and rice exports along with larger losses in network connectivity as the networks evolve due to disruptions in European wheat and Asian rice production. Importantly, our findings indicate that least developed countries suffer greater import losses in more connected networks through their increased dependence on imports for staple foods" [55].

A separate investigation was organized by Lloyd's of London, a global insurance company. The company was interested in the impacts of serious disruptions in food security in regard to the impact on insurance claims [56]. "Research for the project was led by Anglia Ruskin University's GSI, and based on its GRO modelling initiative. The report explores the scenario of a near-term global food supply disruption, considered plausible on the basis of past events, especially in relation to future climate trends. The global food system, the authors find, is 'under chronic pressure to meet an ever-rising demand, and its vulnerability to acute disruptions is compounded by factors such as climate change, water stress, ongoing globalisation and heightening political instability" [57].

Lloyd's scenario analysis shows that food production across the planet could be significantly undermined due to a combination of just three catastrophic weather events, leading to shortfalls in the production of staple crops, and ensuing price spikes. In the scenario, which is 'set in the near future,' wheat, maize and soybean prices 'increase to quadruple the levels seen around 2000,' while rice prices increase by 500%. This leads to rocketing stock prices for agricultural commodities, agricultural chemicals and agriculture engineering supply chains, leading to […] geopolitical mayhem as well as escalating terrorism and civil unrest" [57]. While this report raises troubling issues of global import, it is important to understand that the model used in the research did not include any sociopolitical adjustments made over time that could mitigate the model's projected dire outcomes.

As described in this section, food security will need to adjust for increased numbers of humans. Food security specialists have begun to reflect on what adjustments will be needed and how to achieve them. An interesting reflection comes from a group of water scientists who stated that the world's population may have to switch almost completely to a vegetarian diet over the next 40 years to avoid catastrophic food shortages. Humans now derive about 20% of their protein from animal-based products; this figure may need to decrease to just 5% in order to feed the globe's increased population, expected to grow by two billion by 2050. Animal protein-rich food consumes 5–10 times more water than a vegetarian diet. Water scientists recommended adopting a vegetarian diet as one option to increase the amount of water available to grow more food in an increasingly climate-erratic world [58].

10.6.1.2 Food Waste

A contributor to food insecurity is wasting of food. Food wastage is a major problem, especially in countries that are ill equipped to adequately grow, harvest, transport, distribute, and utilize food supplies. Figure 10.2 shows an example of food wastage. FAO has provided estimates of the globe's food wastage [59]:

- "The global volume of food wastage is estimated at 1.6 billion tons of "primary product equivalents." Total food wastage for the edible part of this amounts to 1.3 billion tons.
- The carbon footprint of food wastage is estimated at 3.3 billion tons of CO_2 equivalent of GHGs released into the atmosphere per year.
- Similarly, 1.4 billion hectares of land—28% of the world's agricultural area is used annually to produce food that is lost or wasted.
- A low percentage of all food wastage is composted; much of it ends up in landfills, and represents a large part of municipal solid waste. Methane emissions from landfills represent one of the largest sources of GHGs emissions from the waste sector.
- Developing countries suffer more food losses during agricultural production, while in middle-and

FIGURE 10.2 Example of food waste. (From UN FAO (UN Food and Agriculture Organization), Food wastage: Key facts and figures, Office of Director-General, Rome, Italy, 2016.)

high-income regions food waste at the retail and consumer level tends to be higher.
- The direct economic consequence of food wastage (excluding fish and seafood) is estimated at $750 billion annually" [59].

Adding to these FAO data are the findings from a study by researchers at the Potsdam Institute for Climate Impact Research in Germany [60]. As previously discussed, the researchers were interested in the relationship between food waste and the waste's GHGs. The study revealed that in the year 2010, food availability was 20% higher than was required on a global scale. Similarly, GHG emissions related to the food surplus increased from 130 Mt CO2eq/year to 530 Mt CO2eq/year, an increase of more than 300%. Moreover, the global food surplus may increase up to 850 kcal/cap/day, while the total food requirement will increase only by 2%–20% by 2050. Consequently, GHG emissions associated with the food waste may also increase tremendously to 1.9–2.5 Gt CO2eq/year [60]. Other aspects of food waste are described in Chapter 12 (Waste Generation and Management).

10.6.1.3 Climate Change

According to a modeling study conducted by University of Oxford investigators, the effects of climate change on food security could be consequential [61]. The investigators linked an agricultural modeling framework, the International Model for Policy Analysis of Agricultural Commodities and Trade, to a comparative risk assessment of changes in fruit and vegetable consumption, red meat consumption, and bodyweight for deaths from coronary heart disease, stroke, cancer, and an aggregate of other causes of mortality. The model was used to calculate the change in the number of deaths attributable to climate-related changes in bodyweight and diets. The model projected that by year 2050, climate change will lead to per-person reductions of 3.2% (SD 0.4%) in global food availability, 4.0% (0.7%) in fruit and vegetable consumption, and 0.7% (0.1%) in red meat consumption.

These changes will be associated with 529,000 climate-related deaths worldwide (95% CI=314,000–736,000), representing a 28% (95% CI=26–33) reduction in the number of deaths that would be avoided because of changes in dietary and weight-related risk factors between years 2010 and 2050. Twice as many climate-related deaths were associated with reductions in fruit and vegetable consumption than with climate-related increases in the prevalence of underweight individuals. The model predicted that most climate-related deaths would occur in South and East Asia. Adoption of climate-stabilization pathways would reduce the number of climate-related deaths by 29%–71%, depending on their stringency [61].

In a different investigation, major "shocks" to global food production were investigated. Examples of major shocks would be protracted droughts, massive flooding, and prolonged high air temperatures. The study found these major shocks will be three times more likely within 25 years because of an increase in extreme weather brought about by global warming. The likelihood of such a shock, where production of the world's four major commodity crops (maize, soybean, wheat, and rice) falls by 5%–7%, is currently once-in-a-century. But such an event will occur every 30 years or more by 2040, according to the study by the UK–US Taskforce on Extreme Weather and Global Food System Resilience [62]. Such shocks could plausibly see the UN's food price index—which measures the international price of major commodities—rise by 50%, based on an analysis of how the market would likely respond. Increased food production volatility will mostly affect those developing countries experiencing high levels of poverty and political instability, such as countries in the Gulf or Sub-Saharan Africa. As climate change causes temperatures to rise even higher in the second half of the century, even more serious food shocks—where production drops by up to 10%—are also likely to occur much more often by the year 2070 [63].

Examples of loss of food security due to climate change are already present. For instance, UN bodies, international aid agencies, and governments have cautioned that droughts and floods triggered by one of the strongest El Niño weather events ever recorded have left nearly 100 million people in southern Africa, Asia, and Latin America facing food and water shortages and vulnerable to diseases including Zika [64]. For example, in Mozanbique, El Niño, the natural weather phenomenon that upturns normal weather patterns every few years in southern Africa, caused the country to come to the end of another dry rainy season 2016. For the second consecutive year, the town of Mbalavala's maize fields were empty and the soil in vegetable gardens was like sand. The small amount of water from an emergency borehole must be shared between cattle and people. Mbalavala and 170,000 people in several hundred similar villages in Gaza and Inhambane, Mozambique's two most vulnerable provinces survived in 2016 and 2017 due to British food aid [65].

Lack of food security poses major economic and social consequences beyond that of hunger and insufficient nutrition. For instance due to widespread food shortages resulting from a prolonged drought, Zimbabwe has been forced to seek $1.6 billion in aid from global aid agencies to help pay for grain and other food [66]. Regarding social impacts of food insecurity, the UN's World Food Programme noted that women and children are bearing the brunt of a malnutrition and hunger crisis in Mauritania, while tens of thousands of Malian refugees face food shortages due to a lack of funding. In 2015 malnutrition reached emergency levels in six of Mauritania's 15 regions, affecting at least one in six people, and the proportion of malnourished children under five across the country rose to 14% from 10% in 2014. Pregnant women were at special risk [67].

A global food source, marine life, will be affected by climate change, which is postulated to seriously impair fish stocks. A 2015 study lists climate change as one of the main reasons for the decline of marine species in the last 30 years.

Another source of food, marine life, will be affected by climate change, which is postulated to seriously impair fish stocks. The Marine Stewardship Council cites a 2015 study

that lists climate change as one of the main reasons for the decline of marine species in the last 30 years. Three billion people rely on fish as their major source of protein. Fish and aquaculture assure the livelihoods of 12% of the world's population, creating economic benefits of $ 2.9 trillion USD per year. Climate change affects fish and fisheries through the following factors: ocean acidification, habit loss due to temperature increase, extreme, unpredictable weather events; and rising sea levels. These changes affect fisheries worldwide, but the impacts are likely to be particularly damaging for fisheries in developing countries [68].

10.6.1.4 Loss of Pollinators

Another factor that affects food security is the decline in numbers and diversity of pollinators. Farmers and gardeners know the vital value of the creatures that serve Nature as pollinators of flora, trees, and others that require pollen transfer in order to reproduce. Loss of pollinators portends loss of food sources and diminished food security. The Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services has reviewed the current situation in regard to loss of pollinators. Excerpts from their findings follow:

1. More than three quarters of the leading types of global food crops rely to some extent on animal pollination for yield and/or quality. Pollinator-dependent crops contribute up to 35% of global crop production volume.
2. Given that pollinator-dependent crops rely on animal pollination to varying degrees, it is estimated that 5%–8% of current global crop production, with an annual market value of $235 billion–$577 billion worldwide, is directly attributable to animal pollination.
3. The vast majority of pollinator species are wild, including more than 20,000 species of bees, some species of flies, butterflies, moths, wasps, beetles, thrips, birds, bats, and other vertebrates.
4. Wild pollinators have declined in occurrence and diversity (and abundance for certain species) at local and regional scales in North West Europe and North America.
5. The International Union for Conservation of Nature Red List assessments indicates that 16.5% of vertebrate pollinators are threatened with global extinction (increasing to 30% for island species). Regional and national assessments indicate high levels of threat for some bees and butterflies. In Europe, 9% of bee and butterfly species are threatened and populations are declining for 37% of bees and 31% of butterflies (excluding data deficient species, which includes 57% of bees). Where national Red List assessments are available, they show that often more than 40% of bee species may be threatened.
6. The abundance, diversity, and health of pollinators and the provision of pollination are threatened by direct drivers that generate risks to societies and ecosystems. Threats include land use change, intensive agricultural management and pesticide use, environmental pollution, invasive alien species, pathogens, and climate change [69].

Perspective: Declines in the prevalence of pollinators portends decreased food production at a time when global food diversity is a challenge. But as with other threats to food security, efforts in conservation, research on causes of declines, and policies on protection of pollinating species will be necessary.

10.6.1.5 Soil Security and Arable Land

Humankind's harvesting of plants grown in soil has sustained our and other species for eons. Over time, humans learned how to cultivate soil, sow seeds or transplant seedlings, harvest crops, and consume the food grown for that purpose. In other words, humans learned how to farm. Unfortunately, as with other threats to food security, there are problems globally with the condition and amount of arable soil. Of note, 40% of the planet's land is now devoted to human food production, up from 7% in 1700. In a study by the University of Sheffield's Grantham Centre for Sustainable Futures, researchers assert that the world has lost a third of its arable land in the past 40 years due to erosion or pollution. Their study calculated that nearly 33% of the world's adequate or high-quality food-producing land has been lost at a rate that far outstrips the pace of natural processes to replace diminished soil. Researchers attribute the continual ploughing of fields, combined with heavy use of fertilizers, as factors in the global degradation of soils. They observed that erosion is occurring at a pace of up to 100 times greater than the rate of soil formation. This is a dire warning, since it takes around 500 years for just 2.5 cm of topsoil to be created amid unimpeded ecological changes [70].

Farming practices and land use are being scrutinized for their impact on the environment and public health. In particular, what is called "intensive agriculture" has become the subject of debate amongst agriculturalist, environmentalists, and public health specialists. Intensive farming is an agricultural intensification and mechanization system that aims to maximize yields from available land through various means, such as heavy use of pesticides and chemical fertilizers. According to one environmental source, this intensification and mechanization has also been applied to the raising of livestock with billions of animals—such as cows, pigs, and chickens—being held indoors in what have become known as factory farms. Intensive farming practices produce more—and less expensive—food per acre and animal, which has helped feed an ever increasing human population and may prevent surrounding land from being converted into agricultural land. However, intensive farming has become a major threat to the global environment through the loss of ecosystem services and as a contributor to global warming [71].

Furthermore, intensive farming kills beneficial insects and plants, degrades and depletes the very soil it depends on, creates polluted runoff and clogged water systems, increases susceptibility to flooding, causes the genetic erosion of crops and livestock species around the world, decreases biodiversity, destroys natural habitats, and, significant contributors to the build-up of

GHGs in the atmosphere. However, certain aspects of intensive farming have helped ease climate change by helping boost yields in already cleared land that may be under-performing, which prevents the clearing of additional land. There are both pros and cons to intensive farming, but compared to the disadvantages, the advantages are fewer. The world is in transition from an era of food abundance to one of food insecurity. With 40% of the planet's land devoted to human food production, up from 7% in 1700, and as the world's demand for food rises 70% by 2050, feeding a rapidly growing human population can and should be done by adopting a sustainable food production approach that can run indefinitely with minimized impacts on the environment, animal welfare and human health [71].

Perspective: As the world's human population grows, demands on food security will correspondingly increase. The production of food supplies will need to adapt to population increase, but to other realities of the twenty-first century, such as climate change. Land use and farming practices, as well as reliance on fish stocks and ocean seafood, will continue to be stressed. Two policies, conservation and sustainability, will need to be globalized if food insecurity is to be avoided.

10.6.1.6 Genetically Modified Food

Food supplies are already being influenced by increased numbers of genetically modified foods, as will be discussed in detail in Chapter 15. As discussed there, controversy has accompanied this development. The nature of policies and attendant controversies about genetically engineered (GE) food are discussed in Chapter 15, but suffice it to say here that GE food is present in the food chain of the U.S. and many other countries. In this section are three examples of this trend.

In May 2015 the FDA approved potatoes that won't bruise and apples that won't brown. The agency approved both GE foods, characterizing them as safe and nutritious as their conventional counterparts [72]. Also in 2015, the FDA gave approval of genetically modified salmon for consumer use. This marked the first GE food animal endorsed for sale in the U.S. [73]. As the third example, in January 2015 the USDA granted "nonregulated" status to genetically modified cotton and soybean plants. These are herbicide-tolerant crops to be used with a new herbicide intended to fight problematic weed resistance on farm fields [74]. For all three examples, considerable criticism arose in reaction to the approvals of these GE foods. It remains to be seen whether any of these approved GE foods will become widespread in commercial food supplies. As a global issue, some countries (e.g., Scotland and Germany) have eschewed GE crops and produce based on concerns from farmers and food consumers [75].

10.6.2 Resources for Enhancing Food Security

Although global production of food exceeds the requirements of the 2016 world population of approximately 7.3 billion people, there remain millions of people who suffer nutritional deficiencies, and famines occur due to catastrophic weather events. In times of food crisis, resources must be mobilized to provide food and assistance. Further, resources are needed for improving land and water security. Some representative food security resources are described herein.

10.6.2.1 UN World Food Programme

The WFP is the world's largest humanitarian agency fighting hunger worldwide. The WFP is part of the UN system and is voluntarily funded. It was established in 1961 by the U.N.'s FAO and the UN General Assembly. The WFP "pursues a vision of the world in which every man, woman and child has access at all times to the food needed for an active and healthy life" [76]. The WFP addresses both the humanitarian and development needs of human populations in need of assistance. In emergencies, it distributes food where it is needed to save the lives of victims of war, civil conflict, and natural disasters. After the cause of the emergency abates, the WFP focuses on development, using food to help communities rebuild their lives.

A review conducted in 2012 of the WFP programs found that on average, the agency annually reaches more than 80 million people with food assistance in 82 countries [77]. For sake of perspective, the Democratic Republic of Congo, Germany, Iran, and Turkey each have a human population of approximately 80 million people [51].

10.6.2.2 Famine Early Warning Systems Network

The Famine Early Warning Systems Network (FEWS NET) is a leading provider of early warning and analysis on food insecurity. The FEWS was created by the U.S. Agency for International Development (USAID) in 1985 to help decision-makers plan for humanitarian crises. "USAID is the lead U.S. Government agency that works to end extreme global poverty and enable resilient, democratic societies to realize their potential" [78]. FEWS NET provides evidence-based analysis on some 35 countries. Implementing team members include NASA, NOAA, USDA, and USGS, along with Chemonics International Inc. and Kimetrica.

Analysts and specialists in 22 field offices work with U.S. government science agencies, national government ministries, international agencies, and NGOs to produce forward-looking reports on more than 36 of the world's most food-insecure countries. FEWS NET's products include: monthly reports and maps detailing current and projected food insecurity, timely alerts on emerging or likely crises, specialized reports on weather and climate, markets and trade, agricultural production, livelihoods, nutrition, and food assistance [78].

FEWS NET works with the humanitarian and development communities, participating in global committees to improve classification, remote sensing, and other aspects of food security analysis. They also support and conduct training and capacity-building for national early warning systems, weather services, and other agencies.

10.6.2.3 Natural Resources Conservation Service

Except for plant food grown via hydroponics, arable soil is the environmental medium on which the world's food is grown. In a planet experiencing climate change and human

population growth, conservation of soil and water is vital to food security. On April 27, 1935 the U.S. Congress passed Public Law 74-46, in which it recognized that "the wastage of soil and moisture resources on farm, grazing, and forest lands… is a menace to the national welfare" and established the Soil Conservation Service (SCS) as a permanent agency in the USDA. In 1994, SCS's name was changed to the Natural Resources Conservation Service to better reflect the broadened scope of the agency's concerns. In doing so, Congress reaffirmed the federal government's commitment to the conservation of the nation's soil and water resources. Farmers, ranchers, and forest landowners can receive financial assistance from NRCS to make improvements to their land. NRCS conservationists provide technical expertise and conservation planning for farmers, ranchers, and forest landowners wanting to make conservation improvements to their land. The NRCS provides incentives to farmers, ranchers, and forest landowners wanting to put wetlands, agricultural land, grasslands, and forests under long-term easements. Local USDA service centers are located across the U.S. The NRCS offers a variety of information, tools, and resources related to conservation [79].

10.6.2.4 Required Agricultural Practices (Vermont)

Food security is intertwined with soil security. Soil barren of essential nutrients and bacteria for grown of plants will not be part of the food chain. Farmers have always known this truth and over the ages learned the principles of soil security. One U.S. state, Vermont, has enacted legislation for purpose of enhancing soil security. In 2006 the Vermont Legislature enacted Bill 6, which mandates the development of regulations for use in protecting water quality and soil security. Specifically, "in accordance with 6 V.S.A. §§ 4810a and 4810, these regulations are intended to establish statewide requirements designed to improve water quality in the State and to assure practices on all farms that eliminate adverse impacts to water. The Required Agricultural Practices Regulations are farm management techniques that will conserve and protect natural resources, maintain the health and productivity of soils and protect the State's waters from nutrient loading associated with farming activities. Persons engaged in farming who are in compliance with these practices shall be presumed to not have a discharge of agricultural pollutants to waters of the State" [80].

The Accepted Agricultural Practices are standards designed to reduce nonpoint source pollutant discharges through implementation of improved farming techniques. Following is a précis of some of the key farming practices [81]:

- Discharges: No direct waste discharge to surface water.
- Nutrient and Pesticide Application: Apply according to soil tests taken every 5 years.
- Soil Cultivation: Manage crop fields so that soil erosion loss does not exceed 2 tons per acre (according to Natural Resource Conservation Service standards). […]
- Buffer Zones: Maintain 10′ buffers of vegetation, 25′ at runoff points; No manure application in buffer zone; Fertilize and tilling only for maintenance; May be harvested. […].

Perspective: Farming and agricultural methods and practices were—and to a considerable extent are still—very much independent of government regulations and local ordinances. Indeed, many chose farming as a profession because of this kind of freedom. But as the human population increased in numbers and complexity, farming became more and more a business, a change that brought business practices and social policy-making. One example: farmers who chose to use pesticides on crops found that government intervened by controlling the choice of pesticides and their application.

10.7 HAZARD INTERVENTIONS

A number of hazard interventions are necessary if food safety and security are to be assured. As presented in this chapter, breakdowns in food safety can have serious consequences. As noted, annually in the U.S. one of every six Americans will experience a foodborne illness; 128,000 are hospitalized, and 3000 die. This public health toll occurs in a country with a strong food safety history and legislation. Globally, it is estimated that approximately 800 million people suffer from undernourishment. Some of the interventions that could reduce the hazard of unsafe food and food insecurity are as follows.

1. Food safety policies should be adopted and implemented at all levels of the food supply and consumption chain. In particular, food inspections and permits for food services are efficacious policies for prevention of foodborne illnesses. The FDA FSMAct of 2011 is an example of a comprehensive food safety statute, with prevention of illness as the operative policy.
2. Because a significant proportion of foodborne illness is due to inadequate preparation of food in home residences, education about food preparation is advocated. This should be a component of school curriculums.
3. Threats to global food security should be understood and appropriate policy actions taken. In particular, use of existing technology for enhancing food security should be encouraged as a matter of global food policy. For example, adoption of the new generation of temperature and humidity controlled warehouses and silos in the least developed countries will enhance food security [81a].
4. The two primary threats to global food security are continued increases in global human population and the impacts of climate change. Resources such as the UN World Food Programme will require both financial and policy support in order to overcome food shortages in geographic areas of famine and undernourishment. And international efforts to mitigate climate change will be necessary if global food insecurity is to be prevented.

5. Because water security and food security are intimately interrelated, policies to protect and conserve water supplies are necessary for food security.
6. Programs and policies to reduce food waste are encouraged in order to mitigate a source of GHGs and to diminish the impact on land and water based food sources.
7. Programs and policies for purpose of conserving land and ocean quality from the impacts of unwise waste disposal methods are encouraged.
8. Individuals, who have the choice, should gravitate to eco-friendly food consumption. In particular, food consumption that contributes to climate change reduction is considered eco-friendly. Eating less food made of animal products and preferring organic food are both eco-friendly [82].
9. Individuals have a responsibility for ensuring that their food supply is healthful and is adequately prepared for consumption.

10.8 SUMMARY

Described in this chapter are three major federal environmental health statutes that are intended to enhance food safety in the U.S. The FDCAct, which dates from 1906, as public health policy prohibits the distribution of adulterated and mislabeled foods, drugs, cosmetics, and medical devices. Similarly, as public health policy, the FMIAct, which also dates from 1906, requires that meat and meat products are subject to federal inspection before entering the human food supply. The third major U.S. food safety statute is the FDA Food Safety Modernization Act of 2011, which is oriented to prevention of foodborne illness and other potential hazards, rather than responding to them. All three federal statutes adopt a policy of federal government involvement in inspection of food quality prior to the release of food products into commerce and for human consumption. By this process, adulterated or impure food is interdicted before entering the food chain. This, of course, is an example of the core principle of public health, prevention of disease and disability.

In distinction to other environmental hazards, government involvement in food safety is rather limited and involves multiple partners in the public health effort to prevent foodborne illnesses. To be more specific, food safety requires the active participation of government, private sector entities, and individual food consumers to a degree not found in issues of air pollution, water contamination, toxics control, and waste management. Indeed, U.S. states have food quality responsibilities that exceed those of the federal government, as illustrated in this chapter by the state of Georgia's food quality statute. Moreover, private sector entities such as food producers, transporters, and food servers (e.g., restaurants) have quite significant roles and responsibilities for protecting against foodborne illness. However, in distinction to other environmental hazards, individuals play the critical role in protecting themselves against foodborne illness. For public health purposes, how individuals prepare food in the home is critical. After all, even the most wholesome food, if prepared under unsanitary conditions, has the portent to cause human illness.

Food security was described in this chapter as an issue complementary to food safety. Presented here were several factors, such as global population increase and climate change, as factors that will challenge global food security. And as discussed in this chapter, food safety and security are also the domain of concern by the EU, China, and India.

10.9 POLICY QUESTIONS

1. Let's consider the matter of food safety. Should food safety be a concern of local health departments through inspections of restaurants and other places of commercial food service? If so, why? If not, why not?
2. Assume you were recently hired by an urban municipal health department. Your first assignment is to design a public health program to improve food safety in public establishments. (a) Discuss the nature and impact of foodborne illness that would be of concern to your health department. (b) Using this material, design a public health program to prevent foodborne illness, choosing any four elements of the eight elements shown in Figure 1.1. Use critical thinking, as described in Chapter 1, to the extent possible.
3. Summarize the public health benefits of the FMIAct. Discuss the ethical implications, if any, of the Act.
4. The FDCAct, as amended, gives the FDA the authority to approve drugs to be placed into commerce. Assume that the act did not exist, leaving the manufacturer solely responsible for the safety of their products. Discuss the public health implications of this kind of market-driven arrangement.
5. Visit a local restaurant and look for a posted food inspection report. Describe the impact, if any, on your patronage of the selected restaurant. (a) What aspects of the food inspection report were of greatest importance to your decision? In your opinion, should food inspection reports be available to the public? If so, how? (b) Discuss the pros and cons of making restaurant inspection scores available to the public. (c) Some county health departments post restaurant scores on the internet. Using such a website, select a restaurant known to you and access its restaurant score and other background information. Critique the adequacy of the restaurant inspection information made available to you.
6. As discussed in this chapter, states have a major responsibility for protecting the public against foodborne illnesses. Discuss your state's responsibilities for food safety. Be specific in regard to which state agencies have specific responsibilities.
7. As discussed in the chapter, foodborne illnesses will annually affect about one in six Americans. A substantial but unknown amount of illnesses

occur because of poor food preparation practices in the home. Discuss some practical means of preventing foodborne illnesses caused by home food preparation.

8. Discuss the pros and cons of giving meat industry inspectors the authority to supplant government meat inspectors.
9. Consider the elements of your most recent meal. Discuss the origins of each major food item. In your discussion, include the geographic location from which each item originated.
10. Discuss three ways that you personally can help reduce the global food shortage. Be specific and elaborate on how your help would benefit those persons facing food insecurity.
11. One food security source has predicted that global food shortages will inevitably lead to vegetarianism as a lifestyle. Assume that this forecast is accurate. Could you accept a vegetarian reliance as your choice? Discuss the ramifications of your choice.
12. In 2016 the U.S. FDA promulgated regulations that curtailed the administration of antibiotics in food sources. In your opinion, was this necessary? Discuss the public health benefits of the FDA regulation. Also discuss the economic impact of the FDA decision.
13. Compare the food safety policies of China and India. List three elements in common. Discuss any element of significant difference, based on your knowledge of principles of public health.
14. Your grandparents still reside on a farm that has been your ancestors' home for five generations. The farm is located in Vermont, which recently enacted a new law that mandates specific farming methods and practices. These requirements will be an economic burden on your grandparents. In an essay of appropriate depth discuss whether a state should enact this kind of mandate.
15. A food expert has suggested that alternate forms of nonanimal protein will be required if global food insecurities are to be avoided. One suggestion is to incorporate insects into the human diet. Discuss how you would react to being served a beetle burger. Discuss any ethical issues that would be a component of your reaction.
16. Assume that you have volunteered to serve a charitable organization that raises funds and delivers food to people residing in areas of food insecurity. Prepare a one page circular that could be used in your fundraising efforts.
17. Assume that you attended a school that provided students with free breakfast and lunch meals funded by a government program. Using Internet resources, prepare a two page analysis of the purpose, function, benefits, and decrements of a school meals program.
18. Discuss the matter of global food security in the context of sustainable development. Present you findings in an essay of appropriate depth. Begin your essay by defining sustainable development and its tenets.
19. This chapter includes nine potential hazard interventions. Present two additional interventions that should be added to this list. Justify your two contributed interventions with evidence of critical thinking.
20. Congratulations! You have completed your diet of material in this chapter. Well done! Please discuss the three most important lessons you learned. Was your personal environmental health behavior changed by the content of this chapter? If so, how? If not, why not?

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11 Hazardous Chemical Substances

11.1 INTRODUCTION

This chapter describes the five major U.S. policies on control of hazardous chemical substances in the general environment. While other chapters have discussed chemical pollutants in air, water, food, and waste, this chapter deals with policies that are specific to hazardous substances found in general commerce. The five U.S. policies specific to control of toxic substances will be discussed, along with those of the EU and World Health Organization (WHO). Associations between hazardous substances and effects on human and ecosystem health are presented herein. It needs to be noted that the terms *hazardous* and *toxic* are distinct terms with somewhat different meanings, but are often used as synonyms by policymakers.

As background, humankind has known since antiquity that some substances possess harmful properties. For instance, ancient peoples gradually learned which noxious plants to avoid eating; in effect, practicing the core principle of public health, prevention of disease and disability. Similarly, humankind learned to avoid venomous creatures whose bites could cause harmful health effects. The common factor between noxious plants and venomous creatures would over time become revealed to be chemical substances that possess toxic properties, one of which, asbestos, is illustrated in Figure 11.1. In time, the study of chemical substances' harmful properties would be called *toxicology*.

The Industrial Revolution led to the manufacture of machines and products that involved the use of metals. In the process, metals had to be mined, smelted, forged, and fabricated into machinery for uses in agriculture, industrialization, transportation, and consumer commerce. In the nineteenth century, through the mid-twentieth century, industrial processes often exposed workers to metal fumes and other harmful substances, and if exposure levels were sufficiently great, adverse health consequences occurred. While acute exposures to high levels of toxic substances certainly occurred, there was also a gradual shift to exposure to substances that manifested their toxicity over long periods of time. For example, lead poisoning and metal fume fever were occupational health outcomes for many workers. As workplace conditions gradually improved in the industrialized countries, workers' exposure to metals lessened, but did not disappear. The toxicity of metals had not changed, but exposure levels had decreased, lessening the adverse health effects in workers.

In the mid-twentieth century, the manufacture of synthetic chemicals became a significant economic force and commercial reality, in part, due to the resource demands of World War II. The chemical industry had arrived, generating products such as therapeutic drugs, pesticides, herbicides, plastics, synthetic rubber, and consumer goods. In a sense, the Chemical Age had arrived. The production and use of these products brought exposure to new, synthesized substances for which toxicology information was lacking. Moreover, the exposures were experienced by persons in the general environment, not solely confined to workplace environments. Exposure occurred at lower levels through contamination of environmental media such as outdoor ambient air and community drinking water supplies. The toxicological implications had changed from those of dealing with the consequence of short-term, high to medium levels of chemical substances, to the condition of long-term exposure to low concentrations of substances found in essential environmental media, i.e., air, water, and food.

One source observes that approximately 10 million chemical compounds have been synthesized in laboratories since the beginning of the twentieth century, but only about 1% is produced commercially and can possibly come into contact with living organisms [1]. Although many substances found in commerce lack adequate toxicity data, there already exist ample data to characterize a large number of substances as being deleterious to human health. The major endpoints known to be affected by toxic substances are shown in Table 11.1, illustrated by specific substances. Standard references in toxicology contain more comprehensive listings of substances hazardous to human health (e.g., the National Institute for Occupational Safety and Health [NIOSH]'s *Registry of Toxic Effects of Chemical Substances* [2], which contains detailed toxicological and industrial hygiene information on a large number of chemicals), and the *Toxicological Profiles* issued by the Agency for Toxic Substances and Disease Registry [3].

11.2 U.S. POLICIES ON HAZARDOUS CHEMICAL SUBSTANCES

In recognition of the need to control environmental releases of hazardous substances and to inform potential at-risk populations, Congress has enacted five major statutes: the Federal Hazardous Substances Act (FHSAct), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRAct), the Toxic Substances Control Act (TSCAct), the Food Quality Protection Act (FQPAct), and the Lautenberg Chemical Safety Act. The last-named act is a major revision of the TSCAct and is therefore considered a separate act for the purposes of this chapter. Each of these statutes is discussed in the following sections.

11.2.1 Federal Insecticide, Fungicide and Rodenticide Act, 1947

Chemicals designed to kill what humans deem as pests have been part of humankind's experience. For example, both arsenic and hydrogen cyanide were used for pest control, but were

FIGURE 11.1 Workplace notification of a hazardous chemical. (From OSHA (U.S. Occupational Safety and Health Administration), Chemical hazards and toxic substances, Directorate of Standards and Guidance, Washington, DC, 2016.)

eventually abandoned as pesticides due to their high toxicity and hazard to humans. The period of post-World War II saw the development and expanded use of synthetic pesticides, such as dichloro diphenyl trichloroethane (DDT) [4]. Because pesticides are specifically designed to kill living creatures, concern gradually evolved about potential adverse effects on human and ecosystem health. This section will give a history of pesticide policymaking in the U.S. and elsewhere.

11.2.1.1 History

Although federal pesticide legislation was first enacted in 1910, its aim was to reduce economic exploitation of farmers by manufacturers and distributors of adulterated or ineffective pesticides. Congress did not address the potential risks to human health posed by pesticide products until it enacted the 1947 version of the FIFRAct. The U.S. Department of Agriculture (USDA) became responsible for administering the pesticide statutes during this period. However, responsibility was shifted to the Environmental Protection Agency (EPA) when that agency was created in 1970. Broader congressional concerns about long- and short-term toxic effects of pesticide exposure on pesticide applicators, wildlife, nontarget insects and birds, and on food consumers subsequently led to a complete revision of the FIFRAct in 1972 (Table 11.2). The 1972 law, as amended, is the basis of current federal policy. Substantial changes were made to the FIFRAct in 1988 in order to accelerate the process of reregistering pesticides, and again in 1996. The 1996 amendments facilitated registration of pesticides for special (so-called minor) uses, reauthorization of collection of fees to support reregistration, and a requirement to coordinate regulations between the FIFRAct and the FDCAct.

> The FIFRAct governs pesticide products and their use in the U.S. [5].

As detailed by Schierow [5], the FIFRAct, as amended, requires EPA to regulate the sale and use of pesticides in the U.S. through registration and labeling of the estimated 21,000 pesticide products currently in use [5]. The act directs the EPA to restrict the use of pesticides as necessary in order to prevent unreasonable adverse effects on humans and the environment, taking into account the costs and benefits of various pesticide uses. The FIFRAct prohibits sale of any pesticide in the U.S. unless it is registered and labeled indicating approved uses and restrictions. It is a violation of the law to use a pesticide in a manner that is inconsistent with the label instructions. The EPA registers each pesticide for each approved use, e.g.,

TABLE 11.1
Toxicity Endpoints and Alphabetized Associated Toxic Substances

Endpoint	Example Substances
Cancer	Arsenic, asbestos, beryllium, cadmium, chromium, PAHs
Cardiovascular diseases	Carbon monoxide, lead, ozone
Developmental disorders	Cadmium, endocrine disruptors, lead, mercury
Endocrine disruption	BPA, atrazine, phthalates, perchlorate
Immune dysfunction	Formaldehyde
Liver disease	Ethyl alcohol, carbon tetrachloride
Nervous system disorders	Lead, manganese, methyl mercury, organophosphates (OPs), PCBs, formaldehyde
Reproductive disorders	Cadmium, endocrine disruptors, DDT, PCBs, phthalates
Respiratory diseases	Nitrogen dioxide, particulate matter, sulfur dioxide
Skin diseases	Dioxins, nickel, pentachlorophenol

Source: ATSDR (Agency for Toxic Substances and Disease Registry), *ATSDR ToxProfiles*, U.S. Department of Health and Human Services, Public Health Service, Division of Toxicology, Atlanta, GA, 2004.

TABLE 11.2
FIFRAct Amendments

Year	Act
1947	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
1964	Amendments
1972	Federal Environmental Pesticide Control Act
1975	FIFRA Extension
1978	Federal Pesticide Act
1980	Amendments
1988	Amendments
1990	Food, Agriculture, Conservation, and Trade Act
1991	Food, Agriculture, Conservation, and Trade Act Amendments
1996	Food Quality Protection Act

Source: Schierow, L., Federal Insecticide, Fungicide, and Rodenticide Act, Summaries of environmental laws administered by the EPA, Congressional Research Service, 1999, http://www.NLE/CRSreports/BriefingBooks/Laws/l.cfm.

to control boll weevils on cotton. In addition, the FIFRAct requires the EPA to reregister older pesticides based on new data that meet current regulatory and scientific standards. Establishments that manufacture or sell pesticide products must be registered by the EPA. Facility managers are required to keep certain records and to allow inspections by the EPA or state regulatory representatives.

The FIFRAct Definition of "Pesticide": *Pesticides* are broadly defined in the FIFRAct §2(u) as chemicals and other products used to kill, repel, or control pests. Familiar examples include pesticides used to kill insects and weeds that can reduce the yield and harm the quality of agricultural commodities, ornamental plantings, forests, wooden structures, and pastures. But the broad definition of *pesticide* contained in the FIFRAct also applies to products with less familiar "pesticidal uses." For example, substances used to control mold, mildew, algae, and other nuisance growths on equipment, in surface water, or on stored grains are considered to be pesticides for the purposes of the FIFRAct. The term also applies to disinfectants and sterilants, insect repellents and fumigants, rat poison, mothballs, and many other substances.

Registration of Pesticide Products: When pesticide manufacturers apply to the EPA to register a pesticide's active ingredient, pesticide product, or a new use of a registered pesticide under the FIFRAct §3, the EPA requires them to submit scientific data on pesticide toxicity and behavior in the environment. The EPA may require data from any combination of more than 100 different tests, depending on the toxicity and degree of exposure. To register a pesticide's use on food, the EPA also requires applicants to identify analytical methods that can be used to test food for pesticide residues and to determine the amount of pesticide residue that could remain on crops, as well as on (or in) food products, assuming that the pesticide is applied according to the manufacturer's recommended rates and methods [5].

Based on the data submitted, the EPA must determine whether and under what conditions the proposed pesticide's use presents an unreasonable risk to human health or the environment. If the pesticide is proposed for use on a food crop, the EPA also determines whether a *safe* level of pesticide residue, called a *tolerance*, can be established under the FDCAct. A tolerance must be established before a pesticide registration may be granted for use on food. If any registration is granted, the EPA specifies the approved uses and conditions of use, including safe methods of pesticide storage and disposal, which the registrant must explain on the product label. The FIFRAct requires that federal regulations for pesticide labels preempt state, local, and tribal regulations. Use of a pesticide product in a manner inconsistent with its label is prohibited [5].

The EPA may classify and register a pesticide product for general or restricted use. Products known as *restricted-use pesticides* are those judged to be more dangerous to the applicator or to the environment. Such pesticides can be applied only by people who have been trained and certified. Individual states, U.S. territories, and Indian tribes are generally responsible for training and certifying pesticide applicators [5].

The FIFRAct §3 also allows conditional, temporary registrations if (1) the proposed pesticide ingredients and uses are substantially similar to currently registered products and will not create additional significant environmental risks, (2) an amendment is proposed for additional uses of a registered pesticide and sufficient data are submitted indicating that there is no significant additional risk, or (3) data requirements for a new active ingredient require more time to generate than normally allowed, and use of the pesticide during the period will not cause any unreasonable adverse effect on the environment and will be in the public interest.

Public Disclosure, Exclusive Use, and Trade Secrets: The FIFRAct §3 directs the EPA to make the data submitted by the applicant publicly available within 30 days after a registration is granted. However, applicants may claim certain data are protected as trade secrets under §10. If the EPA agrees that the data are protected, the agency must withhold the data from the public, unless the data pertain to the health effects or environmental fate or effects of the pesticide's ingredients. Information may be protected if it qualifies as a trade secret and reveals (1) manufacturing processes; (2) details of methods for testing, detecting, or measuring amounts of inert ingredients; or (3) the identity or percentage quantity of inert ingredients [5].

Companies sometimes seek to register a product based upon the registration of similar products, relying upon the data provided by the original registrant that is publicly released. This is allowed. However, §3 of the FIFRAct provides for a 10-year period of *exclusive use* by the registrant of data submitted in support of an original registration or a new use. In addition, an applicant who submits any new data in support of a registration is entitled to compensation for the cost of data development by any subsequent applicant who supports an application with that data within 15 years of its submission. If compensation is not jointly agreed upon by the registrant and applicant, binding arbitration can be invoked [5].

Reregistration of Pesticides: Most pesticides currently registered in the U.S. are older pesticides and were not subject to modern safety reviews. Amendments to the FIFRAct in 1972 directed the EPA to reregister approximately 35,000 older products, thereby assessing their safety in light of current knowledge. The task of reregistering older pesticides has been streamlined by reviewing groupings of products having the same active ingredients, on a generic instead of an individual product basis. Many of the 35,000 products will not be reviewed and their registrations will be canceled because registrants do not wish to support reregistration. Nevertheless, the task for registrants and the EPA remains immense and costly. In 1988, in order to accelerate the process of reregistration, Congress imposed a 10-year reregistration schedule. To help pay for the additional costs of the accelerated process, Congress directed the EPA to require registrants to pay reregistration and annual registration maintenance fees on pesticide ingredients and products. The 1996 amendments to the FIFRAct extended the EPA's authority to collect maintenance

fees through FY 2001. Exemptions from fees or reductions are allowed for minor-use pesticides, public health pesticides, and small business registrants [5].

11.2.1.2 Key Provisions of the FIFRAct Relevant to Public Health

In its current construction, the FIFRAct has the following major functions [5]:

1. *Pesticide Registration*—All new pesticide products used in the U.S. must first be registered with the EPA. To register a new pesticide requires the submission to the EPA of the product's complete chemical formula, a proposed label, and a full description of the tests made of the product and the results upon which the claims are based. Manufacturers can ask for trade secret protection to protect information claimed to be vital to commercial propriety.
2. *Control over Pesticide Usage*—The EPA has authority to restrict use of pesticides. The FIFRAct permits the classification of pesticides into general and restricted categories, with the latter category available only to certified applicators. Certification standards are developed by the EPA to regulate how certified applicators apply restricted pesticides.
3. *Removal of Pesticides from the Market*—The FIFRAct mandates the EPA to take action against those pesticide products considered a risk to public health and the environment. The EPA's actions can include a cancellation order (which is used to initiate review of the substance, during which the product can continue to be manufactured and placed in commerce), or a suspension order (which is an immediate ban on the production and distribution of a pesticide product). There also are different administrative procedures attending a cancellation order or a suspension order that would determine how quickly the EPA's action would take effect.
4. *Imports and Exports*—The FIFRAct §17 directs that imports of pesticide products will be subject to the same requirements of testing and registration as domestic products. However, the FIFRAct excludes U.S. exports from coverage under the Act, other than for certain record keeping provisions.

All new pesticide products used in the U.S. must first be registered with EPA. To register a new pesticide requires the submission to EPA of the product's complete chemical formula, a proposed label, and a full description of the tests made of the product and the results.

The FIFRAct has several implications for hazardous waste generation and management, primarily through linkage to other federal statutes. The Resource Conservation and Recovery Act (RCRAct) of 1976 gives the EPA the authority to regulate the disposal of generated hazardous wastes, including the disposal of pesticides from manufacturers. The federal Waste Pollution Control Act of 1972, under §301, requires all industrial enterprises, including pesticide manufacturers and formulators, to apply to the EPA for discharge permits if they release effluent into any body of water. The same statute, §307 permits pesticides to be controlled as toxic substances, thereby leading to the development of special discharge standards. The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLAct), as amended, directs Agency for Toxic Substances and Disease Registry (ATSDR), in consultation with the EPA and the NTP, to initiate a program of research to fill gaps in scientific knowledge for prioritized CERCLAct hazardous substances. The program of research is, by statute, to be coordinated with the EPA's authorities under the FIFRAct and the TSCAct, in both instances possibly leading to the EPA rulemaking requiring manufacturers of a particular hazardous substance to fill the research gaps identified by ATSDR.

The FIFRAct was amended somewhat by the FQPAct of 1996, which is discussed in a subsequent section of this chapter.

11.2.1.3 Associations between Pesticides and Human Health

Pesticides are chemical substances evolved by nature or synthetically produced to be biologically active. As such, pesticides are intentionally harmful to living organisms, often with biological specificity. Given the mortal purpose of pesticides, their public health implications might seem obvious. However, the implications are a complicated proposition. For example, it can be argued that pesticides have benefited the public's health by reducing mosquito infestation, thereby reducing the number of persons at risk of contracting malaria or West Nile disease. However, some pesticides used to control mosquitoes are environmentally persistent and can cause serious harm to ecological systems. An example is the use of DDT in the tropics for malaria control, even though it causes ecological degradation. DDT and other chemicals are called *Persistent Organic Pollutants* and their use and management is the subject of an international treaty, which is discussed in Chapter 5.

The FIFRAct provides some human and ecological health protection by requiring the EPA to register pesticides, control their uses, and remove those found harmful from the U.S. market. In this regard, the FIFRAct serves as a gatekeeper over which pesticides get into the general environment. But this gatekeeping does not provide complete prohibition of pesticides and similar chemicals from migrating into the U.S. environment. This is because many pesticides are approved for use in the U.S. because of their desirable properties of pest eradication, which can increase crop yields and improve food quality. Are the pesticides in the environment potentially harmful to human and ecological health? And if harmful, does this necessitate further effort to reduce pesticide levels and public health action?

The presence of pesticides, herbicides, and rodenticides in the U.S. environment raises questions about the potential impact on human and ecological health. The U.S. Geological Survey (USGS) [6] observes that about one billion pounds of conventional pesticides are used each year in the U.S. In 2006 the USGS reported the findings from a 10-year program of surveillance of pesticide levels in U.S. rivers, fish, and private

wells. The report is based on data from 51 major river systems from Florida to the Pacific Northwest, Hawaii, and Alaska, and a regional study conducted in the High Plains aquifer system. The USGS study, which covers the years 1992–2001, found that pesticides seldom occurred alone but almost always as complex mixtures. Most stream samples and about half the well samples contained two or more pesticides, and frequently more [6].

Findings showed pesticides were present throughout the year in most streams in urban and agricultural areas of the U.S. When the USGS measurements were compared with EPA drinking water standards and guidelines, the pesticides were seldom found at concentrations likely to affect humans. Concentrations of individual pesticides were almost always lower than the standards and guidelines, representing fewer than 10% of the sampled stream sites and about 1% of domestic and public supply wells. Concerning fish tissues, organochlorine pesticides and their degradants were found in greater than 90% of fish in streams that drained agricultural, urban, and mixed land-use settings. Pesticides were less common in groundwater. More than 80% of urban streams and more than 50% of agricultural streams had concentrations in water of at least one pesticide that exceeded a water quality benchmark for aquatic life, which suggests the need for further control of pesticide releases into the environment.

Regarding the general toxicity of pesticides, the Northwest Coalition for Alternatives Pesticides examined the scientific literature for evidence of pesticides' carcinogenicity and reproductive toxicity [7]. The investigators used EPA data on carcinogenicity of chemicals. They found that of the 250 pesticides evaluated by the EPA, 12 of the 26 with the greatest annual use in the U.S. had been classified as carcinogens in one of the EPA's carcinogenesis categories.* Chronic exposure at lower levels has been associated with adverse neurological and behavioral conditions in young children [8]. Other research on the chronic exposure of adults to pesticides has produced features of Parkinson's disease; ongoing research uses animal models to conduct basic science on the etiology of the disease [9,9a].

The FIFRAct provides the main federal framework for managing the hazard of pesticides. For EPA-approved pesticides, more than one billion pounds are used annually in various agricultural and other commercial applications in the U.S.

A study conducted by Columbia University investigators in 2004 found that insecticide exposures were widespread among minority women in New York City during pregnancy [10]. The study consisted of 314 mother-newborn pairs and insecticide measurements in maternal ambient air during pregnancy as well as in umbilical cord plasma at delivery. For each log unit increase in cord plasma chlorpyrifos levels, birth weight decreased by 42.6 g and birth length decreased by 0.24 cm. Combined measures of cord plasma chlorpyrifos and diazinon (adjusted for relative potency) were also inversely associated with birth weight and length. Birth weight averaged 186.3 g less among newborns possessing the highest compared with lowest 26% of exposure levels. Further, the associations between birth weight and length and cord plasma chlorpyrifos and diazinon were highly statistically significant among newborns born before the years 2000–2001 when the EPA phased out residential use of these insecticides. Among newborns born after January 2001, exposure levels were substantially lower, and no association with fetal growth was apparent. This investigation affirms the toxicological adage, "The dose makes the poison."

In another study with dose-dependent results, investigators from the National Cancer Institute (NCI) (Chapter 3) examined cancer rates in a large cohort of pesticide applicators [11]. The study involved a total of 54,383 pesticide applicators in Iowa and North Carolina. Exposure to the widely used pesticide chlorpyrifos was found to be associated with increased rate of lung cancer. The incidence of lung cancer was statistically significantly associated with chlorpyrifos lifetime exposure-days, suggesting a dose-dependent effect. This study and the one from Columbia University imply that environmental health policies about pesticide use and application should be further strengthened to mitigate or decrease exposure to pesticides.

In summary, the implications of pesticides and similar chemicals in community environments are of continuing concern to environmental and public health authorities, given the purpose of the chemicals. The FIFRAct provides the main federal framework for managing the hazard of pesticides. For EPA-approved pesticides, more than one billion pounds are annually used in various agricultural and other commercial applications in the U.S. Given the commercial value of pesticides, there will be continued releases of them into environmental media. This reality emphasizes the importance of policies that are committed to monitoring of pesticide levels in water, food, and human tissues, and for conducting research on potential human and ecological impacts.

11.2.1.4 Associations between Pesticides and Ecosystem Health

How do pesticides affect ecosystems? As presented by one source, pesticides can travel great distances through the environment [12]. When sprayed on crops or in gardens, pesticides can be blown by the wind to other areas. They can also flow with rain water into nearby streams or can seep through the soil into groundwater. Some pesticides can remain in the environment for many years and pass from one organism to another. In general, insecticides generally are the most toxic pesticides to the environment, followed by fungicides and herbicides.

* *Atrazine*, *metolachlor*, 2, 4-dichlorophenoxyacetic acid, *metam sodium*, methyl bromide, glyphosate, *dichloropropene*, chlorpyrifos, *cyanazine*, *pendimethalin*, *trifluralin*, *acetochlor*, alachlor, dicamba, S-Ethyl dipropylthiocarbamate, *chlorothalonil*, copper hydroxide, propanil, terbfos, *mancozeb*, *fluometuron*, monosodium methanearsonate, bentazone, diazinon, *parathion*, sodium chlorate. The 12 pesticides italicized have been classified by EPA as carcinogenic in one of EPA's carcinogenesis categories (Chapter 11).

The most hazardous pesticides include those that can be distinguished on the basis of water solubility or fat solubility. Water soluble pesticides are easily transported from the target area into groundwater and streams since the pesticides become dissolved in the water. Fat soluble pesticides are readily absorbed in the tissues of insects, fish, and other animals, often resulting in extended persistence in food chains.

Organochlorine pesticides such as DDT are fat-soluble pesticides. When there is a small amount of pesticide in the environment, it will enter the bodies of the animals that are low in the food chain (e.g., grasshoppers). Even though there is only a small amount of the toxicant in each grasshopper, shrews or other predators will receive a larger amount of the toxicant in its body because the predator will eat many grasshoppers. When the secondary consumer is eaten (e.g., shrews), a higher level predator (e.g., an owl) will consume all of its toxicants, plus those of all the other prey it eats. This means that the higher the trophic level, the greater the concentration of toxicants. This process is bioamplification.

Therefore, the top carnivore that has the higher trophic level (e.g., owl) will be the most badly affected as it will have obtained the most concentrated amount of toxicants. This will lead to a decline of the population of the top predator (e.g., owl), causing an increase of the population of shrews as there are not as many of their predators, and leading to a decrease in the population of grasshoppers [12]. This biomagnification process is a major challenge to the proper application of pesticides for crop and gardening use.

The effects of pesticides on specific members of an ecosystem become consequential to public and ecosystem health when the effects are broad in impact. An important example is the effects of pesticides on pollinators. A 2-year study conducted by the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services was the first investigation of the global status of pollinators [13]. The study reported a growing number of pollinator species worldwide are being driven toward extinction by diverse pressures, many of them anthropogenic, threatening millions of livelihoods and hundreds of billions of dollars of food supplies. Pollinated crops include those that provide fruit, vegetables, seeds, nuts, and oils. Many of these are important dietary sources of vitamins and minerals, without which the risks of malnutrition might be expected to increase. Between US$235 billion and US$577 billion worth of annual global food production relies on direct contributions by pollinators.

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In addition to food crops, pollinators contribute to crops that provide biofuels (e.g., canola and palm oils), fibers (e.g., cotton), medicines, forage for livestock, and construction materials. Moreover, nearly 90% of all wild flowering plants depend at least to some extent on animal pollination.

The assessment found that an estimated 16% of vertebrate pollinators are threatened with global extinction—increasing to 30% for island species—with a trend toward more extinction. Although most insect pollinators have not been assessed at a global level, regional and national assessments indicate high levels of threat, particularly for bees and butterflies—with often more than 40% of invertebrate species threatened locally. Declines in regional wild pollinators have been confirmed for North Western Europe and in North America. The assessment found that pesticides, including neonicotinoid insecticides, threaten pollinators worldwide, although the long-term effects are still unknown [13].

Several studies of the effects of neonicotinoid pesticides on the mortality of bees have been reported. Neonicotinoids are compounds that are structurally similar to nicotine, the addictive ingredient in tobacco (Chapter 7). In a large-scale field study, researchers combined large-scale pesticide usage and yield observations from oilseed rape with those detailing honey bee colony losses over an 11-year period. The findings revealed a correlation between honey bee colony losses and national-scale imidacloprid (a neonicotinoid) usage patterns across England and Wales [14]. In a separate study, researchers from Bern, Switzerland, together with partners from Thailand and Germany, found that male honey bees were affected by two neonicotinoid insecticides. The insecticides were associated with reducing male honey bees' life span and number of living sperm [15].

In another study, a research team from Bern, Switzerland, and Wolfville, Canada, found that honey bee queens, which are crucial to colony functioning, are severely affected by two neonicotinoid insecticides [16]. These and other investigations led the EU in 2013 to ban most neonicotinoids for use on flowering crops and spring sown crops, but approved sulfoxaflor, a neonicotinoid, in July 2015 on the basis that it would not have any unacceptable effects on the environment. In stark contrast, the EPA, which had attempted to approve sulfoxaflor for use in the U.S., was blocked by a federal appeals court. The court overturned the EPA's approval for sulfoxaflor, finding that the EPA had relied on "flawed and limited" data, and its approval was unjustified given the "precariousness of bee populations" [17].

Turning from insects to plants, the overuse of an herbicide, glyphosate, has produced weeds that are resistant to the herbicide. Glyphosate comprised 57% of all the herbicides used in the U.S. on corn and soybeans in 2013, according to the USDA. The agency has now identified 14 species of glyphosate-resistant weeds in the U.S., and 32 have been documented worldwide, according to a government-industry-university coalition that tracks the issue globally [18]. Of note, glyphosate, the active ingredient in the herbicide Roundup has become the most heavily used agricultural chemical in the history of the world. A study estimated that globally, about 9.4 million tons of the chemical have been sprayed onto fields. Environmental and health authorities are investigating the efficacy of using this herbicide, given that in March 2015 the International Agency for Research on Cancer (IARC) unanimously determined that glyphosate is "probably carcinogenic to humans" [19]. These concerns have fueled ongoing research on the putative toxicity of glyphosate. For example, in one

study, long-term exposure to low concentrations of glyphosate produced problems in the liver and kidneys. Investigators examined the function of genes in these organs and related changes to liver and kidney damage [20]. The chemical industry disputed IARC's classification and in 2016 undertook actions to reverse the classification, but without success.

11.2.2 Federal Hazardous Substances Act, 1960

One of the early federal statutes on hazardous substances is the FHSAct of 1960 (Public Law 86-613; 74 Stat. 372, as amended). This act requires precautionary labeling on the container of hazardous household products to help consumers safely store and use those products and to give them information about immediate first aid steps to take if an accident happens. The act also allows the Consumer Product Safety Commission (CPSC) to ban certain products that are so dangerous or that the nature of the hazard is such that the labeling the act requires is not adequate to protect consumers [21].

The FHSAct only covers products that, during reasonably foreseeable purchase, storage, or use, may be brought into or around a place where people live. Products used or stored in a garage, shed, carport, or other building that is part of the household are also covered. The act requires hazardous household products ("hazardous substances") to bear labeling that alerts consumers to the potential hazards that those products present and that tells them what they need to do to protect themselves and their children from those hazards.

Whether a product must be labeled depends on its contents and the likelihood that consumers will be exposed to any hazards it presents. To require labeling, a product must first be toxic, corrosive, flammable or combustible, an irritant, or a strong sensitizer, or it must generate pressure through decomposition, heat, or other means. Further, the product must have the potential to cause substantial personal injury or substantial illness during or as a result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

Each of the hazards above has a specific definition in the FHSAct. Where it is appropriate, regulations issued under the act specify the tests to perform to evaluate a product for a specific hazard. The definitions are as follows [21]:

1. Aproduct is toxic if it can produce personal injury or illness to humans when it is inhaled, swallowed, or absorbed through the skin and contain certain tests on animals to determine whether a product can cause immediate injury. In addition, a product is toxic if it can cause long term chronic effects like cancer, birth defects, or neurotoxicity.
2. A product is corrosive if it destroys living tissue such as skin or eyes by chemical action.
3. Aproduct is an irritant if it is not corrosive and causes a substantial injury to the area of the body that it comes in contact with. Irritation can occur after immediate, prolonged, or repeated contact.
4. A strong sensitizer is a product that the Commission declares by regulation has a significant potential to cause hypersensitivity. […]
5. The flammability of a product depends on the results of testing. […]
6. Products that generate pressure, through decomposition, heat, or other means include aerosols, fireworks that contain explosive powder, and certain pool chemicals that, when their containers are heated by sunlight, for example, start to react and generate pressure in the containers.

The label on the immediate package of a hazardous product, and any outer wrapping or container that might cover up the label on the package must have the following information in English [21]:

1. The name and business address of the manufacturer, packer, distributor, or seller;
2. The common or usual or chemical name of each hazardous ingredient;
3. The signal word "Danger" for products that are corrosive, extremely flammable, or highly toxic;
4. The signal word "Caution" or "Warning" for all other hazardous products;
5. An affirmative statement of the principal hazard or hazards that the product presents, […];
6. Precautionary statements telling users what they must do or what actions they must avoid to protect themselves;
7. Where it is appropriate, instructions for first aid treatment to perform in the event that the product injures someone;
8. The word "Poison" for a product that is highly toxic, in addition to the signal word "Danger";
9. If a product requires special care in handling or storage, instructions for consumers to follow to protect themselves; and
10. The statement "Keep out of the reach of children." […]

There are no formal guidelines for evaluating the exposure to a product and the risk of injury. However, among the things to consider are the following: (1) How the contents and form of the product might cause an injury; (2) the product's intended handling, use, and storage; and (3) any accidents that might foreseeably happen during handling, use, or storage that could hurt the purchaser, user, or others, including young children who might get into the package of the product. Details about the FHSAct are available from the CPSC.

11.2.3 Toxic Substances Control Act, 1976

Health and ecological concerns about hazardous substances in the general environment gradually expanded past just the matter of pesticides, in part due to concerns expressed by various environmental organizations. Congress responded with the TSCAct, an action with initial public health promise, but subsequently found to be ineffective.

11.2.3.1 History

Federal legislation to control toxic substances was originally proposed in 1971 by the President's Council on Environmental

The TSCAct authorized EPA to screen existing and new chemicals used in manufacturing and commerce to identify potentially dangerous products or uses that should be subject to federal control [22].

Quality during the Nixon administration. Its report, *Toxic Substances*, defined a need for comprehensive legislation to identify and control chemicals whose manufacture, processing, distribution, use, and/or disposal was potentially dangerous and not adequately regulated under other environmental statutes. The enactment of the TSCAct of 1976 was influenced by episodes of environmental contamination such as the contamination of the Hudson River and other waterways by polychlorinated biphenyl (PCBs), the threat of stratospheric ozone depletion from chlorofluorocarbon (CFC) emissions, and contamination of agricultural produce by polybrominated biphenyls in the state of Michigan. The episodes, together with more exact estimates of the costs of imposing toxic substances controls, opened the way for final passage of the legislation. President Ford signed the TSCAct into law on October 11, 1976 [22].

The TSCAct directs the EPA to execute the following key actions [22]:

- Require manufacturers and processors to conduct tests for existing chemicals,
- Prevent future risks through premarket screening and regulatory tracking of new chemical products,
- Control unreasonable risks already known or as they are discovered for existing chemicals,
- Gather and disseminate information about chemical production, use, and possible adverse effects to human health and the environment.

At the time of the TSCAct's enactment, the law allowed continued production of the 62,000 chemicals already in commercial use, which were called *existing chemicals*. Another 18,000 chemicals have been introduced into commerce since 1976, known as *new chemicals*. In sum, approximately 80,000 chemicals potentially fall under the regulatory provisions of the TSCAct. However, the chemical industry asserts that only about 15,000 chemicals are actively made, which would reduce their testing burden [23].

The TSCAct authorizes the EPA to screen existing and new chemicals used in manufacturing and commerce in order to identify potentially dangerous products or uses that should be subject to federal control. As enacted, the TSCAct also included a provision requiring the EPA to take specific measures to control the risks from PCBs. Subsequently, three titles have been added to address concerns about other specific toxic substances: asbestos in 1986, radon in 1988, and lead in 1992. The amendments to the TSCAct are listed in Table 11.3.

The EPA may require manufacturers and processors of chemicals to conduct and report the results of tests to determine the effects of potentially dangerous chemicals on living organisms. Based on test results and other information, the EPA may regulate the manufacture, importation, processing, distribution, use, and/or disposal of any chemical that presents an unreasonable risk of injury to human health or the environment. A variety of regulatory tools are available to the EPA under the TSCAct, ranging in severity from a total ban on production, import, and use to a requirement that a product must bear a warning label at the point of sale.

TABLE 11.3
Toxic Substances Control Act and Major Amendments

Year	Act
1976	Toxic Substances Control Act (TSCA)
1986	Asbestos Hazard Emergency Response Act
1988	Radon Program Demonstration Act
1989	Asbestos School Hazard Abatement Reauthorization Act
1990	Radon Measurement Act
1992	Residential Lead-Based Paint Hazard Reduction Act

Source: Schierow, L., Toxic Substances Control Act, Summaries of environmental laws administered by the EPA. National Library for the Environment, 1999, http://www.cnie.org/nl3/leg-8/k.html.

11.2.3.2 Key Provisions Relevant to Public Health

The TSCAact is a statute intended to protect the public's health from exposure to toxic substances. As described in the following sections (adapted from [22]), the TSCAct provides the EPA with sweeping authorities to regulate chemical substances.

Testing of Chemicals. TSCAct §4 directs the EPA to require the development of test data on existing chemicals when certain conditions prevail: (1) the manufacture, processing, distribution, use, or disposal of the chemical "may present an unreasonable risk," or (2) the chemical is produced in very large volume and there is a potential for a substantial quantity to be released into the environment or for substantial or significant human exposure. Under either condition, the EPA must issue a rule requiring tests if (1) existing data are insufficient to resolve the question of safety and (2) testing is necessary to develop the data.

ENFORCEMENT EXAMPLE

(Washington, DC—August 22, 2012): The EPA settled with INEOS Chlor Americas, Inc., Wilmington, DE, to resolve violations of the TSCAct. INEOS allegedly imported various chain-length chlorinated paraffins into the U.S. without providing the required notice to the EPA. Under this settlement INEOS ended the importation of short-chained chlorinated paraffins into the U.S. INEOS also agreed to provide to the EPA the notices required by the TSCAct's §5 for any medium or long-chain chlorinated paraffin it proposes to import in the future [26].

Premanufacture Notification. TSCAct §5 requires manufacturers, importers, and processors to notify the EPA at least 90 days prior to producing or otherwise introducing a new chemical product into the U.S. At the time of submission, any

information or test data that is known to, reasonably ascertainable by, or in possession of the notifier, and that might be useful to EPA in evaluating the chemical's potential adverse effects on human health or the environment, must be submitted to the EPA. The TSCAct also requires the EPA to be notified when there are plans to produce, process, or use an existing chemical in a way that significantly differs from previously permitted uses so that the EPA may determine whether the new use poses a greater risk of human or environmental exposure or effects than the former use.

Each year the EPA receives between 1500 and 3000 premanufacture notices (PMNs); most of these chemicals never go into commercial distribution [24]. The EPA has 45 days after notification (or up to 90 days if it extends the period for good cause) to evaluate the potential risk posed by the chemical. If the EPA determines that there is a reasonable basis to conclude that the substance presents or will present an unreasonable risk, the Administrator must promulgate requirements to adequately protect against such risk. Alternatively, the EPA may determine that the proposed activity related to a chemical does not present an unreasonable risk. This decision may be based on the available data, or when no data exist to document the effects of exposure, on what is known about the effects of chemicals in commerce with similar chemical structures and used in similar ways.

The TSCAct notification required of chemical manufacturers does not require them to report how their compounds are used or monitor where their products end up in the environment. Neither do companies have to conduct health and safety testing of their products either before or after they are entered into commerce. According to one source, 80% of all applications to produce a new chemical are approved by the EPA with no health and safety data submitted. Eighty percent are approved in three weeks [25]. As policy, the lack of health and safety data is inconsistent with prudent public health practice because it goes counter to the prevention core of public health practice.

Regulatory Controls. The alternative means available to the EPA for controlling chemical hazards that present unreasonable risks are specified in §6 of TSCA. The EPA has the authority to: prohibit or limit the amount of production or distribution of a substance in commerce; prohibit or limit the production or distribution of a substance for a particular use; limit the volume or concentration of the chemical produced; prohibit or regulate the manner or method of commercial use; require warning labels and/or instructions on containers or products; require notification of the risk of injury to distributors and, to the extent possible, consumers; require recordkeeping by producers; specify disposal methods; and require replacement or repurchase of products already distributed.

Information Gathering. TSCAct §8 requires the EPA to develop and maintain an inventory of all chemicals, or categories of chemicals, manufactured or processed in the U.S. The first version of this inventory identified approximately 55,000 chemicals in commerce in 1979. All chemicals not on the inventory are, by definition, new and subject to the notification provisions of §5. These chemicals must be added to the inventory if they enter commerce. Chemicals need not be listed if they are only produced in very small quantities for purposes of experimentation or research.

To aid the EPA in its duties under TSCA, it was granted considerable authority to collect information from manufacturers. The EPA may require maintenance of records and reporting of: chemical identities, names, and molecular structures; categories of use; amounts manufactured and processed for each category of use; descriptions of byproducts resulting from manufacture, processing, use, and disposal; environmental and health effects; number of individuals exposed; number of employees exposed and the duration of exposure; and manner or method of chemical disposal. In addition, manufacturers, processors, and distributors of chemicals must maintain records of significant adverse reactions to health or the environment alleged to have been caused by the substance or mixture. Industry also must submit lists and copies of health and safety studies. Studies showing adverse effects previously unknown must be submitted to the EPA as soon as they are completed or discovered.

Imminent Hazards. §7 provides the EPA with authority to take emergency action through the district courts to control a chemical substance or mixture that presents an imminent and unreasonable risk of serious widespread injury to health or the environment.

Relation to Other Laws. TSCAct §9 allows the EPA to refer cases of chemical risk to other federal agencies (e.g., OSHA, FDA) with the authority to prevent or reduce the risk. For statutes under EPA's jurisdiction, the TSCAct gives the Administrator discretion to decide if a risk can best be handled under the authority of TSCA.

Enforcement and Judicial Review. TSCAct §11 authorizes the EPA to inspect any facility subject to the TSCAct requirements and to issue subpoenas requiring attendance and testimony of witnesses, production of reports and documents, answers to questions and other necessary information. §16 authorizes civil penalties, not to exceed $25,000 per violation per day, and affords the defendant an opportunity to request a hearing before an order is issued and to petition for judicial review of an order after it is issued. Criminal penalties also are authorized for willful violations. §17 provides jurisdiction to U.S. district courts in civil actions to enforce the TSCAct §15 by restraining or compelling actions that violate or comply with it, respectively. Chemicals may be seized and condemned if their manufacture, processing, or distribution violated the Act. §20 authorizes civil suits by any person against any person in violation of the Act. It also authorizes suits against the EPA to compel performance of nondiscretionary actions under TSCA. §21 provides the public with the right to petition for the issuance, amendment. or repeal of a rule requiring toxicity testing of a chemical, regulation of the chemical, or reporting.

Confidential Business Information. TSCAct §14 provides broad protection of proprietary confidential information about chemicals in commerce. Disclosure by the EPA employees of such information generally is not permitted except to other federal employees or when necessary to protect health or the environment. Data from health and safety studies of chemicals are not protected unless their disclosure would reveal a chemical process or chemical proportion in a

mixture. Wrongful disclosure of confidential data by federal employees is prohibited and may result in criminal penalties.

Chemical Categories. TSCAct §26 allows the EPA to impose regulatory controls on categories of chemicals, rather than on a case-by-case basis. Examples of chemical categories regulated by the EPA under §26 include PCBs and CFCs.

Other Provisions. TSCAct §10 directs the EPA to conduct and coordinate among federal agencies research, development, and monitoring that is necessary to the purposes of the Act. §22 waives compliance when in the interest of national defense. §23 provides protection of employees who assist in carrying out the provisions of the act (i.e., whistle- blowers). §27 authorizes research and development of test methods for chemicals by the Public Health Service in cooperation with the EPA. §28 Grants to states authorization to establish and operate programs to prevent or eliminate unreasonable risks to health or the environment.

It is apparent that the TSCAct gives the EPA broad authority to (1) induce testing of existing chemicals, currently in widespread commercial production or use; (2) prevent future chemical risks through premarket screening and regulatory tracking of new chemicals; (3) control unreasonable risk of chemicals; and (4) gather and disseminate information about chemical production, use, and possible adverse effects to human health and the environment [22].

11.2.3.3 Amendments to the TSCAct

Starting in 1986, several important amendments to the TSCAct provide important public health authorizations to the EPA and other federal agencies in order to undertake programs on asbestos, radon, and lead. Two amendments are specific to reducing the hazard of asbestos in schools. The Asbestos Hazard Emergency Response Act of 1986 amends the TSCAct to direct the EPA Administrator to promulgate regulations for asbestos hazard abatement in schools and set standards for ambient interior concentrations of asbestos after completion of response actions in schools. Other key provisions include the following: inform and protect the public during the phases of asbestos abatement, authorize each state governor to establish administrative procedures for reviewing school asbestos management plans, direct the EPA Administrator to make grants to local educational agencies, and make local educational agencies liable for civil penalties. The Asbestos School Hazard Abatement Reauthorization Act of 1989 amended the 1986 act by deleting certain reporting requirements of states, directed state governors to maintain records on asbestos in schools, and made accreditation requirements of schools' asbestos removal workers applicable to persons working with asbestos in public or commercial buildings [22].

The TSCAct has been amended twice for the purpose of reducing the risk of radon gas in the ambient air of residential buildings. The Radon Program Demonstration Act of 1988 established the national goal of making the air within buildings as free of radon as the outside ambient air. The act contains several significant provisions. The EPA is directed to make available to the public information about radon's hazards, develop model construction standards for buildings, assist state radon programs, provide technical assistance to states, make grants to states on an annual basis for radon assessment and mitigation, and establish regional radon training centers in at least three institutions of higher learning. The Omnibus Budget Reconciliation Act of 1990 authorized the EPA to conduct research on radon and radon progeny measurement methods and mandated an EPA study on the feasibility of establishing a mandatory radon proficiency testing program [22].

Of particular importance to public health, given the toxicity of lead in the environment, Title X of the Housing and Community Development Act of 1992 amended several federal statutes, including TSCA, for the purpose of reducing the health hazard of lead in community and workplace environments. The act directs the Department of Housing and Urban Development to assess lead-based paint hazards in federally assisted housing, and requires housing agencies to take action on evaluating and reducing lead-based hazards. The act amends the TSCAct by requiring that contractors and laboratories be federally certified. The EPA is directed to conduct a comprehensive program to promote safe, effective, and affordable monitoring, detection, and abatement of lead-based paint and other lead exposure hazards. Also, the Secretary of Labor was directed to issue an interim final regulation for workers' exposure to lead in the construction industry.

11.2.3.4 Public Health Implications of the TSCAct

Unfortunately, the potential consequential benefits to the public's health of the TSCAct did not materialize. Of the major environmental health laws, the TSCAct stands out as the major disappointment in public health performance. While there have been some positive impacts, particularly due to the act's amendments, the larger promise of the TSCAct has not been realized. At its core, the TSCAct provides the EPA with the authority to assess and control chemicals in commerce (i.e., existing chemicals) and new chemicals proposed for manufacture. The intent is to protect the public from "unreasonable risk" to human health and the environment. Given these laudable purposes, why has not the TSCAct lived up to its potential as an environmental health force?

One reason why the TSCAct has failed is due of the large number of chemicals (80,000) that fall under regulatory coverage. In theory, the EPA could require producers of these chemicals to conduct toxicity testing under the TSCAct's authorities. However, under TSCA, the EPA must find that a chemical presents an "unreasonable risk" before the agency can mandate toxicity testing. Moreover, the EPA must determine that any risks are not outweighed by a chemical's economic and societal benefits for each way in which the substance might be used [22]. These risks and benefits determinations pose a significant challenge to the EPA, owing to deficiencies in toxicological data for many substances and uncertainties in substances' benefits.

One reason why the TSCAct failed is due of the large number of chemicals (80,000) that fall under regulatory coverage.

The shortcomings of the TSCAct have been described by former EPA Assistant Administrator Lynn Goldman [24]. She

observed, "TSCA has not proven to be a successful tool for managing existing chemicals; indeed, it has created a situation in which new chemicals, which may be more benign, are subject to substantially more risk management activities and reviews than older and possibly more risky ones (which are not managed at all). Likewise, the TSCA procedure of referring chemicals to other EPA programs or agencies for risk management has not been effective." Concerning existing chemicals, only five* have been regulated under the TSCAct. In perspective, more than 60,000 chemicals comprise the EPA inventory of existing chemicals. A major reason for the EPA's failure to regulate more existing chemicals is the TSCAct's unreasonable risk provision, which sets a hurdle too high for the routine regulation of chemicals [24].

New chemicals are also regulated under the TSCAct's provisions. Imposition of these provisions is meant to serve as primary prevention measures to keep hazardous substances out of commerce. As Goldman observes, "EPA's process of premanufacture approval is the *only* safeguard used by the federal government to guard against such risks." "Since 1992, very little progress has been made by EPA in addressing the impacts of new chemicals" [24].

In 2004, the Government Accountability Office (GAO)† released a comprehensive study of the EPA's TSCAct authorities and programs [27]. The shortcomings of the TSCAct as an effective public health instrument were the salient findings. The GAO stated that they reviewed (1) EPA's TSCAct's efforts "[t]o control the risks of new chemicals not yet in commerce, (2) assess the risks of existing chemicals used in commerce, and (3) publicly disclose information provided by chemical companies under TSCA."

The GAO's primary findings, in order of the study's three purposes were as follows. Regarding new chemicals, since 1979 when the EPA began reviewing chemicals for potential placement on the TSCAct's inventory, the GAO found that, on average, about 700 new chemicals are introduced into commerce each year. Of the 32,000 new chemicals submitted to the EPA by chemical companies, only about 570 were designated for chemical companies to submit premanufacture notices for any significant new uses of the chemical, thereby providing the EPA with the data to assess risks to human health or the environment from new uses of the chemical. More disturbing, the EPA estimated that most premanufacture notices do not include test data of any type, and only about 15% include health or safety test data. The EPA reported to the GAO that they had taken actions to reduce the risks of more than 3500 of the 32,000 new chemicals they had reviewed. Of public health significance, GAO concluded, "EPA's reviews of new chemicals provide limited assurance that health and environmental risks are identified before the chemicals enter commerce" ([27], p. 2).

In regard to existing chemicals, GAO found that while the EPA has authority under the TSCAct to require chemical companies to develop test data after an EPA finding of need, this authority has been used for fewer than 200 of the 62,000 chemicals in commerce since 1979 ([27], p. 7). GAO concluded that "EPA does not routinely assess the risks of all existing chemicals and EPA faces challenges in obtaining the information necessary to do so" ([27], p. 7). As noted by GAO in the late 1990s, in cooperation with chemical companies and national environmental groups, the EPA implemented its High Production Volume Challenge Program [27]. Under this program, chemical companies voluntarily provide test data on about 2800 chemicals produced or imported in amounts of one million pounds or more annually. While this testing program seems quite positive in terms of potential new chemical data, there has been no assessment to date of the program's quality and utility for the EPA's chemical regulatory purposes.

As to the third part of GAO's study, according to EPA officials, about 95% of premanufacturing notices for new chemicals submitted by chemical companies contain some information that is claimed by companies as being confidential business information ([27], p. 7). GAO opined that this limits the EPA's ability to share health relevant information with the public, including state environmental and health agencies.

GAO recommended that Congress provide the EPA with additional authorities under the TSCAct to improve its assessment of chemical risks. It was also recommended that the EPA Administrator take specific actions to improve the EPA's management of its chemicals programs. But given the fact that Congress has failed over almost 30 years to improve the TSCAct, any acceptance of GAO's recommendation will be problematic.

If the TSCAct's authorities, as administered by the EPA, have led to regulating only five existing chemicals over the life of the statute and regulatory actions taken on only about 10% of new chemicals, one can ask why the TSCAct was not changed for the better. In other words, why has not such an important law been fixed? The answer lies in part to the legislative challenges and uncertainties when amending any major federal statute. Bringing any existing statute back before Congress or a state legislature always runs the risk of changes for the worst. As policy, it is sometimes better to deal with the "devil we know" than with an unknown one!

ENFORCEMENT EXAMPLE

(Washington, DC—April 17, 2014): Lowe's Home Centers agreed to implement a comprehensive, corporate-wide compliance program to ensure that the contractors it hires will minimize lead dust from home renovation activities, as required by the federal Lead Renovation, Repair, and Painting (RRP) Rule. The company will also pay a $500,000 civil penalty, which is the largest ever for violations of the RRP Rule [28].

11.2.3.5 Associations between Hazardous Substances and Human Health

Adverse effects on health can be caused by many chemical substances in the environment. The nature and effects depend on such factors as the potency of the substance, the route and

* PCBs, chlorofluorocarbons, dioxin, asbestos, and hexavalent chromium.
† Previously named the General Accounting Office.

extent of exposure, and an individual's personal characteristics such as genetics, age, and health status. As shown in Table 11.1, all of the body's major organs and organ systems can potentially be affected by exposure to chemicals that can be toxic under the appropriate circumstances. Of policy relevance, policies to prevent human and ecological exposure to hazardous substances have increased in scope and importance in concert with increased toxicological knowledge. The public health implications of toxic substances can be especially great when a toxic substance is pervasive or widely spread within an environmental medium.

Consider the example of lead. As was discussed in Chapter 8, lead is one of the six criteria air pollutants. Until removed in the U.S. as an additive in gasoline, ambient air lead was a significant source of lead exposure to children and adults, raising blood lead levels (BLLs). Given the known association between prenatal exposure to lead and the adverse effects on children's cognitive development, it was a public health success when lead was removed from gasoline.

Another pervasive source of lead exposure comes from the legacy of lead-based paint, which was used in the U.S. for decades, until lead was banned as an additive to paint. Lead-based paint used in older housing became a public health problem when young children ate paint chips and were additionally exposed to lead-laden dust. Some lead exposures were lethal, depending on the amount of paint ingested. Cities and states found themselves having to respond to an epidemic of childhood lead poisonings. For some states, removing lead-based paint and conducting health surveillance on children with potential or actual exposure to household lead sources became a pressing financial obligation. In 2006, the state of Rhode Island successfully litigated three paint companies known to have produced lead-based paint in past years [29]. This sent a shock wave throughout the paint industry, since costs to them could run in the billions of dollars nationwide as other states pursue their own litigation. Given the public health gravity of these two examples from the U.S. experience with lead, one would expect the potential benefits of the TSCAct would be substantive in regard to preventing the adverse effects of toxic substances.

11.2.3.5.1 Hazardous Substances and Children's Health

A society is not sustainable without children. This truth has been common sense from the origins of societal clustering. Prior to the development of vaccines and other medical interventions, many children succumbed to childhood diseases. In the twentieth century, public health programs of childhood vaccinations, improved nutrition, and better education of parents all contributed to improved mortality rates for children. Unfortunately, environmental hazards coincident with the Chemical Age of industrialized nations have reintroduced some health problems for children.

The worst example of a chemical hazard that impacts young children is environmental exposure to lead. This historically well-known toxicant was added in the twentieth century to gasoline and paint for commercial purposes, without regard for any human health consequences. As a result, generations of young children suffered lead intoxication that caused neurological problems, developmental issues, and impaired social functioning. As the Flint, Michigan, example discussed in Chapter 9 illustrates, the legacy of lead in children remains a public health challenge.

As background, lead is a naturally occurring toxic metal found in the Earth's crust. As noted by WHO, the widespread use of lead has resulted in extensive environmental contamination, human exposure and significant public health problems in many parts of the world. Important sources of environmental contamination include mining, smelting, manufacturing and recycling activities, and, in some countries, the continued use of leaded paint, leaded gasoline, and leaded aviation fuel. More than three-quarters of global lead consumption is for the manufacture of lead-acid batteries for motor vehicles. Lead is, however, also used in many other products, for example, pigments, paints, solder, stained glass, crystal vessels, ammunition, ceramic glazes, jeweler, toys, and in some cosmetics and traditional medicines. As with the Flint, Michigan, episode, drinking water delivered through lead pipes or pipes joined with lead solder may contain lead. Much of the lead in global commerce is now obtained from recycling [30].

The public health impacts on children who experience exposure to lead are characterized by WHO as follows [30]:

- Lead is a cumulative toxicant that affects multiple body systems and is particularly harmful to young children.
- Lead exposure is estimated to account for 674,000 deaths per year with the highest burden in low- and middle-income countries.
- Lead exposure is estimated to account for 9.8% of the global burden of idiopathic intellectual disability, 4% of the global burden of ischemic heart disease, and 5% of the global burden of stroke.
- Lead in the body is distributed to the brain, liver, kidney, and bones. It is stored in the teeth and bones, where it accumulates over time. Human exposure is usually assessed through the measurement of lead in blood.
- There is no known level of lead exposure that is considered safe.
- Lead poisoning is entirely preventable.

The actual number of children in the U.S. with elevated BLLs probably exceeds previously reported numbers, according to researchers at the Public Health Institute's California Environmental Health Tracking Program [30a]. Elevated BLLS were those that exceeded 10 μg/dL. Investigators reported their analysis, using National Health and Nutrition Survey data for the years 1999–2010, estimated 1.2 million children had elevated BLLs, twice the number estimated by CDC. The investigators also reported a wide variability across states in regard to testing of children for lead poisoning.

Young children are particularly vulnerable to the toxic effects of lead and can suffer profound and permanent adverse health effects, particularly affecting the

development of the brain and nervous system. Lead also causes long-term harm in adults, including increased risk of high blood pressure and kidney damage. Exposure of pregnant women to high levels of lead can cause miscarriage, stillbirth, premature birth, and low birth weight, as well as minor malformations.

* * *

Several medical groups have taken policy stands against children's exposure to toxic substances in the environment. For instance, the International Federation of Gynecology and Obstetrics (FIGO) was the first global reproductive health organization to take a stand on human exposure to toxic chemicals. Miscarriage and still birth, impaired fetal growth, congenital malformations, impaired or reduced neurodevelopment and cognitive function, and an increase in cancer, attention problems, attention-deficit hyperactivity disorder (ADHD) behaviors, and hyperactivity are among the list of adverse health outcomes linked to chemicals such as pesticides, air pollutants, plastics, solvents, and more, according to FIGO opinion. The cost of childhood diseases related to environmental toxins and pollutants in air, food, water, soil, and homes and neighborhoods was calculated to be $76.6 billion in 2008 in the U.S. FIGO proposes that physicians, midwives, and other reproductive health professionals advocate for policies to prevent exposure to toxic environmental chemicals; work to ensure a healthy food system for all; make environmental health part of health care; and champion environmental justice [31].

In 2008 an international medical group estimated the cost of childhood diseases related to environmental toxins and pollutants in air, food, water, soil and in homes and neighborhoods to be $76.6 billion in the U.S.

Other medical groups are also becoming more proactive in expressing concern about the adverse health effects of hazardous chemicals. In 2015 the American Academy of Pediatrics signed a petition to the CPSC seeking to ban products that contain organohalogen flame retardants [32]. Similarly, the Endocrine Society, following a review of published scientific literature, concluded there is strong mechanistic, experimental, animal, and epidemiological evidence for endocrine disruption. Obesity and diabetes, female reproduction, male reproduction, hormone-sensitive cancers in females, prostate cancer, thyroid, and neurodevelopment and neuroendocrine systems were cited as being associated with exposure to endocrine-disrupting chemicals (EDCs) [33].

The scientific literature contains many publications that relate various environmental toxicants to adverse health effects in children, fetuses, and pregnant women. A sample of such investigations is illustrated in Table 11.4. Especially noteworthy are findings that suggest transgenerational toxic effects can occur when pregnant mothers are exposed to specific hazardous chemicals, signaling that future generations will share in the adverse health effects. While the studies cited in the table are but a sample of the literature, they still raise health concerns about the potential wide breath of adverse effects on children and pregnant women. Additional science will be required for both clarifications of effects as well as verification of findings.

11.2.3.5.2 Health Effects of Endocrine Disruptors

Toxicology as a science and an academic discipline has evolved slowly over the twentieth century. Early studies were simply

TABLE 11.4
Adverse Health Effects of Children Exposed to Selected Hazardous Chemicals

Toxicant	Effect	Reference
Benzene, NO_x	Women exposed to high levels of traffic pollution during the second trimester of pregnancy are at higher risk of birthing a child with reduced lung function.	[35]
BPA	Mothers of newborns with lower birth weights had significantly higher BPA levels in their urine.	[36]
Common chemicals	Vulnerable exposure windows can occur as early as the preconception period and can lead to disadvantageous "reprogramming" of the genome, thereby potentially resulting in transgenerational effects.	[37]
DDT	Elevated levels of DDT in the mother's blood were associated with almost a fourfold increase in her daughter's risk of breast cancer.	[38]
Diisononyl phthalate (DiNP)	Boys exposed to prenatal high levels of DiNP in vinyl products are born with slightly altered genital development.	[39]
Insecticides	Children who had been exposed to insecticides indoors were 47% more likely to have leukemia and 43% more likely to have lymphoma.	[40]
Pb	Toddlers exposed to lead struggled in school more than those who had not been exposed. As teens, they committed crimes more frequently.	[41]
Pb	Pregnant women with high levels of lead in their blood not only affect the fetal cells of their unborn children but also their grandchildren.	[42]
Pb, OP pesticides, MeHg	The three environmental exposures together would decrease 1.6 IQ point in each of 25.5 million children.	[43]
PCBs	Boys exposed to higher prenatal levels of PCBs are more likely to have ADHD-related problems.	[44]
Phthalates	Women exposed to high levels of a phthalate are more likely to have high blood pressure during pregnancy.	[45]

mortality investigations. Gradually over the middle- and late-twentieth century, the science began to incorporate studies of putative toxic substances on induction of cancer, mutations, adverse reproduction, and effects on other organ systems, e.g., respiratory and neurologic. In the late twentieth century, work by Dr. Theo Colborn (1927–2014), an environmental scientist with the World Wildlife Fund, identified adverse effects of some environmental toxicants on the endocrine system [34]. As observed by Colborn and colleagues, "The endocrine system is involved in every stage of life, including conception, development in the womb and from birth throughout early life, puberty, adulthood, and senescence. It does this through control of the other vital systems that orchestrate metabolism, immune function, reproduction, intelligence and behavior, etc. The endocrine system acts through signaling molecules, including hormones such as estrogens, androgens, thyroid hormones, and insulin, as well as brain neurotransmitters and immune cytokines (which are also hormones) and other signaling molecules in the body" [46]. The endocrine system consists of the pituitary gland, thyroid gland, parathyroid glands, adrenal glands, pancreas, ovaries (in females), and testicles (in males).

As Colborn and other investigators discovered, some environmental toxicants have the capacity to mimic some of the physiological effects of naturally occurring hormones. This mechanism is termed *endocrine disruption* and the mimicking substances are called *endocrine disruptors*. *Endocrine-disrupting chemicals* is another term used by investigators. One's hormones literally shape a person's physiological and anatomical character.

A review by WHO of EDC studies concluded, "[…] endocrine systems are very similar across vertebrate species and […] endocrine effects manifest themselves independently of species. Effects shown in wildlife or experimental animals may also occur in humans if they are exposed to EDCs at a vulnerable time and at concentrations leading to alterations of endocrine regulation. Of special concern are effects on early development of both humans and wildlife, as these effects are often irreversible and may not become evident until later in life" [47]. WHO has identified approximately 800 chemicals that are known or suspected to be endocrine disruptors, yet only a few have been investigated. Included on the list are the following, several of which are rather common in the environmental media: bisphenol A (BPA), dioxin, atrazine, phthalates, perchlorate, fire retardants, lead, arsenic, mercury, perfluorinated chemicals, organophosphate pesticides, and glycol ethers [48].

A substantial published literature exists on the ecological consequences of EDCs as pollutants in lakes, rivers, and streams. Of special note, the association between EDCs and feminizing effects in fish are a basis of ecosystem concern. As examples, 85% of male smallmouth bass tested in or nearby 19 National Wildlife Refuges in the U.S. Northeast had signs of female reproductive parts, according to a study conducted by the USGS and the U.S. Fish and Wildlife Service. Findings also reported that 27% of male largemouth bass in the testing sites were intersex. Investigators interpreted these findings as evidence of EDC pollution [49]. In a similar report, some male black bass and sunfish in North Carolina rivers were found to have eggs in their testes [50]. In a laboratory study, researchers from the University of Wisconsin–Milwaukee exposed young fathead minnows to water containing levels of metformin, a commonly used diabetes drug, often found in wastewater effluent. Eighty-four percent of 31 metformin-exposed male fish exhibited feminized reproductive organs [51]. On a larger geographic scale, a research geologist with the USGS found hormone-disrupting compounds—called alkylphenols—passing through wastewater treatment plants and contaminating rivers and fish in the Great Lakes and Upper Mississippi River regions [52]. These and other published studies indicate that EDCs that pollute waterbodies are a hazard to ecosystem health.

WHO has identified approximately 800 chemicals that are known or suspected to be endocrine disruptors, yet only a few have been investigated [47].

A study by the investigators at the New York University School of Medicine on the health costs associated with human exposure to EDCs estimated an increased risk of serious health problems costing at least US$175 billion per year in Europe alone [53]. Reviewers of the study opined that the health care costs in the U.S. would approximate those in Europe. The researchers detailed the costs related to three types of conditions: neurological effects, such as attention deficit disorders; obesity and diabetes; and male reproductive disorders, including infertility. The biggest estimated costs, by far, were associated with chemicals' reported effects on children's developing brains.

The researchers concluded that there is a greater than 99% chance that EDCs are contributing to the diseases. The estimate was limited to a handful of chemicals commonly found in human bodies: BPA, used in hard plastics, food can linings, and paper receipts; two phthalates used as plasticizers in vinyl products; dichlorodiphenyldichloroethylene (DDE), the breakdown product of the banned insecticide DDT; organophosphate pesticides, including chlorpyrifos used on grain, fruit, and other crops; and brominated flame retardants known as polybrominated diphenyl ethers that were extensively used in furniture foams until they were banned in Europe and the U.S. BPA, DDE, and the phthalates were examined for their links to obesity and diabetes, phthalates for male reproductive effects, and flame retardants and organophosphate pesticides for neurological effects [53].

To put $175 billion in perspective, it exceeds the combined proposed 2016 budgets for the U.S. Department of Education, Department of Health and Human Services, National Park Service, and EPA combined [53].

11.2.3.5.3 Health Effects of Obesogens

An area of nascent development in environmental toxicology is the study of what are called *obesogens*. This area of research has been stimulated by the public health epidemic of obese populations. Obesity has risen steadily in the U.S. over the past 150 years, with a marked uptick in recent decades. In the U.S. today more than 35% of adults and nearly 17% of children aged 2–19 years are obese. While sedentary lifestyle and poor diet are considered the major causal factors

in the obesity epidemic, researchers are gathering evidence of chemical "obesogens," dietary, pharmaceutical, and industrial compounds that may alter metabolic processes and predispose some people to gain weight [54].

As summarized by Grens, "In the early 2000s, Bruce Blumberg of the University of California, Irvine, was at a meeting in Japan when he heard a talk about tributyltin (TBT), a chemical used in marine paints to prevent organisms from growing on the hulls of ships. Blumberg studies endocrine disruptors, and his group was looking at whether certain chemicals, including TBT, could activate a nuclear hormone receptor called the steroid and xenobiotic receptor; among other things, it is important for drug metabolism. The presentation described how TBT could cause sex reversal in fish, and Blumberg wondered what exactly TBT was up to.

Blumberg asked his team in California to test TBT on its entire collection of nuclear hormone receptors *in vitro*. The group found that the compound activated a fatty acid receptor called PPARγ.4 'There's only one way you can go with that data,' says Blumberg. 'This receptor is the master regulator of fat-cell development.' The researchers went on to show that TBT can spur adipocyte precursors to differentiate into fat cells *in vitro*, that live frogs exposed to it develop fat deposits around their gonads, and that mice exposed to TBT *in utero* have greater fat stores as adults. Generations of the exposed animals' progeny are also prone to increased adiposity" [55].

"In a 2006 review, Blumberg and UC Irvine colleague Felix Grün coined a new term for such environmental chemicals linked with fat gain: obesogens. Although Blumberg's work was not the first to implicate such substances in obesity, the term obesogen defined an emerging line of inquiry that questioned the strict calories-in-calories-out dogma of weight regulation" [55]. In laboratory studies other researchers have identified several compounds that can reasonably be called obesogents. These include TBT, organobromines, organochlorines (e.g., DDT, PCBs), OPs, BPA, phthalates, heavy metals (e.g., Pb, Cd, As), and perfluorooctanoic acid" [55].

As to the relevance of specific obesogens and any relationship to human obesity, research is underway with some preliminary observations that BPA, a plasticizer, may be associated with increased weight in children [55]. However, the public health research on obesity prevention is complicated, with sedentary lifestyle and dietary factors remaining the focus of activities to reduce the incidence of childhood obesity.

11.2.3.6 Associations between Hazardous Substances and Ecosystem Health

Similar to the impact of pesticides on ecosystems, substances covered under TSCA also have the potential for deleterious impacts on ecosystem health. Several environmental toxicants and pollutants in air, water, and food, and their effects on human and ecosystem health were described in Chapters 8, 9, and 10 of this book. A few more examples will solidify the fact that the Chemical Age has—and continues to—spread chemical substances into various environments and the life existing within them. For example, chemists at the University of Aberdeen found Cd in all the organs, including the brains, of 21 adult long-finned pilot whales that had been stranded in 2012. The whales had died in a mass grounding between Anstruther and Pittenweem in Fife, Scotland, in September 2012. The investigators interpreted their findings as clear evidence that whales are absorbing high levels of Cd and toxic heavy metals [56]. Whether the Cd in brain tissues was associated with the whales' beaching is unknown.

In a separate kind of investigation, the global fervor for gold has produced severe ecosystem effects in areas where gold mining was conducted without regard for environmental consequences. The majority of the world's gold is extracted from open pit mines, where huge volumes of earth are scoured away and processed for trace elements. The environmental organization Earthworks estimates "that, to produce enough raw gold to make a single ring, 20 tons of rock and soil are dislodged and discarded. Much of this waste carries with it mercury and cyanide, which are used to extract the gold from the rock. The resulting erosion clogs streams and rivers and can eventually taint marine ecosystems far downstream of the mine site. Exposing the deep earth to air and water also causes chemical reactions that produce sulfuric acid, which can leak into drainage systems. Air quality is also compromised by gold mining, which releases hundreds of tons of airborne elemental mercury every year" [57].

On a more positive note, a review of literature study by the Scripps Institution of Oceanography in La Jolla, California reported that fish in today's oceans contain far lower levels of Hg, DDT, and other toxicants than at any time in the past four decades. The researchers looked at nearly 2700 studies of pollutants found in fish samples taken globally between 1969 and 2012. They saw steady, significant drops in the concentrations of a wide range of contaminants known to accumulate in fish from about 50% for Hg to more than 90% for PCBs. The investigators attributed these decreases to clean water regulations, lawsuits, and other forms of public pressure, which have led to bans or sharp reductions in the use of industrial and agricultural contaminants that migrate to creeks, rivers, and oceans [58]. In a similar theme of regulatory impact, paper companies, recyclers, and water treatment plants agreed to fund another $46 million to restore wildlife and habitat in northeastern Wisconsin as part of a massive PCB cleanup in the Fox River and Green Bay. Federal, state, and the Oneida and Menominee tribes settled on an arrangement with the parties deemed responsible for releasing PCBs into waterbodies. This brought the total Natural Resources Damage Assessment claim to $106 million. The settlements are aimed at remediating damage to wildlife as PCBs are being dredged out of sediments [59].

On a positive note, a review of literature study by the Scripps Institution of Oceanography in La Jolla, California reported that fish in today's oceans contain far lower levels of Hg, DDT, and other toxicants than at any time in the past four decades [58].

Perspective: Global monitoring data indicate that hazardous chemicals continue to be released into environmental

media. As a matter of environmental health, chemical contamination of waterbodies and terrestrial resources must remain a concern for human and ecosystem health. But data also indicate that regulatory and other policies are having an impact in reducing the release of hazardous chemicals into the environment. In a global perspective, environmental health policies can be effective if developed, implement, and monitored.

11.2.4 Lautenberg Chemical Safety for the 21st Century Act, 2016

The failure of the TSCAct of 1987 was well known to people knowledgeable about environmental health policymaking; it was unclear as to why Congress did not fix the statute. The answer to the "fix it" question lies with the pressure, action, change, and modeling (PACM) model of Chapter 2. Congress did not act until 2016 when sufficient pressure from environmental organizations and chemical industry trade associations dictated otherwise. This is described in the history of the Lautenberg Chemical Safety for the 21st Century Act.

11.2.4.1 History

Of the body of federal statutes on environmental health and attendant policies, the TSCAct of 1976 stands alone as an abject failure. Under that law, environmental and public health organizations expressed concern that the chemical industry was allowed to put products on the market without safety testing and to keep many of its formulas secret, using "trade secrets" provisions of the TSCAct. In particular, the EPA regulators were prohibited by the TSCAct provisions from taking action unless they could *prove* a chemical poses an "unreasonable risk"—a threshold so burdensome that the EPA could not even ban asbestos, a well-documented carcinogen that is the cause of mesothelioma, a lung cancer disease. Although some discussions regarding how to fix the TSCAct were held over the years by some members of Congress, no updating of the law occurred until 2016 when the Lautenberg Chemical Safety for the 21st Century Act was enacted. This act makes significant changes to the TSCAct and provides the EPA with new authorities to regulate toxic substances. President Obama signed the act into law on June 22, 2016.

The bill is named for the late Senator Frank R. Lautenberg (D-NJ), whose tenure in the Senate included support for environmental health policymaking. This legislation to update the TSCAct originally passed the U.S. House of Representatives by near unanimous consent in June 2015 and cleared the U.S. Senate in December 2015. Because the House and Senate versions of a TSCAct reform bill differed, a conference committee was necessary. This led to 3 years of intense negotiations between a key group of Democrat and Republican lawmakers [60]. The conference committee was eventually successful in drafting a compromise bill, the Lautenberg Chemical Safety for the 21st Century Act.

11.2.4.2 Key Provisions Relevant to Public Health

The new TSCAct rewrite will require the EPA to restrict the use of any chemical that the agency finds to present an unreasonable risk. Certain exemptions are available for substances deemed essential to national defense, for example. The EPA now has more authority to order safety tests for chemicals and set deadlines for the agency to determine whether dangerous compounds should be restricted or forced off the market. The EPA will also be required to take additional steps to ensure pregnant women, children, and other vulnerable populations are protected [60].

The Lautenberg Chemical Safety Act will require the EPA to restrict the use of any chemical that the agency finds to present an unreasonable risk. The EPA now has more authority to order safety tests for chemicals and set deadlines for the agency to determine whether dangerous compounds should be restricted or forced off the market.

Overall, the bill gives the EPA the authority to immediately begin a risk evaluation of any chemical it designates as high priory, such as asbestos. It also requires up front substantiation of industry's claims that disclosure of confidential data could damage a firm's business and mandates that so-called confidential business information protections expire after 10 years unless renewed. Agency officials still will have only 90 days to judge a new chemical before it can enter the market. But the EPA will be able to order testing without years of rulemaking and will be required to identify high-priority chemicals for review, with an initial focus on about 90 compounds.

In addition, the measure also authorizes the EPA to conduct testing to determine whether a chemical should be a high priority for a safety review. Decisions made by the EPA will preempt existing and future state laws to restrict chemicals, in order to create uniform national regulations. The agreement also specifies that if the EPA fails to follow through with plans to regulate a chemical within a 3.5-year period, then states are free to act [60].

In 2006 EPA selected 10 common chemicals for toxicity evaluation under provisions of the Lautenberg Act. Over the next 3 years, the agency will collect information on the uses of the 10 chemicals, extent of human exposure, hazard, persistence in the environment, and other factors. From this information EPA will decide whether any among the 10 pose an "unreasonable risk" to the environment or human health. For those that do, the EPA has 2 years to create regulations that mitigate the risk. The list includes the following chemicals: 1,4-dioxane, 1-bromopropane, asbestos, carbon tetrachloride, cyclic aliphatic bromide cluster, methylene chloride, *N*-methylpyrrolidone, pigment violet 29, trichloroethylene (TCE), tetrachloroethylene (also known as perchloroethylene [PCE]) [60a].

Perspective: The politics of this action by the U.S. Congress are the same as other actions by Congress when yielding to pressure exerted by vested interest groups concerned about U.S. states' policymaking. In this example of interdicting hazardous chemicals prior to their introduction into commerce, the chemical and allied industries preferred not to have to deal with individual states, given that chemical regulations would likely differ across states. One can understand the practicality of the chemical industry's political position, but by essentially diminishing

individual states' role in regulating toxic substances, conditions specific to an individual state get lost as influences on a state's policymaking. As with clothing, one size may not fit all. Additionally, environmental groups had long advocated the need for reform of the TSCAct, but were unpersuasive in garnering Congressional support, given other priorities in Congress, e.g., budget deficits. But the confluence of environmental interests by the chemical industry and environmental organizations over a 6-year period of intense negotiations gave Congress the compromises necessary to enact what became the Lautenberg statute. Whether the EPA can effectuate the Lautenberg Act's provisions any more effectively than those of TSCA will be a matter for history to report. However, adding further uncertainty as to the effectiveness of the Lautenberg Act is the Trump administration's stated preference for lesser regulatory action by EPA, together with some likely judicial actions by U.S. states and commercial interests litigating for purpose of obtaining legal clarification on the Lautenberg Act's statutory language.

11.2.5 The Food Quality Protection Act, 1996

Policymaking by elected officials is sometimes difficult for the public to fathom for a variety of reasons. One reason is when existing policies seem to conflict or overlap. This can occur when policies are enacted by different policymakers at different times. On some occasions a policymaking body, e.g., U.S. Congress, will enact "bridging" legislation whose purpose is to clarify or resolve conflicting authorities between existing policies. An example is the FQPAct of 1996.

11.2.5.1 History

In 1996 Congress enacted major legislation that changed how pesticides are regulated. The FQPAct revises the FIFRAct and the federal FDCAct. The FQPAct legislation constituted the first major revision in decades of U.S. pesticides laws. This dramatically altered how pesticides are registered, used, and monitored in the food chain. The legislation was passed without a dissenting vote in either the House of Representatives or Senate and signed into law by President Clinton.

The overall purpose of the FQPAct is to protect the public from pesticide residues found in the processed and unprocessed foods they eat. Essentially, the FQPAct amended the FIFRAct and the FDCAct so that a single health-based standard would be issued to alleviate problems concerning the inconsistencies between the statutes. The health-based standard would be based on a "reasonable certainty of no harm."

The FQPAct's titles are given in Table 11.5 (P.L. 104–170, 1990). The act provides a standard for pesticide residues in both raw and processed foods. The standard is "reasonable certainty of no harm." The law requires the EPA to review all pesticide tolerances within 10 years, giving particular attention to exposure of young children to pesticide residues. Furthermore, the EPA must consider a substance's potential to disrupt endocrine function when setting tolerances. The statute requires the EPA to give consideration to effects of pesticides on the public's health, requiring the Secretary of DHHS to provide information to the EPA on pesticides that protect the public's health [61].

TABLE 11.5
Food Quality Protection Act's Titles

Title	Name of Title
I	Suspension—Applicators
II	Minor Use Crop Protection, Antimicrobial Pesticide Registration Reform, and Public Health Pesticides
III	Data Collection Activities to Assure the Health of Infants and Children and Other Measures
IV	Amendments to the Food, Drug, and Cosmetic Act
V	Fees

Source: EPA (Environmental Protection Agency), Summary of FQPA amendments to FIFRA and FFDCA, 2003, http://www.epa.gov/oppfead1/fqpa/fqpa-iss.htm.

It is worth noting that the Delaney Clause in the FDCAct was replaced by a risk-based approach (Chapter 19). The Delaney Clause had required the FDA to ban any food additive that caused cancer in laboratory animals or humans, leading to bans some thought were not always pertinent to human health. This was a zero risk policy; total elimination of a substances leads to no risk, at least in theory. Moreover, the Delaney Clause was enacted in 1958, when analytical technology was, by today's standards, relatively crude. As technology became ever more precise, it became possible to measure very minute levels of some carcinogens in food. Under the Delaney Clause, such substances had to be eliminated from the food chain, whether they posed an actual health risk or not. The FQPAct gives government the authority to apply a de minimis standard, rather than a zero risk standard.

The most publicized incident pertaining to the Delaney Clause concerned the artificial sweetener saccharin. The noncaloric sweetener has been used for more than 100 years to sweeten beverages and food, replacing calories that would have come from use of natural sweeteners. In 1977, acting under the Delaney provisions, the FDA proposed to ban the use of saccharin as a food additive. The agency's proposal was driven by the findings from a toxicology study that showed an excess frequency of urinary bladder tumors in rats fed large amounts of sodium saccharin [62].

Given the rat data, under the Delaney Clause, the FDA had no alternative but to initiate action to ban the dietary uses of saccharin. However, consumer advocates and public health officials expressed great concern that the loss of saccharin would lead to use of natural sweeteners (e.g., sugar), which would increase calories in food, lessening the effectiveness of bodyweight reduction programs, and also complicate the dietary needs of diabetics. Moreover, a considerable number of scientists questioned the relevance of the rat data for its relevance to humans. The hue and cry against the FDA's proposed ban of saccharin led Congress in 1977 to enact a moratorium to prevent the FDA's proposed action. In 1991, the FDA withdrew its proposed ban of saccharin in 1991.

11.2.5.2 Key Provisions of the FQPAct Relevant to Public Health

Title I—Suspension–Applicators

§102–Suspension: Allows EPA to suspend a pesticide registration in an emergency situation without simultaneously issuing a notice of intent to cancel. §103–Tolerance: Reevaluation as Part of Reregistration: Specifies that tolerances and exemptions from tolerances must be reassessed as part of reregistration to determine whether they meet the requirements of the FDCAct. §106–Periodic Registration Review: Allows continued sale and use of existing stocks of suspended or canceled pesticides under conditions determined by the EPA Administrator to be consistent with the FIFRAct. […] §120–Training for Maintenance Applicators and Service Technicians: Creates two new types of pesticide applicators: maintenance applicators and service technicians. Authorizes states to establish minimum training requirements for these applicators. […]

Title II—Minor Use Crop Protection, Antimicrobial Pesticide Registration Reform, and Public Health Pesticides

§210–Defines minor use. Allows EPA to waive data requirements for a minor use as long as the EPA Administrator can determine the minor use's incremental risk and that the incremental risk would not present an unreasonable adverse effect. […] §230–Public Health Pesticide Definitions: Amends the definition of unreasonable adverse effects on the environment by specifying that the risks and benefits of public health pesticides are considered separate from the risks and benefits of other pesticides. §232–§234–Reregistration: Allows EPA to exempt public health pesticides from reregistration. Instructs DHHS to provide benefits and use information if a public health use pesticide is subject to a cancellation notice.

Title III—Data Collection Activities to Assure the Health of Infants and Children and Other Measures

This title contains provisions on data collection activities to assure the health of infants and children, and integrated pest management.

Title IV—Amendments to the federal Food, Drug, and Cosmetic Act

Key amendments relevant to public health include the following:

- Outlines situations in which breakdown products of pesticides not be deemed unsafe, such as when the by-products present no greater health risk when ingested than presented by the original pesticides.
- Requires that pesticide residues be allowed in foods only if long-term exposure does not jeopardize human health and use of the original pesticide does not threaten domestic food production.
- Establishes that the EPA Administrator consider with higher priority a petition for allowing in foods pesticide chemical residues that pose less human health risk than residues of other pesticides of similar use.
- Requires the EPA Administrator to respond to these higher priority petitions within 1 year.
- Limits the sharing of information and data on pesticides permitted in food, except, when nonconfidentiality is necessary to protect public health.
- Allows a high, 30-day-turnover-time priority for a state to petition the EPA Administrator for permission to regulate pesticide chemical residues in food that present a significant public health threat.
- Requires the EPA Administrator, in consultation with the Secretaries of the USDA and DHHS, to annually publish and display in large grocery stores information for the general public on pesticides in food.
- Requires the EPA Administrator to take steps necessary to protect public health if any substances such as pesticides are found to stimulate hormones' effects in the human body.
- Requires the EPA Administrator to review current permits in place for pesticide chemical residues in food, giving highest priority to permits that may present the most significant public health risk.

11.2.5.3 Public Health Implications of the FQPAct

In theory, the public health benefits of the FQPAct could be quite consequential, particularly in terms of protecting children from the harmful effects of pesticides. Because children lack fully developed organ systems that are necessary for detoxifying hazardous substances, resulting in higher rates of absorption of toxic substances than adults, they are at greater risk of adverse health effects from exposure to pesticides than are adults. Therefore, prevention of exposure to pesticides is consistent with improved public health. The FQPAct contributes to this kind of primary prevention by requiring the EPA to develop more protective risk assessments of hazardous substances. In particular, the FQPAct directs the EPA to incorporate an additional safety factor of 10 for risk assessments specific to children. Specifically, the law focused on making sure that food was safe for children, requiring that permissible exposures to pesticides be reduced tenfold to protect infants and children unless the EPA was presented with "reliable data" showing that so great a reduction was unnecessary.

11.3 U.S. AGENCIES WITH HAZARDOUS SUBSTANCES POLICIES

In additional to the EPA, there are other U.S. federal government agencies that have responsibilities in regard to hazardous substances in the environment. In particular, the USDA and the U.S. Department of Labor (DOL) have statutory responsibilities in terms of control of various hazardous substances in the environment. Further, additional resources that bear on the research on the toxicology of select environmental toxicants and investigations of incidents of chemical releases will be described in this section.

11.3.1 U.S. Department of Labor

OSHA of the DOL has the responsibility to set workplace standards under the provisions of the Occupational Safety and Health Act of 1970 (Chapter 4). Specifically, 29 CFR 1910 Subpart Z, 1915 Subpart Z, and 1926 Subparts D and Z of the OSHAct direct OSHA to establish, promulgate, and enforce workplace permissible exposure limits (PELs) to protect workers against the health effects of exposure to hazardous substances and other hazards to workers. This responsibility includes limits on the airborne concentrations of hazardous chemicals in the air of workplaces. Most OSHA PELs are 8-h time-weighted averages, although there are also Ceiling and Peak limits, and many chemicals that include a skin designation to warn against skin contact. Approximately 500 PELs have been established. However, as acknowledged by OSHA, many of these limits are outdated. Also, there are many substances for which OSHA does not have workplace exposure limits [63].

Approximately 500 PELs have been established by OSHA. However many of these limits are outdated. Also, there are many substances for which OSHA does not have workplace exposure limits [63].

Given the shortcomings of OSHA's listed PELs, OHSA has provided employers, workers, and other interested parties with a list of alternate occupational exposure limits that may serve to better protect workers. OSHA has chosen to present a side-by-side table with the California/OSHA PELs, the NIOSH Recommended Exposure Limits (RELs) and the American Conference of Government Industrial Hygienists Threshold Limit Values (ACGIH TLVs). The tables list air concentration limits, but do not include notations for skin injury, absorption or sensitization.

As an illustration of OSHA's challenges in updating its PELs, in May 2016, OSHA promulgated its final rule on it new permissible exposure limit for respirable crystalline silica—50 μg per cubic meter of air averaged during an 8-h shift. According to OSHA, silica exposure is a serious threat to nearly two million U.S. workers, including more than 100,000 whose jobs involve stone cutting, rock drilling, and blasting and foundry work. OSHA estimates that the new safety limits will save nearly 700 lives and prevent 1600 new cases of silicosis annually. The agency also estimates that when fully implemented, the rule would result in annual financial benefits of $2.8–$4.7 billion, benefits that far exceed the rule's annual costs [64]. This was the first revision of OSHA's silica PEL in 75 years. The updated PEL is half the previous limit for general industry and five times lower than the previous limit for construction. The rule covers engineering controls, protective clothing, medical surveillance, and other issues. OSHA presents the rule as two standards—one for general industry and maritime and the other for construction [65].

11.3.2 U.S. Chemical Safety Board

The U.S. Chemical Safety Board (CSB) was authorized by the CAAct Amendments of 1990 and became operational in January 1998. The Senate legislative history states: "The principal role of the new chemical safety board is to investigate accidents to determine the conditions and circumstances which led up to the event and to identify the cause or causes so that similar events might be prevented." Congress gave the CSB a unique statutory mission and provided in law that no other agency or executive branch official may direct the activities of the Board. Following the successful model of the National Transportation Safety Board and the Department of Transportation, Congress directed that the CSB's investigative function be completely independent of the rulemaking, inspection, and enforcement authorities of the EPA and OSHA. Congress recognized that Board investigations would identify chemical hazards that were not addressed by those agencies [66].

The legislative history states: "[T]he investigations conducted by agencies with dual responsibilities tend to focus on violations of existing rules as the cause of the accident almost to the exclusion of other contributing factors for which no enforcement or compliance actions can be taken. The purpose of an accident investigation (as authorized here) is to determine the cause or causes of an accident whether or not those causes were in violation of any current and enforceable requirement" [66]. Both accident investigations and hazard investigations can lead to new safety recommendations, which are the Board's principal tool for achieving positive change. Recommendations are issued to government agencies, companies, trade associations, labor unions, and other groups. Implementation of each safety recommendation is tracked and monitored by CSB staff. When recommended actions have been completed satisfactorily, the recommendation may be closed by a Board vote. According to the CSB, it has issued 780 recommendations subsequent to its infestations [66].

The CSB recommendations have the potential for preventing similar chemical events in the future, a policy consistent with the principle of public health. The impact of CSB recommendations lacks current analysis by any academic resource.

11.3.3 National Toxicology Program

As mentioned in Chapter 3, the National Institute of Environmental Health Sciences (NIEHS) provides the scientific and administrative leadership within the DHHS for the National Toxicology Program (NTP). The NTP began as a program conceived and administered by the NCI, a component of the National Institutes of Health (NIH). NCI was reacting to environmental and Congressional pressures to investigate the carcinogenicity of chemicals found in the general environment. NCI's response was a program largely devoted to testing specific toxicants for carcinogenicity, using laboratory animals under controlled exposure conditions. The testing was conducted by commercial toxicology testing laboratories, using a study protocol designed by NCI. Unfortunately for the NCI, one of the major contractors was found inadequate and their alleged poor quality work became the subject of critical news media reports and articles in prestigious scientific journals such as *Science*. Weary of the negative publication, the Secretary of DHHS transferred the NTP to the NIH's NIEHS for the program's administration.

In 1981, under NIEHS's administration, the NTP became the federal government's principal program for assessing the toxicity of substances found in the general environment. As a matter of policy, the NTP receives scrutiny and advice from standing extramural committees comprising experts in toxicology and related disciplines.

A major activity of the NTP is to coordinate the preparation of a biennial report for DHHS on substances judged to be carcinogenic by government scientists. A 1978 Congressional mandate to §301(b)(4) of the Public Health Service Act, as amended, requires that the Secretary of the Department of Health and Human Services (DHHS) publish an annual report that contains a list of all substances that either are known to be human carcinogens or may reasonably be anticipated to be human carcinogens and to which a significant number of persons residing in the U.S. are exposed. The first Report on Carcinogens (RoC) was published in 1980 and published annually until 1993 when the reporting requirement was changed to biennial. According to the NEP, since the RoC inception in 1978, the NTP has used scientifically rigorous processes and established listing criteria to evaluate substances for the RoC. There are two categories for each substance nominated for listing: (1) known to be human carcinogens or (2) reasonably anticipated to be human carcinogens. The RoC is a cumulative report that includes 243 listings since its first publication in 1980. The NTP provides details on the listing process and the review process undergone by each RoC [67].

These biennial reports to Congress on carcinogenic substances (singly or as mixtures) draw the attention of both domestic and international audiences. Domestic audiences span the gamut of industry and environmental interests. Sometimes the listing by the NTP of particular substances, for example, formaldehyde and styrene, can bring pressure from elected policymakers. As an example, an attempt was initiated in 2012 by a Member of Congress to remove funds from the NTP's annual federal budget, resulting in cancellation of the RoC [68]. This effort reflected industry dissatisfaction with the RoC that listed these two chemicals as potential carcinogens. Although this effort by the member failed, this example does illustrate the political scrutiny that some RoCs receive.

11.4 U.S. STATE POLICIES ON HAZARDOUS SUBSTANCES

Some U.S. states have implemented legislation on aspects of hazardous substances. But in general, most states have ceded to the EPA the principal responsibilities of protecting the public against adverse effects of exposure to hazardous environmental substances. As such, states will develop policies and devote resources in support of their responsibilities under federal environmental statutes (e.g., CAAct), which is an example of federalism. There are exceptions to federalism, given the authorities given to states, territories, and tribes under provisions of the U.S. Constitution. Some states choose to act in the absence of federal policies and legislation. This section describes two states programs for controlling adverse effects of contact with hazardous substances. It also describes some states trends in legislating consumers' right-to-know policies concerning hazardous chemicals.

11.4.1 State of California

The State of California is rich in resources and social programs, with a diverse population. The state has often set the course for environmental health policymaking. An example was described in Chapter 8 (Air Quality), wherein the state commenced policies on air pollution in advance of other states and the federal government. Commensurate with this history, in 1986 California voters approved an initiative to address their growing concerns about exposure to toxic chemicals. That initiative became the Safe Drinking Water and Toxic Enforcement Act of 1986, better known by its original name of Proposition 65, often called "Prop 65." In California, propositions approved by voters must be implemented by the California Legislature. Prop 65 requires the State to publish a list of chemicals known to cause cancer or birth defects or other reproductive harm. This list, which must be updated at least once a year, has grown to include approximately 800 chemicals since it was first published in 1987. Prop 65 requires businesses to notify Californians about significant amounts of chemicals in the products they purchase, in their homes or workplaces, or that are released into the environment. California Office of Environmental Health

In California law, Proposition 65 requires the State to publish a list of chemicals known to cause cancer or birth defects or other reproductive harm. Prop 65 requires businesses to notify Californians about significant amounts of chemicals in the products they purchase, in their homes or workplaces, or that are released into the environment.

Hazard Assessment (OEHHA) administers the Prop 65 program [68a].

The list contains a wide range of naturally occurring and synthetic chemicals that are known to cause cancer, birth defects, or other reproductive harm. These chemicals include additives or ingredients in pesticides, common household products, food, drugs, dyes, or solvents. Listed chemicals may also be used in manufacturing and construction, or they may be byproducts of chemical processes, such as motor vehicle exhaust.

There are four ways for a chemical to be added to the Prop 65 list. A chemical can be listed if either of two independent committees of scientists and health professionals finds that the chemical has been clearly shown to cause cancer or birth defects or other reproductive harm. These two committees-the Carcinogen Identification Committee (CIC) and the Developmental and Reproductive Toxicant (DART) Identification Committee-are part of OEHHA's Science Advisory Board. The second way for a chemical to be listed is if an organization designated as an "authoritative body" by the CIC or DART Identification Committee has identified it as causing cancer or birth defects or other reproductive harm. The following organizations have been designated as authoritative bodies: EPA, FDA, NIOSH, NTP, and IARC.

The third way for a chemical to be listed is if an agency of the state or federal government requires that it be labeled or identified as causing cancer or birth defects or other reproductive harm. Most chemicals listed in this manner are prescription drugs that are required by the U.S. FDA to contain warnings relating to cancer or birth defects or other reproductive harm. The fourth way requires the listing of chemicals meeting certain scientific criteria and identified in the California Labor Code as causing cancer or birth defects or other reproductive harm. This method established the initial chemical list following voter approval of Prop 65 in 1986 and continues to be used as a basis for listing as appropriate.

Businesses are required to provide a "clear and reasonable" warning before knowingly and intentionally exposing anyone to a listed chemical. This warning can be given by a variety of means, such as by labeling a consumer product, posting signs at the workplace, distributing notices at a rental housing complex, or publishing notices in a newspaper. Once a chemical is listed, businesses have 12 months to comply with warning requirements.

Prop 65 also prohibits companies that do business within California from knowingly discharging listed chemicals into sources of drinking water. Once a chemical is listed, businesses have 20 months to comply with the discharge prohibition. Businesses with fewer than 10 employees and government agencies are exempt from Prop 65's warning requirements and prohibition on discharges into drinking water sources. Businesses are also exempt from the warning requirement and discharge prohibition if the exposures they cause are so low as to create no significant risk of cancer or birth defects or other reproductive harm.

OEHHA also develops numerical guidance levels, known as "safe harbor numbers" (described in State regulations) for determining whether a warning is necessary or whether discharges of a chemical into drinking water sources are prohibited. OEHHA has developed safe harbor levels. A business has "safe harbor" from Prop 65 warning requirements or discharge prohibitions if exposure to a chemical occurs at or below these levels.

11.4.2 State of Massachusetts

The Toxics Use Reduction Act (TURA) was enacted in Massachusetts in 1989. The act requires Massachusetts companies using certain amounts of listed toxic chemicals ("Large Quantity Toxics Users") to

- Prepare a Toxics Use Reduction Plan assessing the use of toxic chemicals at the facility and evaluating options for reducing the use of toxic chemicals.
- File an annual report for every listed chemical that the facility manufactures, processes, or otherwise uses above applicable thresholds.
- Pay annual toxics fees.

The list of toxic/hazardous chemicals under TURA includes substances listed under §313 of the Emergency Planning and Community Right to Know Act, and the CERCLAct (Chapter 12). Chemicals designated as Higher Hazard or Lower Hazard Substances are drawn from a larger informational list of "more hazardous chemicals" and "less hazardous chemicals."

The higher hazard substances in 2016 are PCE, TCE, Cd and cadmium compounds, and PBTs. The ten lower hazard substances are isobutyl alcohol, *sec*-butyl alcohol, *n*-butyl alcohol, butyl acetate, isobutyl acetate, ferric chloride, ferric sulfate, ferrous chloride, ferrous sulfate (heptahydrate), and ferrous sulfate.

The act also established the Toxic Use Reduction Institute to promote reduction of toxics and use of safer alternatives [69].

11.4.3 States' Legislation on Consumers' Right to Know

Social media and other forms of public communication have helped foster awareness about select consumer products that potentially contain hazardous chemicals. This awareness has been translated into legislative action by some states. A substantial public concern about the chemical bisphenol A was often a driving issue in policymaking. BAP has been demonstrated to be an endocrine disruptor and is a chemical found in many plastic products, including plastic baby bottles and plastic food wraps. In response some states have begun to require greater transparency from companies about what comprises their products. Washington State has been a leader on this issue. The Washington Children's Safe Product Act, passed in 2008, now requires manufacturers of children's products sold in the state to report into a state-managed, publicly accessible database if their products contain any of 66 designated chemicals of high relevance to children.

Vermont enacted a similar law effective in July 2016, and Oregon passed its own law in July 2015. In Maine, manufacturers are required to report their use of BPA and nonylphenols, both known to be endocrine disruptors which have been detected in lakes, streams, and groundwater as well as breast milk, urine, and blood. Although Maine's list is much shorter than Washington's and Vermont's, it applies to many consumer product categories, not just children's products [70]. Oregon has also enacted a law that will require the state to maintain a list of "chemicals of concern" for children's products, require manufacturers to provide notice of chemicals on the list that they use in children's products, and would eventually require manufacturers to remove or use substitutes for certain chemicals [71].

Perspective: State laws concerning hazardous substances, particularly those in consumer products, are emerging due to pressure from consumer groups and environmental organizations. This is an example of the PACM policymaking model discussed in Chapter 2. There are also examples of state laws on consumers' right-to-know policies. As such laws proliferate, often commercial interests determine that it is in their best interests to pressure the U.S. Congress to enact federal legislation that would preclude states from implementing their own statutes. This kind of federal preemption often results from litigation taken by states to federal courts for determination of adherence to the U.S. Constitution.

11.5 GLOBAL PERSPECTIVE ON TOXIC SUBSTANCES

Global policies pertaining to control of hazardous substances in environmental media are largely dealt with through domestic national policies on controlling pollutants in air, water, and food. However, this section describes policies of the EU and WHO, each of which has implemented policies and programs that are specific to the public health issues presented by hazardous chemical substances.

11.5.1 EU Policies on Hazardous Substances

The EU has issued directives and regulations to its Member States in reference to hazardous substances [72]. According to the European Commission, the Directive on Dangerous Substances states, "A European law covering dangerous substances was introduced in 1967 to protect public health, in particular the health of workers handling dangerous substances. The law, known as the Directive on Dangerous Substances introduced EU-wide provisions on the classification, packaging and labelling of dangerous substances.

The classification of dangerous substances places a substance into one or several defined classes of danger and characterizes the type and severity of the adverse effects that the substance can cause. The packaging of dangerous substances protects individuals from the known risks of a substance, and the labelling of dangerous substances provides information about the nature of the substance's risks and about the safety measures to apply during handling and use.

Since it was adopted in 1967 the directive has regularly been updated to take into account the latest scientific and technical progress so as to ensure the highest level of protection for individuals and the environment. This also ensures that the internal market functions most efficiently. The amendments to the directive enable newly identified hazardous materials to be added to the list of dangerous substances. The most recent ones—known as the 30th ATP and 31st ATP (Adaptation to Technical Progress)—introduce or modify the EU harmonised classification and labelling requirements for more than 800 and 600 substances, respectively [72].

REACH places the burden of proof on companies. To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU. They have to demonstrate to the European Chemicals Agency (ECHA) how the substance can be safely used, and they must communicate the risk management measures to the users [73].

One of the most important amendments to the directive was the 6th amendment in 1979, which included measures to protect the environment from the dangerous effects of substances. It also introduced a notification system for "new" substances that required lists of "existing" substances—called EINECS—to be published. EINECS is the European Inventory of Existing Commercial Chemical Substances and lists all substances that were reported to be on the market on or before September 18, 1981. The substances placed on the market for the first time after this target date are considered "new" and are added to ELINCS. ELINCS is the European List of Notified Chemical Substances.

The 7th amendment of the directive occurred in 1992, which introduced risk assessments (Chapter 19) to be carried out for "new" substances. It also introduced the concept of "sole representative" in the notification system and added the Safety Data Sheet as a hazard communication facility for the professional user" [72].

REACH is mentioned in the foregoing directive. It is an EU regulation that stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on June 1, 2007 "REACH is a regulation of the EU, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals" [73].

Under the REACH regulation on chemicals, substances classified as carcinogenic, mutagenic or having reproductive toxic effects may need authorisation to be used or placed on the market [73]. […] The Regulation incorporates the classification criteria and labelling rules agreed at UN level, the so-called Globally Harmonised System of Classification and Labelling of Chemicals (GHS)."

In principle, REACH applies to all chemical substances; not only those used in industrial processes but also in our day-to-day lives, for example in cleaning products, paints as well as in articles such as clothes, furniture and electrical appliances. Therefore, the regulation has an impact on most companies across the EU.

"REACH places the burden of proof on companies. To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU. They have to demonstrate to the European Chemicals Agency (ECHA) how the substance can be safely used, and they must communicate the risk management measures to the users. If the risks cannot be managed, authorities can restrict the use of substances in different ways. In the long run, the most hazardous substances should be substituted with less dangerous ones" [73].

The REACH process comprises the following elements:

- REACH establishes procedures for collecting and assessing information on the properties and hazards of substances.
- Companies need to register their substances and to do this they need to work together with other companies who are registering the same substance.
- The ECHA receives and evaluates individual registrations for their compliance, and the EU Member States evaluate selected substances to clarify initial concerns for human health or for the environment. Authorities and ECHA's scientific committees assess whether the risks of substances can be managed.
- Authorities can ban hazardous substances if their risks are unmanageable. They can also decide to restrict a use or make it subject to a prior authorization [73].

11.5.2 WHO Polices on Hazardous Substances

WHO is active in several areas relevant to preventing the public health impacts of hazardous substances. The organization is a partner with UNEP in implementing their Health and Environment Linkages Initiative (HELI). This initiative is a global effort between WHO and UNEP to assist developing countries' policymakers on issues of environmental threats to health. The two UN organizations note that environmental hazards are responsible for an estimated 25% of the total burden of disease globally, and nearly 35% in regions such as sub-Saharan Africa. The HELI encourages countries to address health and environment linkages as integral to economic development. The two organizations assert that the HELI supports valuation of ecosystem "services" to human health and well-being–services ranging from climate regulation to provision/replenishment of air, water, food, and energy sources, and generally healthy living and working environments. HELI activities include country-level pilot projects and refinement of assessment tools to support decision-making [74].

11.5.2.1 International Agency for Research on Cancer

The IARC is a component organization of WHO. It was created on May 1, 1965, and is based in Lyon, France. IARC's mission "[i]s to coordinate and conduct research on the causes of carcinogenesis, and to develop scientific strategies for cancer control" [75]. IARC is involved in both epidemiological and laboratory research and disseminates scientific information through publications, meetings, courses, and fellowships. IARC's program of work has four main objectives, listed in Table 11.6. Of the four program areas, identifying the causes of cancer has received the greatest public attention, primarily due to the issuance of cancer risk documents on individual chemical and physical agents.

Since 1970, IARC has published assessments of the carcinogenic risks to humans from a variety of agents, mixtures of agents, and exposure circumstances. These assessments, known as the IARC Monographs, are prepared by international experts, assisted by IARC staff. Each monograph is prepared by an international working group that is specific to the agent under review. More than 870 agents (chemicals, groups of chemicals, complex mixtures, occupational exposures, cultural habits, and biological or physical agents) have been evaluated [75]. Each monograph includes basic information about an agent's physical and chemical properties, methods of analysis, production volumes, toxicological data, and epidemiological findings. Sections of the monographs review the evidence for the agent's carcinogenicity. The monographs are available to an international audience of researchers, public health officials, and regulatory authorities. The monographs are particularly relevant to developing countries, where resources to develop similar documents may be lacking.

A significant feature of IARC Monographs is the classification of a chemical or physical agent's potential to cause cancer

TABLE 11.6
IARC's Programs of Work

Program	Illustrative Example
Monitoring global cancer occurrence	Studying cancer incidence, mortality, and survival in many countries
Identifying the causes of cancer	More than 870 agents and exposures have been examined for evidence of carcinogenicity
Elucidation of mechanisms of carcinogenesis	Laboratory research examines the interaction between carcinogens and DNA
Developing scientific strategies for cancer control	Programs are directed to finding ways to prevent human cancer

Source: IPCS (International Programme on Chemical Safety), About IPCS, 2002, http://www.who.int/pcs/html.

A significant feature of IARC Monographs is the classification of a chemical or physical agent's potential to cause cancer in humans. An IARC finding that a particular agent is a human carcinogen has genuine public health importance. Such a statement from IARC can be the impetus for international regulatory actions (e.g., trade bans), public health education programs, and legislative actions.

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In the course of developing the IARC Monographs, working groups are asked to categorize each agent or exposure circumstance based on its carcinogenicity. Over time, IARC has developed guidelines for use in the categorization process. Although the guidelines provide considerable direction to a monograph's working group, scientists' professional judgment is still required. For example, different scientists may disagree over the quality and implications of the same toxicological study or epidemiological investigation. These disagreements are usually worked out in the course of assigning a category (e.g., Group 2A) of carcinogenicity for a particular agent. Following are IARC's carcinogenicity criteria [76]. Table 11.7 shows the IARC's current categories of carcinogens.

The agent, mixture, or exposure circumstance is described according to the wording of one of the following categories, and the designated group is given. The categorization of an agent, mixture or exposure circumstance is a matter of scientific judgment, reflecting the strength of the evidence derived from studies in humans and in experimental animals and from other relevant data.

These guidelines on carcinogenicity classification are in effect a policy statement from IARC, because they specify a course of action to be followed by working groups that develop individual monographs. Without such a policy, each working group would be able to make its own rules for carcinogenicity determination, making it impossible to compare carcinogenicity levels across monographs.

A comparison of IARC's grouping of carcinogens and those of the EPA is also shown in Table 11.7. There are obvious similarities and some minor differences in wording. Even though the two sets of carcinogen categories have very similar wording, occasionally IARC and EPA will come to different conclusions regarding a compound's carcinogenicity. This is because IARC and EPA working groups may differ when reviewing the same scientific data as to what is "sufficient" evidence. However, both sets of categories serve their purpose of providing guidance on weight-of-evidence assessment for the carcinogenicity of individual chemical compounds and mixtures.

11.5.2.2 International Programme on Chemical Safety

The International Programme on Chemical Safety (IPCS) resulted from the UN Conference on the Human Environment, held in Stockholm in 1972. From the conference came the recommendation that programs, to be guided by WHO, should be undertaken for the early warning and prevention of harmful effects of chemicals to which human populations were being exposed [78]. The IPCS functions through the cooperation of WHO, UNEP, and the International Labor Organization. These three organizations coordinate the development of technical reports, share personnel and other resources, and work together on education programs that address the impacts of chemical hazards on human health.

The two main roles of the IPCS are to establish the scientific health and environmental risk assessment basis for safe use of chemicals and to strengthen national capabilities for chemical safety. The latter role is particularly important for developing countries, which often lack the technical and economic resources to develop national programs in chemical safety. WHO has the overall administrative responsibility for the work of the IPCS, working through a central office that is based in Geneva, Switzerland. IPCS's work is divided

TABLE 11.7
Comparison of IARC [76] and EPA [77] Carcinogen Groups

IARC	EPA
Group 1: Carcinogenic to humans (118 agents)	Group A—Carcinogenic to Humans: Agents with adequate human data to demonstrate the causal association of the agent with human cancer (typically epidemiologic data).
Group 2A: Probably carcinogenic to humans (80 agents)	Group B—Probably Carcinogenic to Humans: Agents with sufficient evidence (i.e., indicative of a causal relationship) from animal bioassay data, but either limited human evidence (i.e., indicative of a possible causal relationship, but not exclusive of alternative explanations; Group B1), or with little or no human data (Group B2).
Group 2B: Possibly carcinogenic to humans (289 agents)	
Group 3: Not classifiable as to its carcinogenicity to humans (502 agents)	Group C—Possibly Carcinogenic to Humans: Agents with limited animal evidence and little or no human data.
Group 4: Probably not carcinogenic to humans (1 agent)	Group D—Not Classifiable as to Human Carcinogenicity: Agents without adequate data either to support or refute human carcinogenicity.
	Group E—Evidence of Non-carcinogenicity for Humans: Agents that show no evidence for carcinogenicity in at least two adequate animal tests in different species or in both adequate epidemiologic and animal studies.

into four main areas: risk assessment of specific chemicals, risk assessment of methodologies, risk assessments for food safety, and management of chemical exposures [78]. Much of the IPCS work is conducted in collaboration with regional and national organizations that address chemical safety issues. These organizations include the U.S. EPA, the U.S. NIEHS, the U.S. Agency for Toxic Substances and Disease Registry, the European Commission, the International Life Sciences Institute, the International Union of Pure and Applied Chemistry, the International Union of Toxicology, and others.

The IPCS develops and coordinates several products and services of considerable importance to global environmental health. In particular, several information resources—some of which overlap each other—on chemical substances are available to environmental and health officials, as well as the general public. These documents include the following [78]:

- Environmental Health Criteria (EHC) documents, which are reasonably comprehensive reports of a substance's toxicity, exposure routes, and human health effects. RELs are usually contained in each document [79]. Approximately 250 chemicals have been subjects of EHC documents. The primary audience for these documents consists of national policymakers, environmental and health officials, and government and private sector risk assessors.
- International Chemical Safety Cards (ICSCs) are cards that summarize essential health and safety information on chemicals. They are intended for use by workers and employers in factories, agriculture, construction, and other workplaces. They provide their users with a quick, credible resource for use in preventing chemical emergencies and responding to them if they occur. ICSCs are similar to Material Safety Data Sheets developed by chemical producers and some national governments.
- Concise International Chemical Assessment Documents (CICADs) are summary documents that provide information on the relevant scientific information pertinent to the adverse effects of a specific substance on human health and the environment. As stated by the IPCS, "The primary objective of CICADs is characterization of hazard and dose-response from exposure to a chemical. CICADs are not a summary of all available date on a particular chemical; rather, they include only that information considered critical for characterization of the risk posed by the chemical" [79]. The primary audience appears to be practicing risk assessors, whether in government or industry.

Methodological publications are part of an effort to improve the methodology of chemical risk assessment, developed by expert panels convened by the IPCS [80]. The documents include such documents as Human Exposure Assessment, Biomarkers in Risk Assessment, Principles for Evaluating Health Risks to Reproduction Associated with Exposure to Chemicals, and Guidelines on Studies in Environmental Epidemiology. The documents are used by national governments, professional organizations, and individual risk assessors. The IPCS also conducts regional and local training sessions in risk assessment, using their methodological publications as teaching materials.

Chemical incidents and emergencies are global problems, irrespective of whether they occur in industrialized or developing countries. Such incidents include spills of oil from tankers, explosions in chemical factories, and mishaps in overland transportation of chemical products and substances. The primary role of IPCS in such episodes is to interact with public health and medical authorities. More specifically, the IPCS provides guidance and training to member states in their planning on how to respond to chemical incidents and emergencies. The IPCS also serves as a source of technical information, advice, and assistance on the health implications of chemical incidents. In particular, WHO keeps a World Directory of Poisons Centres for access by first responders and health professions responding to chemical incidents and emergencies.

INCHEM is an IPCS database that offers access to "[t]housands of searchable full-text documents from international bodies on chemical risks and chemical risk management" [81]. The database can be accessed through the Internet and is free of charge. Included in the INCHEM database are the IPCS's EHCs, CICADS, Health and Safety Guides, ICSCs, and documents from non-IPCS sources. This database would seem to have a broad-based audience, ranging from emergency responders to academic researchers.

INTOX [82] is an IPCS database that is primarily directed to poison centers and health care providers who respond to chemical poisonings. Poison centers in particular need information on the toxicity of toxins and toxicants when caring for victims of exposure to both natural hazards (e.g., snake venom) as well as anthropogenic chemicals (e.g., industrial solvents). INTOX gives health professionals direct access to a database that will assist them in the diagnosis and treatment of poisonings, complemented by data management software. The INTOX system is a primary resource for health professionals in developing countries, where local databases on poisonings may not exist.

11.5.3 World Health Assembly's Resolution on Chemicals Management, 2016

The World Health Assembly is the decision-making body of WHO. It is attended by delegations from all 192 WHO Member States and focuses on a specific health agenda prepared by its Executive Board. The main functions of the World Health Assembly are to determine the policies of the Organization, appoint the WHO Director-General, supervise financial policies, and review and approve the proposed program budget. The Health Assembly is held annually in Geneva, Switzerland. At the 69th World Health Assembly, May 23–28, 2016, Member Nations urged WHO:

1. To engage proactively, including by strengthening the role of the health sector, in actions to soundly manage chemicals and waste at the national, regional and international levels in order to minimize the risk of adverse health impacts of chemicals throughout their life cycle;
2. To develop and strengthen, as appropriate, multisectoral cooperation at the national, regional and international levels in order to minimize and prevent significant adverse impacts of chemicals and waste on health, including within the health sector itself;
3. To take account of the Strategic Approach's overall orientation and guidance towards the 2020 goal, including the health sector priorities, as well as the strategy for strengthening engagement of the health sector, and consider Emerging Policy Issues and Other Issues of Concern, and to take immediate action where possible and where appropriate to accelerate progress towards the 2020 goal;
4. To encourage all relevant stakeholders of the health sector to participate in the Strategic Approach and to ensure appropriate linkages with their national and regional Strategic Approach focal points, and to participate in the reports on progress for the Strategic Approach;
5. To strengthen individual, institutional and networking capacities at the national and regional levels to ensure successful implementation of the Strategic Approach;
6. To encourage health sector participation in the intersessional process established through the fourth session of the International Conference on Chemicals Management to prepare recommendations regarding the Strategic Approach and the sound management of chemicals and waste beyond 2020, including in the third meeting of the Open Ended Working Group;
7. To continue and, where feasible, increase support, including financial or in-kind scientific and logistic support to WHO's Secretariat's regional and global efforts on chemicals safety and waste management, as appropriate;
8. To pursue additional initiatives aimed at mobilizing national and, as appropriate, international resources, including for the health sector, for the sound management of chemicals and waste;
9. To strengthen international cooperation to address health impacts of chemicals and waste, including through facilitating transfer of expertise, technologies and scientific data to implement the Strategic Approach, as well as exchanging good practices [83].

In pursuit of these urgings from the World Health Assembly, the Director-General of WHO was directed: (1) To develop, in consultation with Member States, and other relevant stakeholders, a road map for the health sector at the national, regional and international levels towards achieving the 2020 goal and contributing to relevant targets of the 2030 Agenda for Sustainable Development, taking into account the overall orientation and guidance of the Strategic Approach to International Chemicals Management, and the intersessional process to prepare recommendations regarding the Strategic Approach and the sound management of chemicals and waste beyond 2020 established through the fourth session of the International Conference on Chemicals Management, and building on WHO's existing relevant work. […] [84].

Perspective: WHO, as the primary health organization within the structure of the UN, performs the invaluable task of protecting and promoting the planet's human health. The organization has increasingly become active in issues of environmental health, several of which were described in this section. With the urging of the World Health Assembly, WHO will provide additional leadership in environmental health, assuming that resources are commensurate with the organization's responsibilities.

11.6 HAZARD INTERVENTIONS

The Chemical Age has brought many benefits to humankind, along with substantial problems. One can assert that chemical pesticides have improved food crop production and quality of food products. Further, insecticides and fungicides have been useful for combating insects and fungi that can cause serious adverse human health effects; for example, mosquitoes that transmit the Zika virus. One can also assert that chemicals are beneficial for producing commercial products such as vehicles, clothing, appliances, furniture, and such. But the Chemical Age has also brought deleterious health consequences to human and ecosystem health, as described in this chapter. Hazard interventions are required as means to render these consequences to acceptable terms.

1. Hazardous chemical substances should continue to be subject to societal controls, given their potential to harm health.
2. Support of policymakers who advocate for safe production, distribution, and consumer use of chemicals is necessary if human and ecosystem health is to be protected.
3. Education about the hazards of environmental hazardous substances should be a component of elementary schools.
4. Labels on containers of hazardous substances should be informative, up to date, and monitored for accuracy.
5. Alternatives to use of chemical pesticides should be considered when and wherever practicable.
6. Organic products should be considered for food and other domestic supplies.
7. Children's exposure to hazardous chemical substances should be monitored by parents and mitigated where possible.

8. Public health departments should incorporate environmental health expertise and programs as essential ingredients of their public service.
9. Individuals can reduce their exposure to hazardous substances by appropriate disposal of containers and other products that contained hazardous substances.

11.7 SUMMARY

The five major U.S. policies on control of hazardous chemical substances in the general environment are presented in this chapter. While other chapters have discussed chemical pollutants in air, water, food, and waste, this chapter deals with policies that are specific to hazardous substances found in general commerce. The five U.S. policies specific to control of toxic substances were discussed, along with those of the EU and the WHO. Associations between hazardous substances and effects on human and ecosystem health were presented herein. Each of the federal statutes on the control of pesticides and toxic substances described in this chapter has the public health objective of preventing or reducing human contact with chemical substances that could exert toxic effects. Each statute has some interesting policies of relevance to public health. Of the discussed statutes, the FIFRAct is the oldest, dating to 1910 when federal pesticides legislation was first enacted by Congress. The core purpose of the FIFRAct is to control the release into the environment of pesticides and other chemical substances expressly designed to kill specific life forms.

There are several the FIFRAct policies of importance to public health. The FIFRAct requires that pesticides must be registered with EPA and used only under prescribed conditions of application. This can be considered as the permit policy, without calling it such in the FIFRAct. It is also a kind of command and control policy, in that manufacturers are commanded to register their products with the EPA, which has authority to control how the products are used. Two other policies of relevance to public health practice include (1) public disclosure of pesticides information, unless it is classified as a trade secret, and (2) holding pesticides imported into the U.S. to the same requirements as domestically produced pesticides. The former policy is a statement of the public's right to know; the latter policy closes a potential gap in the distribution and application of pesticides in the U.S. It is an extra measure of prevention that is consistent with hazard elimination practices by public health officials.

The TSCAct was intended by Congress to regulate chemical substances. In particular, substances that have toxic properties are to be banned, or given restricted use, from commerce in the U.S. In a sense, this is a kind of quarantine for toxic substances. The act also adopted the policy of requiring chemical producers, importers, and processors to give premanufacture notification (PMN) to EPA. This information is to be used by the EPA for evaluating chemicals' potential adverse effects on human health and the environment. This policy places responsibility on the chemical industry to test their products and furnish the information to the EPA as a component of the PMN. This is an example of accountability as public policy in action. Unfortunately, as noted in this chapter, TSCA was a failure in terms of regulating hazardous substances, since language in the act made it essentially impossible for EPA to act.

The FQPAct is primarily about updating and strengthening the regulation and control of pesticides. In particular, the act targets the need for extra protection of children potentially exposed to pesticides. The act directs the EPA to apply an additional safety factor of 10 in risk assessments where children may at risk of exposure. This policy, extra protection for children, is consistent with the public health practice of special attention given to vulnerable populations.

The FHSAct requires companies that produce commercial hazardous substance products to label the products in ways which facilitate consumer protection. As such, the embedded policy is that of the public's right to know. An auxiliary policy is that of manufacturers' responsibility to inform the government (i.e., CPSC) of their products' properties.

Also discussed in this chapter were policies on hazardous substances developed and implemented by the EU and the WHO. Both international organizations' policies on controlling the release into environmental media and preventing adverse effects on human and ecosystem health are noteworthy. EU directives and regulations that pertain to hazardous substances require chemical manufacturers to provide toxicological data and environmental impact information to the EU for review and registration. WHO programs are primarily informational, with the needs of developing countries paramount in the organizations actions. WHO's IARC work on identifying carcinogens has a global impact on public health, given that the agency's pronouncements are used globally to shape programs of chemical interdictions.

11.8 POLICY QUESTIONS

1. Concerning the practical significance of the FQPAct: (a) using EPA resources, ascertain the Act's impact on that agency's children's health program; (b) in your opinion, should the act have repealed the Delaney Clause, formerly a component (and embedded policy) of the FDCAct, as amended? Why?
2. The FIFRAct requires the EPA to regulate the sale and use of pesticides in the U.S. of products known as "restricted-use pesticides," which are those assessed by EPA to be dangerous to the applicator or to the environment. Using EPA resources, identify such a pesticide and discuss why it was classified for restricted use. What special precautions were developed for the pesticide's use and application?
3. Using Internet resources published by the responsible federal agencies, develop a summary of the programs, policies, and progress that comply with Title X of the Housing and Community Development Act of 1992.

4. The TSCAct, as amended, divides chemicals into two broad categories: existing and new. Discuss the EPA's regulatory responsibilities and regulatory policies for each category.
5. TSCA §7 provides the EPA with the authority to take emergency action through the federal district courts in order to control a chemical substance or mixture that presents an imminent and unreasonable risk of serious widespread injury to human health or the environment. Discuss why the EPA must work through a court in order to interdict an "imminent" hazard.
6. Assume that you work in a county health department. The county has become infested with mosquitoes, raising anxiety in the public that mosquito-borne diseases could result. Your department decides to use Malathion, a pesticide, to periodically spray those areas known to have high concentrations of mosquitoes. You are assigned the task of informing the public of the department's plans. What do you say to the public?
7. Why should the government require that pesticides be registered?
8. What are trade secrets and how do they relate to the FIFRAct?
9. Examine the warning label on a commercially available pesticide. Discuss its content in the context of personal and public health.
10. §26 of the TSCAct permits the EPA to impose regulatory controls on categories of chemicals, not just individual chemicals. Discuss the advantages to public health of regulating categories of chemicals.
11. The NTP coordinates the preparation of biennial reports to Congress on the subject of chemical carcinogens (RoC). (a) Using Internet resources access the most current RoC and identify five listed carcinogens of interest to you. Discuss the RoC's characterization of each of the five. (b) As a public health specialist, what do you consider to be the public value of the RoC.
12. The Lautenberg Chemical Safety for the 21st Century Act is touted by chemical industry representatives and some environmental organizations as an improvement to the TSCA, as amended. Do you agree? If so, why? If not, why not?
13. Access the TEDX website (www.TEDX.org) and prepare an essay of appropriate depth on the public health significance of endocrine disruptors. Be specific and provide references to any material you have cited in your essay. Further, assume that your essay is to be orally presented to a community grassroots environmental group.
14. Using Internet and other resources, discuss the EU's REACH policy and program. List the most significant provisions of the REACH program that in your opinion are protective of public health.
15. As the senior public health officer in your local health department, a community group of concerned parents of young children has asked to meet with you in regard to a new issue of concern to them. They have heard via social media about something called "obesogens" and are seeking your advice on whether the local school district's food program is serving obesogens to their children. Will you meet with them? If so, how will you prepare for the meeting? What will you tell them? Will you involve the school district's food administrators?
16. Congratulations! You have been accepted as a summer intern at a local food distribution company. On your first day of work you observe a commercial pesticide company is spraying the company's food storage warehouse. As a person well versed in the requirements of the FIFRAct, do you take any action? If so, what? If not, why not? Be specific.
17. What is your personal opinion about organic food? Do you purchase organics? If so, why? If not, why not? Be specific.
18. The local school district has reached out to your local public health department for advice on assessing any health risk to children who drink water from school water fountains. Knowing of your expertise in environmental health policies, the department's director assigns you to respond to the school district. What will you do? Be specific.
19. Your cousin's young children are under the care of a senior pediatrician at a local medical practice. A routine blood assay indicated the presence of a minute amount of blood lead in both children. The pediatrician says not to worry because it's only a trace indicator of lead exposure. As a public health specialist, what advice would you provide your cousin? Be specific and cite any references to material that would attend your advice.
20. Well, you have completed another chapter in this book. We trust that the material has not caused any toxic reactions. Please discuss the three most important lessons you learned. Was your personal environmental health behavior changed by the content of this chapter? If so, how? If not, why not?

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12 Waste Generation and Management

12.1 INTRODUCTION

This chapter is about waste generation and its management, with mismanagement of waste constituting a hazard to human and ecological health. The definition of "waste" used in this text is simply "material that is discarded." Other more elaborate definitions can be found in dictionaries and elsewhere, but this definition is preferred due to its simplicity. This definition leaves open the reality that one person's waste could become another person's desirable resource, i.e., the idea of recycling of "waste."

As related in this chapter, waste in general requires careful management, lest human and ecological consequences ensue. Of particular note is the problem of contemporary sources and kinds of waste: e-waste (electronics products) and plastics as waste material. Figure 12.1 illustrates an example of plastic waste floating in the Pacific Ocean. As described in this chapter, plastics are a major threat to marine life and coastal ecosystems. Moreover, as an alarming human and ecological health portent, the World Bank forecasts that global waste is on pace to triple by year 2100 [1].

While waste was undeniably left by our primordial ancestors, as humankind grew in population size, social complexity, and outreach, one factor became strongly associated with the nature and volume of waste generated, especially in the context of waste's impact on the human environment. It is asserted here that technology has been a prime factor in humankind's waste generation and its management. For instance, the Industrial Revolution of the seventeenth and eighteenth centuries began the development, manufacture, and distribution of goods and services that in turn generated waste. The wastes came from such factors as inefficiencies in manufacturing of goods, sinks that were too easily available for waste disposal, and social acceptance of wastes as a sign of industrialization and economic growth. Irrespective of these and other factors, the outcome was the same: materials were discarded into air, water, and land. As industrialization continued to increase across national borders, waste concomitantly grew in volume and character.

Two world wars of the early twentieth century fueled further growth of industrialization, followed by what could be called the Chemicals Age, which continues today. The globalization of the production of various chemicals, ranging from cosmetics to pharmaceuticals to weapons has been accompanied by wastes of special character and challenge. As described in this chapter these chemical wastes can have properties that are hazardous to human and ecological health. These kinds of chemical wastes are in addition to the solid and liquid wastes produced daily by human populations, as subsequently described herein.

In addition to a description of U.S. waste management policies, the policies of the EU are presented, as well as details on contemporary waste issues of waste management of discarded electronic products, plastics, and food. Of particular note will be a presentation of issues of the recycling of waste materials.

12.2 POLICY OVERVIEW

As preface, involvement of the U.S. federal government in regulation of solid and hazardous waste was not part of the environmental movement of the early 1960s [1a]. Environmentalists had given priority to supporting legislation that would improve air and water quality. Moreover, U.S. states, territories, and municipalities had long had the responsibility for managing municipal waste collection, waste dumps, and sanitary landfills. In an earlier age, during the years of Colonial America and the agrarian period that followed, farmers disposed of their own solid wastes, much of which was recycled as fertilizer for soil and crop enrichment. Towns and cities during this period continued the longstanding practice of creating open waste dumps, usually located at a distance from occupied areas. Human wastes were disposed of in privies and some cities established rudimentary sewage management facilities. These were local responsibilities; the federal government simply was not involved until early in the twentieth century.

Perhaps the earliest federal involvement in solid waste management is found in the PHSAct, which in 1913 stated, "The Public Health Service may study and investigate the diseases of man and conditions influencing the propagation and spread thereof, including sanitation and sewage [...]." [2]. While this authority led to research on waste disposal, almost two decades passed before federal legislation specific to management of solid and hazardous waste appeared. In 1965, Congress enacted the Solid Waste Disposal Act (SWDAct). It was the first federal statute focused solely on waste management. Congress had found "[t]hat the problem presented by solid waste disposal was national in scope and necessitated federal action in assistance and leadership" [3]. However, the act also stated that the collection and disposal of solid waste should continue primarily to be the function of state, regional, and local agencies. Under the SWDAct, funds were made available for research on solid waste disposal. In effect, the Act continued, but more directly focused, research on waste disposal already authorized in the Public Health Service Act (PHSAct).

In 1965, Congress enacted the Solid Waste Disposal Act. It was the first federal statute focused solely on waste management.

FIGURE 12.1 Plastic waste pollution in the Pacific Ocean. (From NOAA Marine Debris Program, 2016.)

The proper disposal of hazardous wastes became a concern of Congress commencing in the 1970s. Described in this chapter are the SWDAct, the Resource Conservation and Recovery Act (RCRAct), two acts that deal with the permitted disposal of solid and hazardous wastes; and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLAct), enacted by Congress to address the environmental and human health problems caused by uncontrolled hazardous waste, particularly abandoned hazardous waste sites (HWS). Also described are federal statutes for controlling dumping of waste into oceans and for preventing environmental pollution from oil spills. The chapter includes a discussion of the Pollution Prevention Act (PPAct), a statute that expressly focuses on the prevention of pollution through means of recycling and improved waste management.

12.3 U.S. RESOURCE CONSERVATION AND RECOVERY ACT, 1976

This section describes what could be called the master federal legislation, as amended, for regulation of solid and hazardous waste in the U.S. And as with other federal environmental health statutes, concern for the public's health was a motivating factor in the statute's enactment. The act has an interesting history, providing some insight into evolving and enlarging concerns about the consequences of waste mismanagement in the U.S.

12.3.1 History

The RCRAct established the federal program that regulates solid and hazardous waste management. The RCRAct amends earlier legislation, the SWDAct of 1965, but the amendments were so comprehensive that the act is commonly called RCRAct rather than by its official title [4]. The RCRAct defines solid and hazardous waste, authorizes the Environmental Protection Agency (EPA) to set standards for facilities that generate or manage hazardous waste, and establishes a permit program for hazardous waste treatment, storage, and disposal facilities. As policy, controlling waste releases through a permitting system for individual waste generators emulates the permitting system in the CWAct. Amendments to the RCRAct have set deadlines for permit issuance, prohibited the land disposal of many types of hazardous waste without prior treatment, required the use of specific technologies at land disposal facilities, and established a new program regulating underground storage tanks. The EPA is also given authority to inspect hazardous waste facilities coverable under the RCRAct and is given enforcement powers to ensure compliance with federal RCRAct requirements [4].

* * *

The amounts of waste generated in the U.S. are huge and as such bring challenges to waste managers. As characterized by the National Research Council, the three categories of waste are municipal solid waste, medical wastes, and hazardous waste [5]. An appreciation of the generated amounts and composition of these wastes is useful for public health considerations.

Municipal solid waste (MSW)—This category of waste is defined as "[t]he solid portion of the waste (not classified as hazardous or toxic) generated by households, commercial establishments, public and private institutions, government agencies, and other sources" [5]. The volume of MSW has steadily increased in the U.S., as shown as EPA data in Figure 12.2. The per capital rate has begun to decrease,

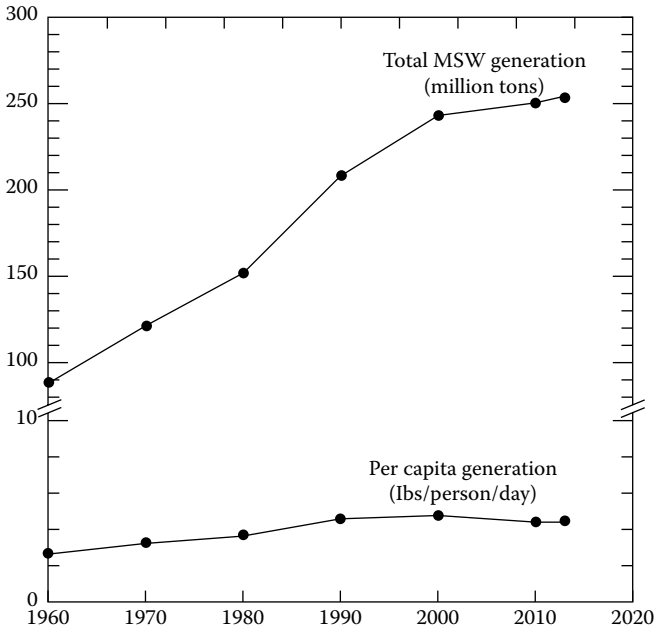

FIGURE 12.2 MSW generation rates in the U.S., 1960–2017. (From EPA (Environmental Protection Agency), MSW generation rates in the U.S., 1960–2017, 2017, https://www.google.com/search?q=MSW+generation+rates+in+the+U.S.,+1960-2017&tbm=isch&tbo=u&source=univ&sa=X&ved=0ahUKEwigo8q47uPTAhUHbSYKHd-9A3AQsAQIOQ&biw=1024&bih=714.)

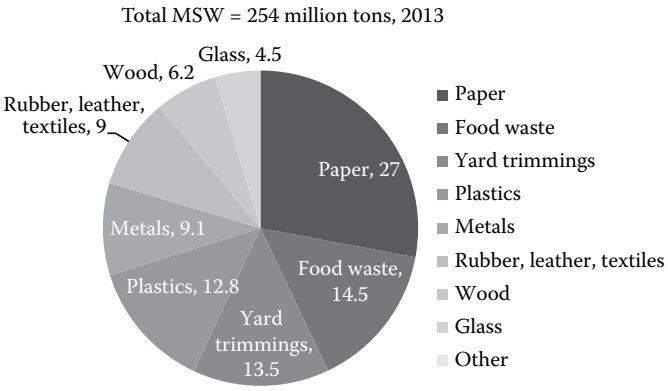

FIGURE 12.3 Total MSW generation in the U.S., 2013. (From EPA (Environmental Protection Agency), Municipal solid waste, Office of Solid Waste and Emergency Response, Washington, DC, 2016.)

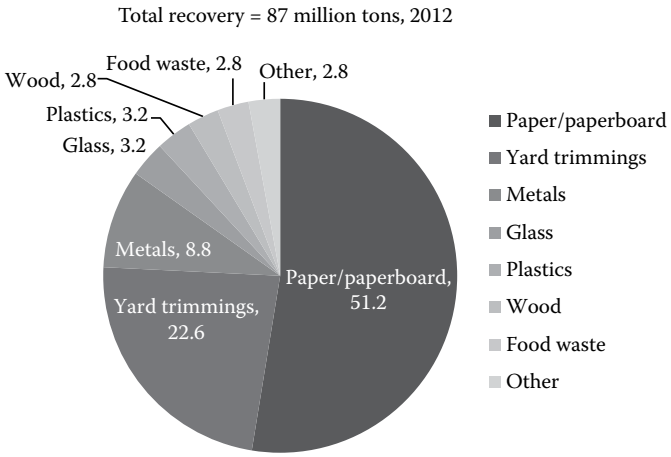

FIGURE 12.4 Percentage of total MSW recovery (by material), 2012. (From EPA (Environmental Protection Agency), Municipal solid waste generation, recycling, and disposal in the United States: Facts and figures for 2012, EPA-530-F-14-001, Office of Solid Waste and Emergency Response, Washington, DC, 2014.)

The Solid Waste Disposal Act and the Resource Conservation and Recovery Act provide regulation of solid and hazardous wastes [4].

commencing in year 2000, which suggests that programs of recycling have occurred [4a]. Figure 12.3 shows the top eight generators in the U.S. of MSW in 2013 with a total volume of 254 million tons. Of this volume, the EPA estimated that the U.S. recycled or composted about 87 million tons of this material, equivalent to a 34.3% recycling rate [6].* As shown in Figure 12.4, some MSW is recovered through recycling or other means. Noteworthy in the figure is that about 50% of this total represents paper and paperboard products. In the EU, the average amount of municipal waste generated in 2003 ranged from 2.1 to 3.5 lbs a person per day across the then 25 member states, of which two-thirds came from households [7]. The environmental health policy implication is that recycling of paper and paperboard can significantly reduce the amount of MSW that is taken to permitted landfills, thereby decreasing landfills' volume and area.

Medical waste—These wastes constitute a particularly important hazard to human health. Medical wastes are generated throughout the U.S. health-care system. Hospitals, in particular, produce the greatest volume of medical waste, according to one source generating about 26 lbs. of waste per bed per day [5]. An estimate of the annual volume of generated medical wastes is unknown. A crude division of medical wastes consists of that part which contains infectious pathogens (e.g., HIV) and wastes that do not pose an infectious hazard. Under the provisions of the RCRAct, infectious medical wastes must be incinerated or otherwise handled by permitted waste disposal facilities. Noninfectious medical wastes under the RCRAct can be handled as MSW and taken to permitted landfills.

Hazardous waste—Under the provisions of the RCRAct, hazardous waste is a waste material that can be categorized as potentially dangerous to human health or ecosystems. Figure 12.5 shows the five greatest forms of hazardous waste [118]. As inferred from the figure, the chemical and allied industries are the top generators. According to the EPA, more than 20,000 hazardous waste producers annually produce more than 40 million tons of hazardous waste regulated under the RCRAct [6]. Of this amount, about 4% is hazardous waste produced in households (i.e., more than 1.6 million tons). Leftover household products that contain corrosive, toxic, ignitable, or reactive ingredients are considered by the EPA to be household hazardous waste [8]. Products such as paints, cleaners, oils, batteries, pest poisons, and pesticides contain potentially hazardous substances that require special care for proper waste disposal.

As previously described, the amount of municipal, medical, and hazardous wastes produced in the U.S. is enormous. If one accepts the proposition that waste generation is fundamentally wasteful, having important consequences such as environmental quality (e.g., air pollution, landfills), economic burdens (e.g., cost of waste disposal), health impacts (e.g., effects of air pollution on children's health), and social disruption (e.g., disputes on where to site landfills), what can be done to lessen these impacts? Some waste will always be inevitable, but a policy of waste reduction and minimization comports with good public health practice.

As shown in Table 12.1, the EPA promotes the three Rs of waste reduction: Reduce, Reuse, and Recycle [9], to which the authors of this book have added Redesign. The following material elaborates on EPA's three Rs, as well as elaborating on Redesign:

- Reduce:—Source reduction, often called waste prevention, means consuming and throwing away less. Source reduction includes purchasing durable, long-lasting goods and seeking products and packaging that are as free of toxics as possible. It can be as complex as redesigning a product to use less raw material

* Solid waste refers here to household and industrial wastes, not bodily wastes.

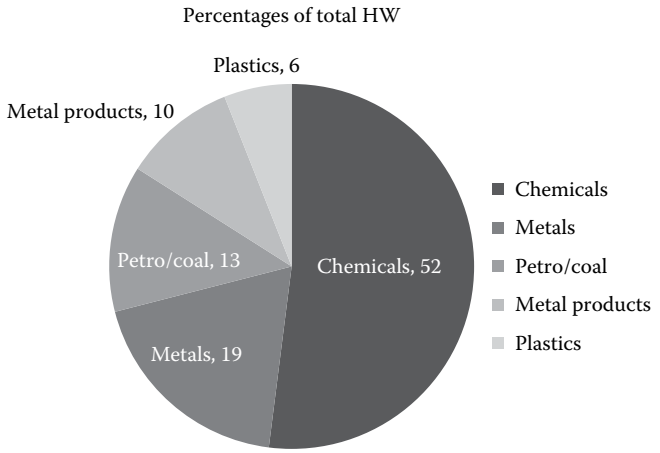

FIGURE 12.5 Top five hazardous wastes by percentage of total hazardous waste generation in the U.S. (From EPA, Skinner, J., Hazardous waste treatment trends in the U.S., *Waste Manag. Res.* 9, 55, 1991.)

TABLE 12.1
The Four Rs of Waste Reduction

R	Action
Redesign	Eliminate or reduce waste via redesign
Reduce	Consume and discard less
Reuse	Do not discard if reuse is possible
Recycle	Convert waste into usable products

Source: EPA (Environmental Protection Agency), Municipal solid waste. Reduce, reuse, and recycle. Office of Solid Waste, Washington, DC, 2005.

in production, have a longer life, or be used again after its original use is completed. Because source reduction actually prevents the generation of waste in the first place, it is the most preferable method of waste management and goes a long way toward protecting the environment.

- Reuse:—Reusing items by repairing them, donating them to charity and community groups, or selling them also reduces waste. Use a product more than once, either for the same purpose or for a different purpose. Reusing, when possible, is preferable to recycling because the item does not need to be reprocessed before it can be used again.
- Recycle—Recycling turns material that would otherwise become waste into valuable resources and generates a host of environmental, financial, and social benefits. After collection, materials (e.g., glass, metals, plastics, and paper) are separated and sent to facilities that can process them into new materials or products [9].

Redesign—All products and devices must go through a design phase. This occurs for new products as well as for existing products or devices that already exist, but are being considered for update or revision. At this stage of development, consideration should be given to whether a redesign should occur in order to reduce or eliminate waste.

According to the EPA, recycling is one of the best environmental success stories of the late twentieth century. By the agency's assessment, recycling—including composting—diverted 68 million tons of material away from landfills and incinerators in 2001, an increase of 34 million tons from 1990 [9]. Further, EPA credited curbside waste recycling programs with producing a diversion of about 30% of the U.S.'s solid waste in 2001.

* * *

The RCRAct contains a statement of national environmental health policy, "The Congress hereby declares it to be the national policy of the U.S. that, wherever feasible, the generation of hazardous waste is to be reduced or eliminated as expeditiously as possible. Waste that is nevertheless generated should be treated, stored, or disposed of so as to minimize the present and future threat to human health and the environment [10]. This pollution prevention policy set a course for subsequent federal and state regulatory action.

The RCRAct is a regulatory statute designed to provide "cradle to grave" control of hazardous waste by imposing management requirements on generators of hazardous waste and transporters, and upon owners and operators of treatment, storage, and disposal facilities. The statute principally applies to operating waste management facilities, whereas the CERCLAct applies mainly to uncontrolled HWS. The RCRAct deals with both hazardous waste and nonhazardous waste, although the main emphasis in the act is on the former. More than 500,000 companies and individuals in the U.S. who generate more than 172 million metric tons (MTs) of hazardous waste each year are covered under the RCRAct regulatory programs [11,12]. The RCRAct, as amended, represents a significant challenge to the regulated community. In particular, industry is challenged to find new ways to minimize, treat, and dispose of hazardous waste. The use of innovative technologies, like bioremediation, to reduce waste is the subject of active research and development.

Wastes covered under the RCRAct are defined in the statute. The RCRAct, Subtitle A, defines solid waste as being "any garbage; refuse; sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility; and other discarded material including solid, liquid, semisolid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations, and from community activities; but does not include solid or dissolved material in domestic sewage, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to permits under §402 of the Federal Water Pollution Control Act, as amended, or source, special nuclear, or byproduct material as defined by the Atomic Energy Act of 1954, as amended" [10].

The SWAct Amendments of 1980 banned open waste dumps, thereby eliminating a public health hazard that had existed since antiquity.

Under the RCRAct, Subtitle A, hazardous waste "means a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may either cause, or significantly contributed to an increase in mortality or an increase in serious irreversible or incapacitating reversible illness; or pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed" [10].

The RCRAct therefore applies to almost any waste regardless of its physical form. EPA regulations have further clarified the definition of wastes coverable under the RCRAct. It is a complex and comprehensive statute, implemented by the EPA through a set of extensive regulations.

12.3.2 Amendments to the RCRAct

Starting in 1980, Congress has enacted seven amendments to the RCRAct (Table 12.2). As subsequently elaborated, the amendments of 1980 and 1984 were substantive and made major changes in how solid waste is managed in the U.S. The other amendments were largely technical adjustments to existing legislation. The amendments address specific areas of solid and hazardous waste management, but have not changed the basic thrust of the RCRAct's basic principles. Following are descriptions of the major amendments to the RCRAct.

The Used Oil Recycling Act of 1980 amended the SWDAct by defining the terms *used oil*, *recycled oil*, *lubricating oil*, and *re-refined oil*. The EPA Administrator was directed to promulgate regulations to establish performance standards and other requirements necessary to protect the public health and environment from the hazards of recycled oil. Moreover, the EPA was authorized to provide grants to states with approved solid waste plans that (1) encourages the use of recycled oil, (2) discourages uses hazardous to the public's health and environment, (3) calls for informing the public of the uses of recycled oil, and (4) establishes a program for the collection and disposal of used oil in a safe manner [4].

Also in 1980, the SWDAct Amendments were substantive and gave the EPA broader powers to deal with illegal disposal of hazardous waste. Two provisions were of special import. One provision prohibited open dumping of solid waste and hazardous waste. This prohibition brought to close a human practice that dates to antiquity. Moreover, banning of open dumps was a major public health contribution. Gone were the open dumps that were rife with disease-carrying vermin and which provided human access to areas that contained decomposing food, hazardous chemicals, and physical hazards. Further, standards were developed for the sanitary disposal of solid waste in dump sites that are designed to prevent releases of hazardous substances into ambient air and underground aquifers [4].

The other important provision authorized the EPA Administrator to issue orders requiring individual facility operators to do monitoring, testing, analysis, and reporting necessary to abate hazards to human health and the environment. Other key changes included: (1) transferred from the EPA to the Department of the Interior all responsibilities for managing coal mining wastes, (2) expanded the EPA's standards applicable to generators of hazardous waste and their responsibility for the arrival of wastes at waste management facilities, (3) set forth criminal and civil penalties for failures to comply with waste management permits, and (4) directed each state to submit to the EPA an inventory of hazardous waste storage and disposal sites.

An even more significant set of amendments to the SWDAct were the Hazardous and Solid Waste Amendments of 1984, comprising six titles and accompanying subtitles [11]. Title I revised findings and objectives of the act to include minimizing the generation and the land disposal of hazardous waste, and declared it to be the national policy that, wherever feasible, the generation of hazardous waste is to be reduced or eliminated as expeditiously as possible, but without stating how. This title states, "Waste that is nevertheless generated should be treated, stored, or disposed of so as to minimize the present and future threat to human health and the environment."

One of the most significant provisions of the 1984 amendments to the RCRAct is the prohibition of land disposal of hazardous wastes [11]. In a phased approach, the act bans the

TABLE 12.2
SWDAct and RCRAct Amendments

Year	Act
1965	Solid Waste Disposal Act
1970	Resource Recovery Act
1976	Resource Conservation and Recovery Act
1980	Used Oil Recycling Act
1980	Solid Waste Disposal Act Amendments
1984	Hazardous and Solid Waste Amendments
1988	Medical Waste Tracking Act
1992	Federal Facility Compliance Act
1996	Lead Disposal Program Flexibility Act
2012	Hazardous Waste Electronic Manifest Establishment Act

Source: McCarthy, J.E. and M. Tiemann, Solid Waste Disposal Act/Resource Conservation and Recovery Act, Congressional Research Service, Report RL 30022, http://www.ncseonline.org/nle/crsreports/briefingbook/laws/h.cgm, 1999.

ENFORCEMENT EXAMPLE

(Washington, DC—October 1, 2015) The EPA and U.S. Department of Justice announced a settlement with Mosaic Fertilizer, LLC that will ensure the proper treatment, storage, and disposal of an estimated 60 billion pounds of hazardous waste at six Mosaic facilities in Florida and two in Louisiana. The settlement resolves a series of alleged violations by Mosaic of the federal RCRAct, which provides universal guidelines for how hazardous waste must be stored, handled, and disposed. The 60 billion pounds of hazardous waste addressed in this case is the largest amount ever covered by a federal or state RCRAct settlement [13].

disposal in landfills of bulk or non-containerized liquid hazardous wastes, and hazardous wastes containing free liquids. The act then required the EPA to determine whether to ban in whole or in part the disposal of all the RCRAct hazardous wastes in land disposal facilities. At the same time, the EPA must establish treatment standards for each restricted waste based on the Best Demonstrated Available Technologies (BDAT). If the restricted waste is first treated to BDAT levels, the treated waste or residue can then be placed in land disposal facilities.

The Medical Waste Tracking Act of 1988 had the purpose "To amend the Solid Waste Disposal Act to require the Administrator of the EPA to promulgate regulations on the management of infectious waste" [14]. The act had been precipitated by the discovery of medical waste that had washed ashore along the coasts of some northeastern states, particularly in New Jersey. Two provisions were at the heart of the Act. One provision required the EPA, in cooperation with five states, to establish a 2-year demonstration program to track listed medical wastes, and segregate, contain, and label such wastes to protect waste handlers and the public. The act also directed the Agency for Toxic Substances and Disease Registry (ATSDR) Administrator to report to the Congress within 2 years of this Act's enactment on the health effects of medical waste. The outcomes of these two provisions are discussed in a subsequent section.

The Federal Facility Compliance Act of 1992 amended the SWDAct to (1) waive the sovereign immunity of the U.S. for purposes of enforcing federal, state, interstate, and local requirements with respect to solid and hazardous waste management; (2) make federal employees subject to criminal sanctions under such laws; (3) prohibit federal agencies from being subject to such sanctions; (4) require the Secretary of Energy to develop a treatment capacity and technology plan for each facility at which the Department of Energy (DOE) generates or stores mixed wastes; (5) direct the Administrator to promulgate regulations identifying when military munitions become hazardous waste and providing for the safe transportation and storage of such waste; (6) exclude from the definition of "solid waste" solid or dissolved material in domestic sewage; and (7) require the Administrator to establish a program to assist small communities in planning and financing environmental facilities and compliance activities [4].

The Land Disposal Program Flexibility Act of 1996 exempted small landfills located in arid or remote areas from groundwater monitoring requirements, provided there is no evidence of groundwater contamination. This act also exempts hazardous waste from the RCRAct regulation if it is treated to a point where it no longer exhibits the characteristics that made it hazardous, and is subsequently disposed in a facility regulated under the CWAct or SDWAct [11a].

12.3.3 Key Provisions of the RCRAct Relevant to Public Health

The subtitles of the RCRAct, as amended, are listed in Table 12.3 [10]. Those subtitles with particular relevance for public health policies and practices are discussed in the following sections.

TABLE 12.3
RCRAct, as Amended, Subtitles

Subtitle	Name of Subtitle
A	General Provisions
B	Office of Solid Waste: Authorities of the Administrator
C	Hazardous Waste Management
D	State or Regional Solid Waste Plans
E	Duties of Secretary of Commerce in Response and Recovery
F	Federal Responsibilities
G	Miscellaneous Provisions
H	Research, Development, Demonstration and Information
I	Regulation of Underground Storage Tanks
J	Demonstration Medical Waste Tracking Program

Source: EPA (Environmental Protection Agency), RCRA, Superfund and EPCRA hotline training module. EPA530-R-99-063, Office of Solid Waste and Emergency Response, Washington, DC, 2000.

Subtitle B—*Office of Solid Waste; Authorities of the EPA Administrator*—Establishes the EPA Office of Solid Waste and the authorities of the EPA Administrator in carrying out the provisions of the Act.

Subtitle C—*Hazardous Waste Management*—This part of the act is specific to the management of hazardous waste. §3001: requires that the Administrator develop and promulgate criteria for identifying the characteristics of hazardous waste. §§3002,3001(d),3003, 3004: require EPA to compile listings of hazardous wastes and to develop standards applicable to: generators of hazardous waste; transporters of hazardous waste; owners and operators of hazardous waste treatment, storage, and disposal facilities. Permits for treatment, storage, and disposal of hazardous waste are required. EPA is given authority to inspect hazardous waste facilities coverable under the RCRAct and is given enforcement powers to ensure compliance with federal RCRAct requirements. Each state is required to submit to EPA a continuing inventory that describes the location of each site at which hazardous waste has at any time been stored or disposed of. Similarly, each federal agency must provide the same kind of information to EPA. §3004(u) authorizes EPA or a state to require corrective action for all releases of hazardous waste or constituents from any solid waste management unit at a TSDF seeking a permit under Subtitle C, regardless of the time at which the waste was placed in the unit. Under §3008(h) EPA is authorized to assess a civil penalty to any interim status facility that has released hazardous waste into the environment. §3005 requires that each application for a final determination about a permit for a landfill or surface impoundment shall be accompanied by information reasonably ascertainable by the owner or operator on the potential for the public to be exposed to hazardous wastes or hazardous constituents through releases related to the unit. The exposure information is to be provided to EPA, which, in turn, shall

make it available to ATSDR for public health purposes. When EPA or a state determines that a particular landfill or surface impoundment poses a substantial potential risk to public health, they may request that ATSDR conduct a health assessment of the population at potential risk. However, ATSDR can conduct the requested health assessment "[...]. If funds are provided in connection with such request the Administrator of such Agency [i.e., ATSDR] shall conduct such health assessment." §3017 sets forth requirements on the export of hazardous waste to other countries. In general, the exporter must furnish EPA with information about the nature and amount of the waste, the country of destination, the ports of entry, the manner of transport, and the name and address of the ultimate treatment, storage, or disposal facility. Following receipt of the export information, EPA must request the Secretary of State to contact the receiving country to obtain that country's written consent to receive the exported hazardous waste.

Subtitle D—*State or Regional Solid Waste Plans*—Regulation of nonhazardous waste, under the RCRAct, is the responsibility of the states. The federal involvement is limited to establishing minimum criteria that prescribe the best practicable controls and monitoring requirements for solid waste facilities. Disposal of solid waste in open dumps is prohibited, but the RCRAct provides EPA with no enforcement authority for banning open dumps. (EPA's enforcement authority under the RCRAct covers only hazardous waste.)

Subtitle E—*Federal Responsibilities*—Federal statutes sometimes exempt federal agencies from an act's coverage. This may be for reasons of national security, economic factors, or political reasons. However, the RCRAct holds each department, agency, and instrumentality of the executive, legislative, and judicial branches of federal government having jurisdiction over any solid waste management facility or disposal site, or engaged in any activity resulting, or which may result, in the disposal or management of solid waste or hazardous waste to the same expectations and requirements "[a]s any person is subject to such requirements." Only the President can exempt a department's solid waste management facility if it is in the Nation's paramount interest.

Subtitle F—*Research, Development, Demonstration, and Information*—EPA is given authority to conduct research and studies on a range of areas that include adverse health and welfare effects of solid waste releases; resource conservation systems [...].

Subtitle G*—Regulation of Underground Storage Tanks*—EPA is directed to develop a comprehensive regulatory program for "underground storage tanks" [15]. The RCRAct directs EPA to promulgate release, detection, prevention, and correction regulation applicable to all owners and operators of underground storage tanks (UST), as may be necessary to protect human health and the environment. EPA estimates there are 700,000 UST facilities with about 2,000,000 tanks covered by this regulation.

Subtitle H—*Demonstration Medical Waste Tracking Program*—As previously stated, the Medical Waste Tracking Act of 1988 required EPA to create a demonstration program for tracking the shipment and disposal of medical wastes in a selected number of states. The participating states were Connecticut, New Jersey, New York, Rhode Island, and the commonwealth of Puerto Rico [16]. Apparently no report of the demonstration project's findings was prepared [16], and there was no follow-up by EPA on the development of federal regulations that would have mandated tracking of infectious medical waste [16], which was the original intent of the Act.

However, the Act's requirement that ATSDR prepare a report to Congress on the hazard presented by uncontrolled medical waste was accomplished, with the primary finding that such waste was not a national public health hazard, but that medical waste posed a greater than supposed hazard to municipal waste workers and that medical waste from in-home health care was a previously unrecognized health hazard. Given these findings, the ATSDR report contributed to states' enacting more stringent regulations and codes for purpose of controlling medical waste management [17]. This is an example of where a demonstration project, together with a comprehensive public health analysis, dissuaded Congress on the need for comprehensive regulations on an environmental hazard.

12.3.4 Associations between Solid Waste and Human Health

The human health consequences of permitted incinerators and landfills have not been the subject of any sustained program of research. However, one study in 2001 of adverse birth outcomes in populations residing near landfill sites found small excess risks of congenital anomalies (neural tube defects, hypospadias, and abdominal wall defects) and low to very low birth weight babies. The landfills in the study included some HWS [18]. The National Research Council reported in 2000 that few studies have tried to establish a link between an incinerator and illness in the surrounding area, and that most studies found no adverse health effects [5]. In contrast, some studies have shown that municipal incinerator workers have been exposed to high concentrations of dioxins and metals, but any adverse health effects have not been pursued in follow-up studies [19].

Medical waste incinerators are of public health concern because highly toxic dioxins are formed as a byproduct of incinerated plastic materials. The EPA has issued standards to reduce emissions from waste incinerators, based on a standard of "maximum achievable control technology" (BACT), and emissions should decrease over time. As public health policy, emissions from incinerators merit scrutiny by state environmental departments in order to assure that harmful emissions are not occurring.

12.3.5 Associations between Solid Waste and Ecosystem Health

The associations between solid waste and ecosystem health are largely confined to issues of landfills. Incinerated solid waste has not been a subject of ecosystem investigation, given little evidence that a problem exists. Solid waste, especially plastics, that reach oceans and other bodies of water are discussed in a subsequent section of this chapter. Therefore, the ensuing material focuses on the impacts of solid waste landfills on ecosystems. A review of landfills and ecosystem impacts conducted by the Chicago Metropolitan Agency for Planning (CMAP) follows [20]:

> *"Hazardous gas emissions*: In 1987, the EPA estimated that the nation's 7124 landfills emitted 15 million tons of methane per year and 300,000 tons of other gases like toluene and methylene chloride. As mentioned in Chapter 6 (Climate Change), methane is a powerful greenhouse gas and landfills contributed 23% of total emissions in 2006. In addition to its effect in the ozone layer, methane is also a highly combustible gas that may be responsible for various explosion hazards in and around landfills.
>
> *Water quality/contamination*: There is no expert consensus about the impact of MSW on surface and groundwater sources. Some argue that even common MSW items such as newspaper pose a significant risk to water quality, while others argue that the effect of landfills on groundwater would be negligible if hazardous materials (e.g., motor oil, paint, chemicals, and incinerator ashes) were prohibited from the sites. Experts also argue that while leachate is a clear environmental liability, the frequency and severity of leachate-related problems is uncertain and can be minimized through proper siting and sealing measures. However, if leachate does seep into groundwater, it can be the source of many contaminants, specifically organic compounds that may decrease the oxidation–reduction potential and increase the mobility of toxic metals. Locally, some solid waste managers catch errant leachate and pump it back into the landfill. This process helps keep it from seeping away and actually hastens the decomposition of the landfill contents.
>
> *Energy consumption*: As a community's tolerance for landfills decreases, they are moved farther from densely populated areas, requiring collection trucks to drive farther distances to unload. Also, the complexity of collection routes can affect energy consumption. This frequent and lengthy travel by gas-consuming vehicles is also detrimental to air quality and results in increased greenhouse gases.
>
> *Natural habitat degradation*: As land is claimed for landfills, it is no longer hospitable to many plants and wildlife. Often, this fertility cannot be completely reclaimed, even after the landfill is capped.
>
> *Biodegradation*: Responsibly sited and managed landfills are often preferred over other waste disposal methods, such as incineration, because, aside from being more economical, they allow most waste to decay safely and naturally. Conversely, the positive effects of biodegradation are often overstated when, in reality, landfills tend to mummify their contents, severely prolonging oxidation and natural breakdown processes" [20].

12.3.6 Illustrative State Solid Waste Act

As previously noted, the Solid Waste Act (SWAct), as amended, places solid waste management primarily as the responsibility of the states. This responsibility is effectuated by enactment of state laws, regulations, and solid waste codes. While state laws vary in content according to specific needs and circumstances, all state laws contain provisions that require permits to manage solid waste. This provision reflects requirements found in the SWAct, as amended. Other provisions are illustrated in one state's solid waste law. Following are excerpted provisions of the State of Georgia's solid waste code [21].

12.3.6.1 Permits*

"(a) No person shall engage in solid waste or special solid waste handling in Georgia or construct or operate a solid waste handling facility in Georgia [...] without first obtaining a permit from the director authorizing such activity.

(b)(1) No permit for a biomedical waste thermal treatment technology facility shall be issued by the director unless the applicant for such facility demonstrates to the director that a need exists for the facility for waste generated in Georgia by showing that there is not presently in existence within the state sufficient disposal facilities for biomedical waste being generated or expected to be generated within the state [...].

(c) On or after 30 March 1990, any permit for the transportation of municipal solid waste from a jurisdiction generating solid waste to a municipal solid waste disposal facility located in another county shall be conditioned upon the jurisdiction generating solid waste developing and being actively involved in, by 1 July 1992, a strategy for meeting the state-wide goal of waste reduction by 1 July 1996.

12.3.6.2 Permit Revocation

(e)(1) The director may suspend, modify, or revoke any permit issued pursuant to this Code section if the holder of the permit is found to be in violation of any of the permit conditions or any order of the director or fails to perform solid waste handling in accordance with this part or rules promulgated under this part [...].

* These headings were added for purpose of enhancing clarity. They do not appear in the cited Georgia code.

12.3.6.3 Site Modification

(2) Prior to the granting of any major modification of an existing solid waste handling permit by the director, a public hearing shall be held by the governing authority of the county or municipality in which the municipal solid waste facility or special solid waste handling facility requesting the modification is located [...].

(3) Except as otherwise provided in this part, major modifications shall meet the siting and design standards applicable to new permit applications in effect on the date the modification is approved by the director [...].

12.3.6.4 Site Inspection

(j) The director or his designee is authorized to inspect any generator in Georgia to determine whether that generator's solid waste is acceptable for the intended handling facility [...] ."

Perspective: A bit of reflection on the Georgia code shows several environmental health policies. The core policy is the permitting of waste managers, with provisions for permit revocation. State and federal permits for management of environmental hazards are a feature of many statutes. Permits provide a legal means for application of the command and control policy that leads to regulations and actions that are intended to ensure accountability of solid waste managers.

Other policies of note in the Georgia code include the following: (a) provisions for upgrading solid waste facilities when they undergo major modifications, with the intention of keeping such facilities in compliance with current management practices, and (b) provisions for on-site inspections by state inspectors. In a sense, both provisions are an expression of the public health policy of prevention of disease and disability.

12.3.7 Policy Issues

The SWAct, as amended, is an example of federalist policy. The states work with a federal agency, the EPA, to implement a federal environmental statute. As such, states bear considerable responsibilities for conducting their duties under the Act. For example, federal funding is not within states' control and, therefore, some states must supplement their solid waste program's funding via state funds. On a different policy plane, states must issue permits and conduct inspections of facilities that manage solid waste. These kinds of state policies can lead to variability between states, given differences in sociopolitical conditions and funding.

12.4 COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY ACT, 1980

As discussed in other parts of this book, nothing motivates policymakers to act more quickly and resolutely than the occurrence of a catastrophe. No legislator or other policymaker wants to be characterized as having turned a blind eye and deaf ear to dealing with a disaster. The Federal Meat Inspection Act (Chapter 10) is but one of several examples of environmental health policies that could be termed "disaster reaction" legislation. Another example, as will be evident from its history, is the CERCLAct of 1980.

12.4.1 History

The CERCLAct (aka Superfund) was enacted in 1980 and was reauthorized by the Superfund Amendments and Reauthorization Act of 1986 [12]. The statute was a direct consequence of the discoveries of releases of hazardous substances from abandoned landfills into community residences, in particular, the community of Love Canal, a suburb of Niagara Falls, New York, which was evacuated following the discovery that it overlay an abandoned chemical dump. Love Canal captured the public's attention because of intense news media coverage. Rarely did a day pass without national news media interviewing Love Canal residents, who expressed their concerns about the health of their children and future generations of children. They associated health problems in the community's children with the release of noxious chemicals that had seeped into their homes. As will be subsequently described in this chapter, health investigations confirmed some of the residents' fears that adverse health outcomes had occurred.

The CERCLAct, as revised, requires EPA, in cooperation with states, to identify and remediate uncontrolled hazardous waste sites, identify Potentially Responsible Parties (PRPs), collect cost-recovery fees from PRPs, and directs ATSDR to address public health concerns [12].

The drama of Love Canal occurred during the waning months of President Jimmy Carter's administration. In 1979, the federal government offered to buy the homes of Love Canal residents and assisting with their relocation elsewhere. Approximately 950 families were evacuated from the Love Canal area [22]. Over the next 20 years, more than $400 million was spent to remediate the Love Canal area. While this is an impressive expenditure, it is noteworthy that the 21,000 tons of chemical soup that characterized the Love Canal site are still there. To remediate the site, the EPA capped it with a thick layer of clay, installed pumps and drains to control runoff of chemicals from the site, and replaced miles of contaminated sewer pipe. The chemicals themselves were left in the contained site and the area was surrounded by a fence [23].

As policy, leaving hazardous substances in place, but interdicting human contact with them has evolved into a risk management decision by the EPA, states, and some private sector entities. The theory is that interdiction of contact between hazardous substances and humans and ecological systems will prevent adverse effects. The costs of containment are generally less than for removal of contaminated soil or water. In theory, the cost savings could be used to remediate more sites that require cleanup. On the other side of this argument

is the problem that failure to remove hazardous contamination can simply prolong the life of a HWS and there are no guarantees that future cleanup actions will ever occur. Moreover, even contained sites, using current best available technology, will in time deteriorate. Therefore, the costs of site maintenance and upkeep are passed along to future generations.

In March 2004, the EPA removed the Love Canal site from its list of most significant uncontrolled HWS, ending 21 years of government and community concern that uncontrolled hazardous waste was a threat to public health. Today the former Love Canal neighborhood is called Black Creek Village, a neighborhood constructed largely of new houses [23].

The CERCLAct was therefore the product of great public concern that toxic materials could invade private homes and cause harm to children and future generations. The intent of the law is stated to be, "To provide for liability, compensation, and emergency response for hazardous substances released into the environment and the cleanup of inactive hazardous waste disposal sites." The CERCLAct's basic purposes are to provide funding and enforcement authority for remediating (i.e., cleaning up) uncontrolled HWS, and for responding to hazardous substance spills. The statute includes provisions for remediating waste sites, responding to public health concerns, enforcement authorities to identify "potential responsible parties," and emergency removal of chemical spills [24].

The Hazardous Substance Trust Fund was created by the CERCLAct, which was intended by Congress to be a source of funds for site remediation when other sources were unavailable. Until 1995 the trust fund was financed primarily by a tax on crude oil and certain chemicals and an environmental tax on select corporations [29]. The authority for these taxes expired in December 1995 and has not been reauthorized by Congress. Neither the Clinton nor subsequent administrations sought reauthorization of the Superfund taxes. The trust fund also receives revenue from interest accrued on the unexpended balance, recovery of cleanup costs from responsible parties, and collections of fines and penalties [29]. This trust fund fulfills part of the Act's philosophy of "the polluter pays" for environmental cleanup. (The other part of this philosophy is the authority given to EPA to identify polluting parties and force them to bear the cost of site remediation.).

One effect of not imposing the Superfund tax has been a general decrease in the Hazardous Substance Trust Fund. Less reliance on trust fund monies means more reliance on funds from general revenue; i.e., taxpayers pay for a greater portion of CERCLAct site cleanups [29].

* * *

The CERCLAct places special emphasis on those uncontrolled HWS ranked by the EPA to pose the greatest hazard to human health and natural resources damage. The worst of the HWS comprise what is called the National Priorities List (NPL). As policy, ranking the worst HWS provides decision-makers at the EPA and states with a means to prioritize sites and remediate first those sites posing the potential greatest risk to human and ecological health. Under the CERCLAct, *Potentially Responsible Parties* (PRPs) must be identified by EPA and costs recovered from them to pay for site remediation. Further the CERCLAct stipulates that all NPL sites must receive a health assessment conducted by ATSDR for purpose of ascertaining any adverse effects in persons impacted by HWS. Uncontrolled waste storage/treatment facilities and former manufacturing facilities constitute about 75% of NPL sites. Both categories represent industrial operations that operated in the past and then went out of operation, leaving a legacy of hazardous waste in the environment.

Sites can be placed on the NPL by three mechanisms: (1) the EPA's Hazard Ranking System (HRS), (2) states or territories designate one top-priority site regardless of HRS score, or (3) ATSDR has issued a health advisory that recommends relocating people from the site [25]. The HRS uses a structured analysis for scoring and ranking sites. This approach assigns numerical values to factors that relate to risk, based on conditions at the site under consideration. The factors are grouped into three categories: (1) likelihood that a site has released or has the potential to release hazardous substances into the environment, (2) characteristics of the waste (e.g., toxicity and waste quantity), and (3) people or sensitive environments affected by the release of hazardous substances [25]. Sites proposed by the EPA for placement on the NPL are published in the *Federal Register* for public comment over a 60-day period. Sites can be deleted from the NPL if EPA determines that no further action is required to protect human health or the environment.

* * *

At the heart of the CERCLAct process is the process of identification, inspection, remediation, and closure of NPL sites. The processes used by the EPA to effectuate this process are complex in details, but fairly straight forward overall if considered as a step-by-step program. The following steps, when followed in the order given below, comprise what can be called the CERCLAct process for remediation of uncontrolled HWS [26].

Site Discovery—Potential CERCLAct sites are typically identified through state and county inspections and reports from concerned citizens. Federal facilities are required to conduct investigations of past waste management activities, in response to the Superfund Amendments and Reauthorization Act of 1986 (SARA) §120(d) (Federal Facilities).

Preliminary assessment and site investigation—The first step in the CERCLAct process comprises two initial studies known as the Preliminary Assessment (PA) and Site Investigation (SI). Both studies include collecting and reviewing available information to determine the magnitude of the problem posed by the site. At the conclusion of the SI, the site is then scored by EPA using the HRS [27]. The HRS considers potential relative risks to public health and the environment from release or threatened release of chemicals at the site.

NPL listing—If the overall potential risks at a site are determined to be significant based on its HRS score, the site will be nominated for placement on the NPL. The NPL is a listing by EPA of the top-priority sites that are eligible for investigation and remediation under the federal CERCLAct program. Typically, sites must receive a score of at least 28.5 out of 100 points in order to be included on the NPL.

Remedial investigation and feasibility study—After a site has been placed on the NPL, two related studies, the Remedial Investigation (RI) and the Feasibility Study (FS), are conducted. An RI/FS may take several years to complete, depending on the size and scope of the site. This phase includes comprehensive sampling and data collection to evaluate the nature, extent, and magnitude of impacts both on- and off-facility. As part of the RI/FS, a risk assessment is performed to identify and quantify the risks that the site poses to public health, welfare (e.g., odors, appearance) and the environment. The risk assessment evaluates current and future risks in the absence of any remediation and helps determine the need for and extent of remediation requirements. During the FS, remedial alternatives are identified and evaluated based on technical feasibility, protectiveness, effectiveness, impacts to the community, institutional concerns, conformance with other applicable relevant and/or appropriate environmental laws, and costs. A preferred cleanup alternative is proposed as part of the FS.

Removal actions—A removal action can be conducted at any time during the CERCLAct process if the site poses an immediate threat to public health or the environment. A Removal Action is an immediate (short-term) action, such as the implementation of a temporary alternative water supply that is taken to safeguard public health or the environment. In cases where more than a 6-month planning period exists before a removal action will begin, an Engineering Evaluation/Cost Assessment (EE/CA) is prepared in order to identify the objectives of the removal action and evaluate various alternatives with respect to cost, effectiveness, and implementability. After the Removal Action is completed, the environmental investigation or remediation process resumes according to the appropriate step in the CERCLAct process.

Proposed plan and public comment period—Upon completion of the FS, a Proposed Plan is published that summarizes the remediation alternatives evaluated in the FS. The Proposed Plan describes the preferred cleanup strategy proposed by the lead agency (e.g., the EPA) and the supporting regulatory agencies. The Proposed Plan is then submitted for public comment for a 30-day period, which may be extended an additional 30 days upon timely receipt of a request from a member of the community.

Record of decision—At the conclusion of the public comment period and following consideration of all community comments, the lead agency with regulatory approval will make the final remedy selection. This final remedy selection is issued in a Record of Decision (ROD), a legal public document that sets forth and explains the remediation alternatives to be used at a CERCLAct site. The ROD includes a Responsiveness Summary that contains responses to all public comments received during the public comment period on the Proposed Plan.

Remedy design and implementation—After the ROD is signed, the Remedial Design (RD) phase of work is initiated. The RD includes preparation of engineering reports, technical drawings, and specifications to describe implementation of the selected remedy. Upon approval of the RD by the supporting regulatory agencies, the Remedial Action (RA), or the actual construction and implementation of the selected cleanup alternative, is initiated. The final long-term remedial action may take 1–2 years to construct, although treatment may take several more years. The RA is implemented until cleanup objectives are achieved.

NPL de-listing—A site can be removed from the NPL upon determination that no further response is required to protect human health or the environment. Under §300.425(e) of the National Contingency Plan (NCP), as amended (Chapter 4), a site may be de-listed after all appropriate response actions are completed. Partial deletions can also be conducted at NPL sites. For example, soil remediation may be completed and be de-listed prior to de-listing groundwater at the same NPL site.

Long-term monitoring/review—After RD/RA activities have been completed, the site is monitored to ensure the effectiveness of the response. Typically, CERCLAct sites undergo reviews every 5 years after implementation of the remedy in order to evaluate the continued protectiveness of the remedy.

* * *

The CERCLAct's central philosophy is to require parties, called the Potentially Responsible Parties (PRPs), to bear the costs of remediating sites to which the parties had contributed wastes and for costs attending environmental and health problems created by releases of substances from the waste sites. The CERCLAct gives EPA broad legal authority to identity PRPs for each NPL site. PRPs include the past and current owners and/or operators of a site, those who arranged for the transportation of hazardous substances to the site, and those who arranged for the treatment or disposal of the substances, and they are subject to retroactive liability. This is established under the legal concept of *retroactive joint and several liability* for parties whose wastes had contributed to environmental degradation at the waste sites. The concept means that a

company or other accountable entities that had disposed of wastes long ago could now be held responsible for all of a site's remediation costs unless other responsible parties can be identified and costs shared. Needless to say, retroactive joint and several liability have often led to litigation as to who pays what portion of a site's remediation [29].

The CERCLAct authorizes the EPA to pay for site cleanups out of the Hazardous Substances Superfund and, where possible, out of the liability scheme of the Act; that is, from costs recovered from the PRPs. The liabilities of PRPs cover not only the actual costs of remediation, but also the site investigation, feasibility study, design costs, and cost of health studies. The types of parties who may be liable for site-associated costs are specified by the CERCLAct to be followed: (1) current and past "owners or operators" of the site; (2) parties who transported wastes to the site; and (3) parties (usually referred to as "generators") who arranged for wastes to be disposed or treated, either directly with an owner/operator or indirectly with a transporter [29]. It is common to have multiple PRPs associated with a particular CERCLAct site.

The CERCLAct's central philosophy is to require parties, called the Potentially Responsible Parties (PRPs), to bear the costs of remediating sites to which the parties had contributed wastes and for costs attending environmental and health problems created by releases of substances from the waste sites.

In addition to the identification, ranking, remediation, and cost recovery provisions of the CERCLAct that pertain to uncontrolled releases of hazardous substances from sites, the CERCLAct contains other provisions of note [28]:

- Removal actions are conducted by the EPA in instances where a short-term, limited response to a manageable environmental release is indicated (e.g., spills of hazardous substances from transportation mishaps), rather than a long-term remedy (i.e., remediation) is indicated, e.g., for an NPL site.
- As discussed in Chapter 3, the CERCLAct of 1980 created ATSDR within the U.S. Public Health Service for the purpose of investigating public health implications of hazardous substances in the community environment, with emphasis on those released from NPL sites. ATSDR conducts public health assessments of all NPL sites, develops Toxicological Profiles for priority hazardous substances, conducts epidemiological and other applied research, provides medical education for physicians and other health professionals, responds to emergency releases of hazardous substances (e.g., through transportation spills), and maintains a national registry of persons exposed to specific hazardous substances known to have been released from NPL sites [28].

Sometimes confusion arises about the differences between the CERCLAct and the RCRAct. For example, what does one law cover that the other law does not? Is there a difference between the authorities of the EPA and the states? Do the laws have different purposes? The key differences between the CERCLAct and the RCRAct are summarized in Table 12.4. As shown in the table, states have the primary responsibility for the RCRAct facilities, whereas the federal government (i.e., the EPA) has primacy on CERCLAct sites. It should be noted that most states also have their own programs to remediate those uncontrolled HWS that were not designated as NPL sites by EPA.

TABLE 12.4
Comparison of Key Differences between RCRAct and CERCLAct

RCRAct	CERCLA
Focus is on *controlled* facilities that treat, store, and destroy solid and hazardous waste	Focus is on *uncontrolled* hazardous waste sites
States have primacy in setting emission standards and enforcement	Federal government has primacy in setting cleanup standards and enforcement

12.4.2 Key Provisions of the CERCLAct, as Amended, Relevant to Public Health

The CERCLAct, as amended in 1986, contains four titles, under which are found the various sections that constitute the statute. Several standard references contain all sections in the statute (e.g., [29]).

Title I—Provisions Relating Primarily to Response and Liability:

§101—Definitions—(14) The term *hazardous substance* means (A) any substance designated pursuant to §11(b)(2)(A) of the Federal Water Pollution Control Act [...], (B) any element, compound, mixture, solution, or substance designated pursuant to §9602 of this title, (C) any hazardous waste having the characteristics identified under or listed pursuant to §3001 of the Solid Waste Disposal Act [...], (D) any toxic pollutant listed under §307(a) of the Federal Water Pollution Control Act [...], (E) any hazardous air pollutant listed under §112 of the CAAct [...], and (F) any imminently hazardous chemical substance or mixture with respect to which the Administrator has taken action pursuant to §7 of the TSCAct (15 U.S.C. 2606). [...] The terms "remove" or "removal" means the cleanup or removal of released hazardous substances from the environment, [o]r the taking of such other actions as may be necessary to prevent, minimize, or mitigate damage to the public health or welfare or to the environment [...]. (24) The terms *remedy* or *remedial action* means instead of or in addition to removal actions in the event of a release or threatened release of a hazardous substance into the environment,

ENFORCEMENT EXAMPLE

(Washington, DC—September 9, 2014) The EPA entered into a settlement agreements under the CERCLAct with two subsidiaries of The Lightstone Group to conduct sampling, cleanup work, and other measures along the Gowanus Canal. The Gowanus Canal is a 100-ft wide, 1.8-mile long canal in the New York City borough of Brooklyn, Kings County, New York. The settlement provides liability relief for prospective purchasers under the CERCLAct in exchange for cleanup work which may otherwise fall upon the EPA to perform. The subsidiaries are in the process of developing 700 residential units adjacent to the canal. The estimated value of the work under the settlements is approximately $20 million [30].

to prevent or minimize the release of hazardous substances so that they do not migrate to cause substantial danger to present or future public health or welfare or the environment. [...]

§104—(i) ATSDR; establishment, functions, etc. (1) There is hereby established within the Public Health Service an agency, to be known as the ATSDR, which shall report directly to the Surgeon General of the United States. Health officials effectuate and implement the health related authorities of this chapter [...].

§117—Public participation—(a) Proposed plan—Before adoption of any plan for remedial action to be undertaken by the President, by a state, or by any other person, under §9604, 9606, 9620, or 9622 of this title, the President or state, as appropriate, shall take both of the following actions: (1) Publish a notice and brief analysis of the proposed plan and make such plan available to the public. (2) Provide a reasonable opportunity for submission of written and oral comments and an opportunity for a public meeting at or near the facility at issue about the proposed plan and regarding any proposed findings under §9621(d)(4) of this title (relating to cleanup standards) [...].

§120—Federal facilities—(a) Application of chapter to Federal Government: (1) In general—Each department, agency, and instrumentality of the United States (including the executive, legislative, and judicial branches of government) shall be subject to, and comply with, this chapter in the same manner and to the same extent, both procedurally and substantively, as any nongovernmental entity, including liability under §9607 of this title.

§121—Cleanup standards—(b) General rules—[T]he President shall select a remedial action that is protective of human health and the environment, that is cost effective, and that utilizes permanent solutions and alternative treatment technologies or resource recovery technologies to the maximum extent practicable [...].

§311—Research, development, and demonstration—(a) Hazardous substance research and training (1) The Secretary of Health and Human Services [s]hall establish and support a basic research and training program (through grants, cooperative agreements, and contracts [...]. (b) Alternative or innovative treatment technology research and demonstration program [...]. (c) Hazardous substance research [...]. (d) University hazardous substance research centers [...].

Businesses covered by Title III must notify state and local emergency planning entities of the presence and amounts in inventory of hazardous materials on their premises and to notify federal, state, and local authorities of planned and uncontrolled environmental releases of those substances.

Title II—*Miscellaneous Provisions*—includes sections on transportation of hazardous materials (§202), leaking underground storage tanks (§205), citizen suits (§206), Indian tribes (§207); research, development, and demonstration (§209), Department of Defense environmental restoration program (§211), oversight and reporting requirements (§212), Love Canal property acquisition (§213).

Title III—*Emergency Planning and Community Right-to-Know*—The Emergency Planning and Community Right-to-Know Act of 1986 was enacted as a freestanding provision of the Superfund Amendments and Reauthorization Act of 1986 [31], constituting Title III of the CERCLAct, as amended. Title III is a significant statement from Congress concerning the obligations of government and private industry to protect the public from releases of hazardous substances. Under Title III, state and local governments are required to develop emergency plans for responding to unanticipated environmental releases of acutely toxic materials [32]. (Title III required different kinds of notifications according to groups of chemical substances.) Additionally, businesses covered by Title III must notify state and local emergency planning entities of the presence and amounts in inventory of hazardous materials on their premises and to notify federal, state, and local authorities of planned and uncontrolled environmental releases of those substances. Regulatory agencies, in turn, are required to make available to the public the data on releases of substances in the environment.

Title III includes sections on establishment of state commissions, planning districts, and local committees (§301); substances and facilities covered and notification (§302), comprehensive emergency response plans (§303), emergency notification (§304), emergency training and review of emergency systems (§305), material safety data sheets (§311), emergency and hazardous chemical inventory forms (§312), toxic chemical release forms (§313), trade secrets (§322), providing information to health professionals (§324); public availability of plans, data sheets, and follow-up notes (§324); enforcement (§325), and regulations (§328).

The EPA has developed a reporting system for businesses to use when providing information required of them for placement in the Toxics Release Inventory (TRI).* The TRI database can be accessed through the EPA website (http://www.epa.gov). Citizen and environmental groups have used the TRI data to bring attention to the amounts of hazardous substances released by industry within geographic areas of concern. The impact of this has been to bring the weight of public opinion to bear on companies' reduction of emissions.

Another use of TRI data is for research purposes. As an example of one organization's use of TRI data, the Greater Boston Physicians for Social Responsibility found that of the 20 TRI chemicals with the greatest total releases into the environment, about 75% were known or suspected neurotoxicants [33]. On a more positive note, the EPA reported in 2005 that TRI data showed that the amount of toxic substances released into the U.S. environment had declined 42% between the years 1999 and 2003 [34]. It is unclear if this decline is a product of relaxed changes in how industry reports emissions data to EPA; or actual reductions due to public pressure; or reductions as a consequence of federal, state, or local emission standards.

Title IV—*Radon Gas and Indoor Air Quality Research*—includes sections on findings (§402); radon gas and indoor air quality research programs (§403), authorizations (§405).

12.4.3 Associations between Uncontrolled Hazardous Waste and Human Health

The consequences to the health of persons who reside near uncontrolled HWS are both feared and real. Communities located near these kinds of sites often create grassroots groups that actively express their fears that excess cancer rates and reproductive health problems are caused by substances released from HWS into their midst. Although relating a specific community's health problems to a given HWS is very challenging to investigate, there is, nonetheless, a compelling body of epidemiological and toxicological data that associates adverse effects on community health with residential proximity to some HWS.

The effects on human reproductive outcomes from exposure to hydrocarbon solvents such as trichloroethylene (TCE) released from HWS constitute the strongest evidence for a HWS–human health association. According to one source who comprehensively reviewed relevant epidemiological literature, residential proximity to HWS is associated with lower birth weight and an increased risk of congenital malformations that include defects of the heart, neural tube, and oral palate [19]. Particularly compelling were findings from two investigations of two NPL sites: Love Canal, New York and Lipari, New Jersey [35,36]. For both sites, average birth weights decreased during the span of time when documented releases of hazardous substances were migrating from the waste sites. For both HWS, when the releases of substances were interdicted, mean birth weights in the geographic areas returned to normal. In 2002, a study of congenital anomalies and residence near hazardous waste landfill sites compared 245 cases of chromosomal anomalies to 2412 controls that lived near 23 landfills in Europe [37]. After adjusting for confounders, a higher risk of chromosomal anomalies was found in people who lived close to sites (0–3 km) than in persons who lived farther away.

Association between residential proximity to HWS and elevated cancer rates is not as well substantiated as adverse reproductive effects. A review of the epidemiological literature indicates elevated rates of certain cancers, primarily those of the urinary bladder and gastrointestinal tract, in counties that contain HWS and for which groundwater contamination was either documented or assumed (e.g., [38,39]). There also exists published work that associates increased rates of childhood leukemia with the presence of TCE in municipal wells that supplied segments of Woburn, Massachusetts, with residential water (e.g., [40,41]).

There are also toxicological data that have importance for cancer rates in communities impacted by releases of substances from HWS. One source examined the most frequently occurring substances released into groundwater supplies and noted that of these 30 chemicals, 18 were known or reasonably anticipated to be human carcinogens [19]. Given the long latency associated with most cancers, whether these toxicological observations portend any increase in cancer rates will not be known for many years. But generally, clusters of cancer in persons residing near HWS have not been identified. This outcome could be a consequence of investigating any kind of disease clusters, given the required rigor needed for epidemiological associations between outcome and potential causal factors. It is also possible that actual exposure to carcinogens released from HWS did not occur.

In general, there is sufficient published scientific data to designate some uncontrolled HWS as a hazard to the public's health. Given this knowledge, and as a matter of public health, remediation of HWS is an example of primary disease prevention in action. That is, adverse health effects are prevented by elimination of the causal hazard.

12.4.4 Associations between Uncontrolled Hazardous Waste and Ecosystem Health

As discussed, exposure to uncontrolled hazardous waste can be harmful to human health, depending on the circumstances of substances' toxicity and receptor characteristics. Additionally, exposure to hazardous waste can be extremely harmful to plants and animals. Hazardous waste stunts plant growth, much of which is useful to humans for consumption or manufacturing. In addition, the elimination of plant life reduces the natural food supply for feral and domesticated animals. Similarly, hazardous waste can harm fish and other animals in bodies of water contaminated by hazardous waste.

* As described in this chapter, the Pollution Prevention Act of 1990 requires that industrial facilities also report data on recycling of wastes and other information on pollution prevention.

12.4.5 Successes and Criticisms of the CERCLAct

The CERCLAct stands atop the federal environmental laws in regard to criticism. Over the years of its existence, the volume and rancor of criticism exceeds that of any other federal environmental statute. Yet, the CERCLAct has been a valuable statute in terms of environmental restoration and reduced public health impacts. Some of the principal criticisms of the CERCLAct are shown in Table 12.5. The law is alleged to be unfair because it holds polluters accountable for their past actions, actions that were sometimes in compliance with existing laws pre-1980 when the CERCLAct was enacted into law. Critics also allege that the CERCLAct program has remediated too few NPL sites, that the costs of cleanups are too great, cleanups take too long, too much litigation accompanies site cleanup, and moreover, there are no health problems in communities located near CERCLAct sites. Some of these criticisms have been voiced by industry and trade groups who have historically opposed the CERCLAct. Also, some states have expressed some of the same criticisms, preferring to adopt their own state-based waste site remediation programs, rather than having to accept cleanup standards and priorities from the federal government.

The criticisms of the CERCLAct should be viewed in comparison to the successes of the CERCLAct program, shown in Table 12.5. Remediation of HWS is a contribution to the public's health. Removal of a site's hazardous substances and interdiction of human exposure pathways (e.g., well water used for drinking) prevent adverse human health effects. Table 12.6 shows the status of NPL sites through September 2016 [42]. Since 1980, 1185 NPL sites have completed all cleanup construction [42]. As of fiscal year 2016, there were 1337 NPL sites that were in various stages of site remediation. Of note, over the life of the CERCLAct program, as of fiscal year 2002 the EPA has reached settlements with private parties with an estimated value exceeding $30 billion [43]. These funds are used for site remediation and related purposes.

Another success of the CERCLAct is that it provides the EPA with the authority to conduct emergency removals of hazardous substances from sites. Examples of such sites include urban abandoned warehouses that contain barrels of hazardous chemicals and train derailments where industrial chemicals are spilled. The EPA has conducted more than 6400 removal actions through fiscal year 2000 [43]. Emergency responding by local authorities to chemical releases have been substantially improved under Title III of the CERCLAct. State and local governments are required to develop emergency plans for responding to unanticipated environmental releases of several acutely toxic materials [32]. Additionally, businesses covered by Title III must notify state and local emergency planning entities of the presence and amounts in inventory of hazardous materials on their premises and to notify federal, state, and local authorities of planned and uncontrolled environmental releases of those substances. Regulatory agencies, in turn, are required to make available to the public the data on releases of substances in the environment. This is a public health success story in terms of preventing human exposure to hazardous substances. Table 12.6 shows cumulative data on the status of the CERCLAct NPL sites.

Further, as the result of the CERCLAct, a considerable body of illuminating public health and science findings have accrued. The public health findings in the preceding section resulted from funding from the CERCLAct programs at ATSDR and NIEHS. Without these funds, waste site health investigations and basic toxicological research would likely not have occurred. Moreover, these research findings have utility for other sources of environmental contamination (e.g., air pollutants) when the contaminants are the same as found released from CERCLAct sites.

In another area, environmental justice concerns arose from minority communities' fear that hazardous waste disposal was targeting their communities (Chapter 18). In response, both the Clinton and George H.W. Bush administrations generated policies to guard against environmental injustices. Without the CERCLAct, it is doubtful that the federal government would have had the resources and resolve to institute environmental justice offices at the EPA and other federal agencies.

Because of the CERCLAct, the public now has access to TRI data, which are provided to the EPA by generators of pollutants released into the environment. TRI data can be used by individuals, community groups, and local government to identify pollution sources of public health concern.

TABLE 12.5
Criticisms and Successes of the CERCLA Program

Criticism	Success
Unfair enforcement	Many sites remediated
Too many sites to remediate	Emergency removal of hazardous substances
Site remediation is too costly	Human health effects database
Takes too long to remediate sites	Emergence of environmental justice
Little impact on community health	Toxic Release Inventory (TRI)
Too litigious	Improved emergency responding
Too little monitoring of remediated sites	Improved management of hazardous waste

TABLE 12.6
Status of NPL Sites, September 26, 2016

Milestone	Non-Federal (General)	Federal	Total
Proposed NPL sites	50	3	53
NPL sites	1180	157	1337
Deleted NPL sites	375	17	392
NPL sites with partial deletions	43	19	62
NPL sites with construction completions	1107	78	1185

Source: EPA, Number of NPL site actions and milestones, Office of Solid Waste and Emergency Response, Washington, DC, 2004

Lastly, management of hazardous waste has undoubtedly improved in the U.S. due to the CERCLAct. Generators of hazardous waste know the penalties that come with violating waste management regulations. Not only can violations result in civil penalties, private party litigation can result in large monetary settlements against the generators. The so-called "midnight dumpers," who existed pre-1980 and literally dumped liquid hazardous waste along roads in rural America, have largely faded into history.

12.4.6 EPA's Brownfields Program

Brownfields is an EPA program akin in concept to the CERCLAct program of site remediation. A brownfield is a property, the expansion, redevelopment, or reuse of which may be complicated by the presence or potential presence of a hazardous substance, pollutant, or contaminant. Brownwfields are often urban properties located in underserved communities. Since its inception in 1995, the EPA's Brownfields Program is designed to empower states, communities, and other stakeholders in economic redevelopment to work together in a timely manner to prevent, assess, safely clean up, and sustainably reuse brownfields. It is estimated that there are more than 450,000 brownfields in the U.S. Remediating and reinvesting in these properties increases local tax bases, facilitates job growth, utilizes existing infrastructure, takes development pressures off of undeveloped, open land, and both improves and protects the environment.

Beginning in the mid-1990s, the EPA provided small amounts of seed money to local governments that launched hundreds of 2-year Brownfields "pilot" projects and developed guidance and tools to help states, communities, and other stakeholders in the cleanup and redevelopment of Brownfields sites. The 2002 Small Business Liability Relief and Brownfields Revitalization Act (the "Brownfields Law") codified many of the EPA's practices, policies, and guidance. The Brownfields Law expanded the EPA's assistance by providing new tools for the public and private sectors to promote sustainable Brownfields cleanup and reuse [44].

The EPA asserted in 2016, "Since the inception of EPA's Brownfields Program in 1995, cumulative brownfields program investments have leveraged more than $20 billion from a variety of public and private sources for cleanup and redevelopment activities. This equates to an average of $17.79 leveraged per EPA brownfields dollar expended. These investments have resulted in approximately 108,924 jobs nationwide. EPA's Brownfields Program empowers states, communities and other stakeholders to work together to prevent, assess, safely clean up, and sustainably reuse brownfields sites" [45].

Table 12.7 shows a cumulative summary of EPA's Brownfields Program accomplishments. The economic impact of the program is demonstrated by the jobs and dollars leveraged (108,924, $20.96 billion, respectively) [46].

TABLE 12.7
Summary of Brownfields Program Cumulative Accomplishments as of March 2016

Performance Measure	Accomplishments
Properties assessed	23,932
Jobs leveraged	108,924
Dollars leveraged	$20.96 Billion
Acres made ready for anticipated reuse	59,149

Source: EPA (Environmental Protection Agency), Brownfields program accomplishments and benefits, Office of Land and Emergency Management, Washington, DC, 2016.

12.5 OCEAN WASTE POLLUTION

Earth's oceans are vital for humankind's well-being in myriad ways. As a few examples, oceans provide food, transportation, security, recreation, and contributions to climate stability. Yet in spite of this vital importance, humans have proceeded to damage our oceans by harmful mismanage of wastes, especially toxic waste. According to the MarineBio Conservation Society, a nonprofit marine conservation organization, "The most toxic waste material dumped into the ocean includes dredged material, industrial waste, sewage sludge, and radioactive waste. Dredging contributes about 80% of all waste dumped into the ocean, adding up to several million tons of material dumped each year. Rivers, canals, and harbors are dredged to remove silt and sand buildup or to establish new waterways. About 20–22% of dredged material is dumped into the ocean. The remainder is dumped into other waters or landfills and some is used for development. About 10% of all dredged material is polluted with heavy metals such as cadmium, mercury, and chromium, hydrocarbons such as heavy oils, nutrients including phosphorous and nitrogen, and organochlorines from pesticides. Waterways and, therefore, silt and sand accumulate these toxins from land runoff, shipping practices, industrial and community waste, and other sources. When these materials find their way into the ocean, marine organisms suffer toxic effects and seafood is often contaminated" [47].

In addition to dredged materials being dumped into oceans, the volume of plastic waste has become a major factor in marine pollution. According to one source, in 2010, coastal countries dumped eight million tons of plastic trash in the ocean, which was much greater than the total that has been measured floating on the surface in the ocean's "garbage patches." The study also identified the major sources of plastic debris and named the top 20 countries generating the greatest amount of ocean bound trash. China ranked first. After China were 11 other Asian countries, Turkey, 5 African countries, and Brazil. The U.S. was ranked 20th. Researchers estimated that the tonnage is on target to increase 10-fold in the next decade unless waste collection and management policies are improved globally [48].

TABLE 12.8
Top 10 Items Found at Ocean Beaches by the International Coastal Cleanup in 2012

Number of Items (% Total)	Category	Number of Items	Category
2,117,931 (24.2)	Cigarettes/cigarette filters	692,767 (7.9)	Cups, plates, fork, knives, spoons
1,140,222 (13.0)	Food wrappers/containers	611,048 (6.9)	Straws, stirrers
1,065,171 (12.1)	Beverage bottles (plastic)	521,730 (6.0)	Beverage bottles (glass)
1,019,902 (11.6)	Bags (plastic)	339,875 (3.9)	Beverage cans
958,893 (10.9)	Caps, lids	298,332 (3.4)	Bags (paper)

Source: Ocean Conservancy, International coastal cleanup top 10 items found, http://www.oceanconservancy.org/our-work/international-coastal-cleanup/top-10-items-found.html?referrer=https://www.google.com/, 2012.

The variety and extent of ocean debris is suggested by the variety and volume of waste that washes up on coastal beaches. An NGO organization, Ocean Conservancy, conducts periodic collection by volunteers of coastal marine trash. Table 12.8 shows the top 10 items collected by Coastal Cleanup volunteers in 2012 [112]. Noteworthy is the distribution of items found on beaches. Cigarettes/cigarette filters (24.2%) are the most prevalent trash, as itemized by the Conservancy. However, plastic items dominate (38.4%) across the spread of items collected if those that are designated as plastic and those assumed to be plastic (straws/stirrers, forks, spoons, etc.) are summed. As will be subsequently discussed, plastic waste in Earth's oceans is a major global environmental health problem. In summary, plastic items and cigarette parts are the two dominant items found in coastal trash.

12.5.1 U.S. Policies on Maritime Pollution

U.S. federal policies on controlling ocean pollution consist of two statutes, the Ocean Dumping Act (ODAct) and the Act to Prevent Pollution from Ships. Both acts are intended to reduce the release of waste into ocean waters. The older of the two acts, the ODAct, is discussed first.

12.5.1.1 Ocean Dumping Act, 1972

The U.S. has derived enormous benefits from a geography positioning of the nation next to three major oceans (Atlantic, Arctic, and Pacific) and one ocean basin (Gulf of Mexico). These bodies of water are sources of seafood, transportation, revenue, and protection for the U.S. Regrettably, the U.S. and other coastal nations have over their histories chosen to use these oceans as dumping basins for waste. As related in this section, recognition of the impact of ocean dumping has led to both international and domestic policies meant to control ocean dumping. The ODAct implements policies to control waste dumped into ocean waters [52].

The ODAct focuses on the regulation of intentional disposal of materials into ocean waters and authorizing related research [52].

12.5.1.1.1 History

Earth's oceans have historically served as rich sources of life support, both aquatic and terrestrial. Fish and other aquatic life have long been a staple of the human diet. Unfortunately, the very vastness of the oceans has led to their use by humankind as places to dump anthropogenic wastes. As human populations increased in number and industrial pollution appeared due to global industrialization, the need for inexpensive methods of waste disposal emerged. Bodies of water were selected for waste dumping in the mistaken belief that dilution of pollution would minimize any threats to human and ecological health. Of course, the flaw in this theory is the failure to acknowledge that any pollution sink has a limit in its capacity to receive waste, even a sink as vast as the oceans.

By the late 1960s and early 1970s, it had become evident that the oceans were in ecological trouble. Centuries of marine pollution had taken their toll. Beaches had become contaminated with pollution washed ashore, marine life had become bearers of chemical pollutants and solid waste, and reefs were dying from the pollution load. Actions to reverse this march of marine pollution began with the adoption of key international protocols to reduce pollution of the oceans and seas.

In June 1972, the United Nations Stockholm Conference on the Human Environment called for action to protect marine environments, followed by a treaty drafted in London

ENFORCEMENT EXAMPLE

The captain of the *MN Katerina*; the ship's chief engineer; and its second engineer were all arrested in the Los Angeles area on September 21, 2004 on charges that they had allegedly been involved in the dumping of oil-contaminated water into the Pacific Ocean. The U.S. Coast Guard inspected the ship on September 14 and 15, 2004. During these inspections, they discovered that the ship's oil-water separator was not being used and that a bypass had been constructed around the separator. All three defendants are charged with failing to properly maintain the *Katerina's* Oil Record Book, making false statements to Coast Guard investigators, and obstructing justice by falsifying records [51].

at the Intergovernmental Conference on the Convention on the Dumping of Wastes at Sea [49]. The Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, also called the London Convention, entered into effect on August 30, 1975, after 15 countries had ratified the treaty, including the U.S. In 1972, the U.S. Congress enacted the Marine Protection, Research, and Sanctuaries Act (MPRSA), commonly called the ODAct. Title I of the act implements the U.S.'s agreements in the London Convention. This is therefore an example of an U.S. environmental statute that emerged from the need to comply with an international treaty.

The ODAct has two basic aims: to regulate global ocean disposal of materials and to authorize related research. Title I of the ODAct, contains permit and enforcement provisions for ocean dumping [52].

Title I of the act prohibits all ocean dumping, except that allowed by permits, in any ocean waters under U.S. jurisdiction, by any U.S. vessel, or by any vessel sailing from a U.S. port. Dumping of a radiological, chemical, and biologic warfare agents and any high-level radioactive waste is banned. Permits for dumping any other materials can be issued by the EPA where it is determined that the dumping will "[n]ot unreasonably degrade or endanger human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities." Permits issued under the ODAct must specify the kind of material to be disposed, the amount to be transported for dumping, the location of the dumpsite, the length of time the permit is valid, and special provisions for surveillance [52.]. Subsequent amendments to the ODAct prohibited the dumping of municipal sewage sludge and industrial waste.

Four federal agencies have responsibilities under the ODAct [52]. The EPA has primary authority for regulating ocean disposal of all substances except dredged soils, for which the Army Corps of Engineers has authority. Provisions concerning general and ocean disposal research are contained in **Title II**, under which NOAA has authority for researching the effects of anthropogenic-caused changes to the marine environment, while the EPA is authorized to carry out research and demonstration activities pertaining to phasing out sewage sludge and industrial waste dumping. The U.S. Coast Guard is charged with maintaining surveillance of ocean dumping [52.].

Title III of the ODAct authorizes the establishment of marine sanctuaries. **Title IV** establishes a regional marine research program, and **Title V** addresses coastal water quality monitoring.

12.5.1.1.2 Public Health Implications of the ODAct

It is unknown to what extent the ODAct and international agreements structured to reduce ocean pollution have been effective. However, it is apparent that large quantities of ocean pollutants exist, as measured by what washes up on beaches. In 1991, the Center for Marine Conservation organized 118,200 volunteers to clean 3800 miles of U.S. coastline in one day. They picked up 2.8 million pounds of trash [50]. That amount obviously represents only a tiny fraction of what is in the oceans and the creatures that live there. If one assumes that human health is dependent on a healthy ecosystem, then pollution in the seas and oceans of the world has the potential to degrade the public's health, particularly as it pertains to human consumption of fish and other food taken from the ocean.

12.5.1.2 Act to Prevent Pollution from Ships, 1980

Ocean pollution has doubtless occurred from the time that humans first found ways to traverse great bodies of water. Whether human waste of mariners, or damaged goods being dumped, or oil from leaking vessels, the oceans and its resident creatures have continuously been victims of pollution from ships.

12.5.1.2.1 History

As ocean pollution became a concern to the global environmental protection community, international maritime treaties emerged to regulate and control pollution from ships. These treaties are in addition to laws enacted by individual nations, such as the ODAct. In concert with other nations, the U.S. has enacted policies to restrict waste from being released from ships that bear U.S. credentials. The Act to Prevent Pollution from Ships implements the international MARPOL Convention. The act restricts pollution from ships, establishes record keeping of materials released from ships, and provides penalties for violations of the act [53].

12.5.1.2.2 Public Health Implications of the Act to Prevent Pollution from Ships

As with the ODAct, the impact on human health of pollution dumped from ships is unknown. However, the consequences of marine pollution on ecosystems and marine life are undeniable and consequential. The deleterious effects of ocean pollution on birds and other wildlife dependent on the oceans have been well chronicled in news reports. Moreover, the presence of toxic substances in the tissues of marine life has also been well reported. In brief, ocean pollution affects the quality of human life and can contribute to adverse human health consequences. An environmental health policy such as the Act to Prevent Pollution from Ships that attempts to prevent ocean pollution comports with pollution prevention goals in much of the body of U.S. environmental health statutes.

ENFORCEMENT EXAMPLE

The Chairman of Sabine Transportation Company, Cedar Rapids, Iowa, was sentenced by a U.S. District judge in Miami, Florida, to 33 months in prison and fined $60,000 for violations of the Act to Prevent Pollution from Ships. The company was found guilty by a jury for dumping grain contaminated with diesel oil into the ocean during a vessel's trip from Singapore to Portland, Oregon. The company had previously been fined $2 million for similar dumping violations [54].

12.5.2 International Policies on Maritime Pollution

Because maritime pollution is a global issue, as related previously by description of ocean pollution, international treaties and actions by the UN have been implemented.

12.5.2.1 London Convention and Protocol, 1972

The Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter of 1972, known as the London Convention, is one of the first global conventions to protect the marine environment from human activities. The Convention has been in force since 1975. The Convention is an international treaty and is administered by the International Maritime Organization (IMO). The objective of the Convention is to promote the effective control of all sources of marine pollution and to take all practicable steps to prevent pollution of the sea by dumping of wastes and other matter [56].

In 1996, the "London Protocol" was accepted in order to further modernize the Convention and, eventually, replace it. Under the Protocol, all dumping is prohibited, except for possibly acceptable wastes on the so-called "reverse list". This list includes the following: (1) dredged material; (2) sewage sludge; (3) fish wastes; (4) vessels and platforms; (5) inert, inorganic geological material (e.g., mining wastes); (6) organic material of natural origin; (7) bulky items primarily comprising iron, steel, and concrete; and (8) CO_2 streams from CO_2 capture processes for sequestration.

The London Protocol entered into force on March 24, 2006. According to the IMO, "Under the unregulated dumping and incineration activities that developed in the late 1960s and early 1970s have been halted. Parties to the Convention agreed to control dumping by implementing regulatory programmers to assess the need for, and the potential impact of, dumping. They eliminated dumping of certain types of waste and, gradually, made this regime more restrictive by promoting sound waste management and pollution prevention. Prohibitions are in force for dumping of industrial and radioactive wastes, as well as for incineration at sea of industrial waste and sewage sludge. Under the Protocol all dumping is prohibited, except for the so-called "reverse list" [56]. The U.S., Russia, Brazil, and other South American countries are Parties to the Convention, but not Parties to the Protocol, which indicates that they accept the general principals of the Convention, but reserve the right to determine how to implement the Convention's protocol.

12.5.2.2 International Maritime Organization

On an international scale, the IMO, an agency of the UN, has led the development and implementation of treaties to control ocean pollution from ships. Created in 1948, the IMO's purposes include, "[t]o provide machinery for cooperation among Governments in the field of governmental regulation and practices relating to technical matters of all kinds affecting shipping engaged in international trade; to encourage and facilitate the general adoption of the highest practicable standards in matters concerning maritime safety, efficiency of navigation and prevention and control of maritime pollution from ships" [53].

Concerning marine pollution from ships, in 1973 the IMO issued the International Convention for the Prevention of Pollution from Ships, modified by the Protocol of 1978, both being referred to as MARPOL 73/78. The MARPOL Convention covers pollution by chemicals, goods in packaged form, sewage, garbage, and air pollution, as well as accidental and operational oil pollution (i.e., oil pollution from operation of a ship).

As an international treaty, adoption of the MARPOL Convention requires national legislation for its implementation. In the U.S., the Act to Prevent Pollution from Ships implements the provisions of the Convention. As stated in the Act, it "[a]pplies to all U.S. flag ships anywhere in the world and to all foreign flag vessels operating in the navigable waters of the U.S. or while at a port or terminal under the jurisdiction of the U.S. The oil and noxious liquid substances provisions apply only to seagoing ships. The regulations implementing Annex I and Annex II of MARPOL limit discharges of oil and noxious substances, establish report requirements for discharges, and establish specific requirements for monitoring equipment and record keeping aboard vessels" [55].

The act contains provisions for both criminal and civil penalties for violations.

An example of IMO's actions on setting global regulations applicable to maritime commerce is the establishment of limits on sulfur emissions from ships [55a]. In October 2016, the IMO set global regulations to limit the amount of sulfur emissions from vessels. The new requirements will result in sulfur emissions decreasing from the current maximum of 3.5% of fuel content to 0.5%. The regulation will come into force after year 2020. Analysts estimate the additional costs for the container shipping sector alone could be $35–$40 billion [55a]. The goal of the IMO regulation is to reduce air emissions of sulfur compounds released from vessels' diesel engines.

12.5.2.3 EU Maritime Pollution Policies

Many of the Member States of the EU have historic ties to Earth's oceans. These nations continue to derive multiple benefits from their seafaring endeavors. As such, the quality of ocean waters is of concern. One concern is the nature and volume of litter deposited in oceans. In response, the EU is developing a marine litter program that will be constructed around a directive issued by the European Commission (EC). Within the context of the European Marine Strategy Framework Directive [57], the Task Group for Marine Litter recommended that the overriding objective should be a measurable and significant decrease of the total amount of marine litter in comparison with initial baseline values by 2020. In support of developing the directive, the EC has provided important data on the extent of marine litter that impacts the EU, stated as follows [58]:

- Approximately 80% of marine litter is land-based.
- In 2004, marine water samples contained six times more plastic than plankton, i.e., out of 7 kilo, 6 kilos of plastic vs. 1 kilo of plankton.

- Cruise ships: 95,000 m³ of sewage from toilets and 5,420,000 m³ of sewage from sinks, galleys, and showers are released into the oceans each day.
- 250,000 kg of waste are removed from the North Sea yearly.
- Marine litter can cause serious economic damage: losses for coastal communities, tourism, shipping, and fishing.
- Potential cost across the EU for coastal and beach cleaning was assessed at almost €630 million per year, while the cost to the fishing industry could amount to almost €60 million, which would represent approximately 1% of total revenues of the EU fishing fleet in 2010. Taking into account its accumulation and dissemination, marine litter may be one of the fastest growing threats to the health of the world's oceans.

The 7th Environment Action Programme calls for the development of an EU-wide "quantitative reduction headline target for marine litter, supported by source-based measures and taking into account marine strategies established by Member States". Efforts in that direction are ongoing with discussions also to be held in the context of the Circular Economy review [59].

12.6 U.S. OIL POLLUTION ACT, 1990

Environmental disasters can serve as impetus for federal and state/provincial policymaking. Legislators do not want to be seen as ignoring catastrophes that have drawn public attention. A case in point is the U.S. Oil Pollution Act (OPAct) of 1990, which followed a massive oil spill in Alaska.

12.6.1 History

The OPAct was enacted by Congress in reaction to the large number of oil spills occurring annually in the U.S., and in particular, the legislation was markedly influenced by the 1989 oil spill in Alaska from the ruptured vessel *Exxon Valdez*. The act is a comprehensive amendment to the CWAct, §311. The OPAct is designed to enhance oil spill prevention, preparedness, and response capabilities and authorities of government agencies [60]. The act established a new liability and compensation regime for oil pollution incidents in the aquatic environment and provided the resources necessary for the removal of discharged oil.

The OPAct expands oil spill prevention, preparedness, and response capacities of the federal government and industry [62].

The Oil Spill Liability Trust Fund, which is similar in statutory concept to the CERCLAct's Hazardous Substance Trust Fund, created a $1 billion fund to be used to respond to, and provide compensation for damages caused by, discharge of oil. Similar to authorities in the CERCLAct, the OPAct provides that the responsible party for a vessel or a facility from which oil is discharged, or which poses a substantial threat of a discharge, is liable for certain damages and costs of removal of oil. In addition, the OPAct provides new requirements for contingency planning both by government and industry and establishes requirements on construction (e.g., §4115 of the act mandates newly constructed tank vessels must be equipped with double hulls, with the exception of vessels used only to respond to discharges of oil or hazardous substances), manning, and licensing for tank vessels [60].

Several federal agencies are responsible for implementing the OPAct. In general, the EPA is responsible for oil spill prevention, preparedness, and response activities associated with nontransportation-related onshore activities. The U.S. Department of Transportation is generally responsible for oil spill planning and response activities for tank vessels, transportation related onshore facilities, and deep water ports. The U.S. Department of Interior is responsible for oil spill planning and response activities for offshore facilities except deep water ports. States that have laws governing oil spill prevention and responses are covered under the Act. For example, §1019 provides states the authority to enforce, on the navigable waters of the state, OPAct requirements for evidence of financial responsibility.

ENFORCEMENT EXAMPLE

In 2010, British Petroleum's (BP's) Deepwater Horizon rig exploded and created the largest offshore oil disaster in history [63]. Eleven workers died. Millions of barrels of oil leaked into the Gulf of Mexico, producing massive water pollution and ecological damage across a swath of beaches and waterways along the Gulf coast. Since 2010, more than 1,400 dolphins have been found dead on the Northern Gulf of Mexico, with credible estimates of the loss of up to 1 million birds. BP agreed to pay more than $20 billion in fines [64]. The Clean Water Act sets the penalties, and in 2012 Congress passed the RESTORE Act, which ordered that the majority of civil fines be spent on Gulf Coast restoration.

When oil spills occur, the authorities and resources of the NCP) (Chapter 4) are used to quickly respond to emergency conditions that involve the release of oil or hazardous substances. The NCP, because it is based in law, brings together the coordination between federal government agencies and others in order to protect the public's health and the well-being of ecosystems. As policy, yoking government agencies in a legally binding rope of coordination well serves the public, since such cooperation is often difficult to achieve in the absence of law.

12.6.2 Public Health and Ecosystem Implications of the OPAct

The direct consequences to human health of the OPAct are not great. When spills or other releases of oil have occurred, few acute or chronic impacts on the public's health have been documented. For instance, ocean spills of oil released from large tanker ships have certainly fouled the surrounding environment, but had little impact on the health of persons tasked with emergency responding, beach restoration, waterfowl rescue, and ecosystem remediation. This can be attributed to

the training of responding personnel, use of protective equipment, and low toxicity of neat oil.

In contrast, the indirect impacts of oil spills on the environment are considerable. Large ocean spills of oil can contaminate fish, mammals, birds, and other living creatures, both in the water and on land. Although both the sea and land can absorb large scale oil pollution, there is always a residual amount that can work its way into the human food chain. Although the human health risk is very small, any chronic effects have not been investigated. Of a more acute nature, ocean spills that contaminate focal geographic areas can lead indigenous people to forego customary seafood and turn to less healthful alternative foods.

12.7 U.S. POLLUTION PREVENTION ACT, 1990

Much of U.S. federal environmental health policymaking has in a sense been focused on controlling ongoing releases of pollutants into various environmental media such as air and water. This is understandable in the context of legislative awareness of trying to respect economic interests but contemporaneously attempting to protect society against harm from environmental hazards. In other words, most policies have been directed at managing ongoing pollution, rather than preventing it from occurring. An exception to this theme is the PPAct, which is described in this section.

12.7.1 History

The PPAct is an example of a federal environmental statute whose genesis derives substantively from an EPA initiative. While the Executive Branch of the U.S. government has the authority, indeed, the responsibility, to propose legislation to the Congress, in fact, the main body of federal environmental law has generally been the outcome of Congressional interest and action. With the election of President George H.W. Bush came the appointment of William Reilly as EPA Administrator. Reilly was at the time the president of the World Wildlife Federation, a respected and venerable international environmental organization. He is the only EPA Administrator to have served as the leader of a major environmental organization.

The PPAct seeks to prevent pollution through reduced generation of pollutants at their point of origin [65].

One of Reilly's priorities was pollution prevention, which was thought to be preferable to dealing with "after-the-fact" pollution management. This prevention orientation is, of course, identical to the central thesis of public health—prevention of disease and disability. Reilly's pollution prevention priority found favor in Congress, contributing to the enactment of the PPAct.

The PPAct declares "[i]t to be the national policy of the United States that pollution should be prevented or reduced at the source whenever feasible, pollution that cannot be prevented should be recycled in an environmentally safe manner, whenever feasible; pollution that cannot be prevented or recycled should be treated in an environmentally safe manner whenever feasible; and disposal or other release into the environment should be employed only as a last resort and should be conducted in an environmentally safe manner [65]." This act encourages voluntary reduction of pollution and is, therefore, a complement to the command and control regulatory approach whereby pollution control is mandated of polluting sources.

Under authorities in the PPAct, the EPA is directed to implement several key actions of relevance to public health, as follows [65]:

§13103: EPA Activities—The EPA is directed to establish an office to promote multimedia (i.e., air, water, and soil) approaches to source reduction of pollution. The EPA is directed to review its regulations before and after proposal to determine their effects on source reduction, promoting source reduction by other federal agencies, and methods to assure the public's access to data collected under federal environmental statutes, and facilitating use of source reduction methods by business.

§13104: Grants to States for State Technical Assistance Programs—The EPA is directed to make matching grants to states for programs that promote business' use of source reduction techniques.

§13105: Source Reduction Clearinghouse—The EPA is required to establish a Source Reduction Clearinghouse to serve as a center for source reduction technology transfer, to undertake outreach and educational programs, and to collect and compile information from states that received grants under the provisions of the PPAct.

§13106: Source Reduction and Recycling Data Collection—Each owner or operator of a facility required to file an annual toxic chemical release form under the Emergency Planning and Community Right-to-Know Act* must also include a toxic chemical source reduction and recycling report for the preceding year [66].

§13107: EPA Report—The act required the EPA to report biennially to Congress on actions to implement the strategy to promote source reduction of pollution. The biennial report is required to contain an industry-by-industry analysis of data submitted by facilities to EPA; barriers to source reduction of pollution; recommendations on incentives to encourage research, development, and investment in source reduction; analyses of cost and technical feasibility of source reduction; and evaluation of methods to improve the public's access to the data collected by EPA under the provisions of the PPAct.

* * *

The requirements of the PPAct were extended to U.S. federal agencies under Presidential Executive Order 12856, signed by President Clinton on August 3, 1993 [67]. The Executive Order states, "[t]he head of each Federal agency is responsible for ensuring that all necessary actions are taken for the prevention of pollution with respect to that agency's

* Title III of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended by the Superfund Reauthorization Act of 1986.

activities and facilities, and for ensuring that agency's compliance with pollution prevention and emergency planning and community right-to-know provisions established pursuant to all implementing regulations issued pursuant to EPCRA {i.e., Emergency Planning and Community Right-to-Know Act, which is Title III of the CERCLAct} and the PPAct {i.e., Pollution Prevention Act of 1990}."

It should be noted that federal environmental laws generally exempt U.S. federal government agencies from responsibilities required of the private sector (e.g., businesses and corporations), unless specifically specified by statute. Another example of an environmental statute that specifies accountability required of federal agencies is found in the CERCLAct, where uncontrolled HWS under the control of federal agencies must be remediated, as is the situation with private sector responsibility. Presidential Executive Orders, such as the aforementioned one on pollution prevention, is one way to bring federal agencies into compliance with environmental laws directed at the private sector.

12.7.2 Public Health Implications of the PPAct

At its heart, the PPAct encourages reduction of pollution at its source. This is a complementary strategy to the command and control approach, which figures so prominently in environmental protection actions taken by federal regulatory agencies. Critics of command and control allege that, in concept, it allows too little flexibility in how to reduce specific sources of pollution and mandates actions not always consistent with current technologies. Supporters of command and control argue that absent strong, mandated, specific regulatory statements from government, pollution reduction would not occur; that is, voluntary actions to reduce pollution would be unreliable and uncoordinated across pollution generators. In fact, both sides of the command and control argument have some truth, and the PPAct attempts to bridge these two positions.

Given that air pollution, water contamination, hazardous waste sites, and toxic substances in workplaces and community environments are considered as hazards to human health, it is good practice to eliminate or reduce pollution sources. Toward that end, the PPAct contributes to improved public health.

12.8 GLOBAL PERSPECTIVE OF WASTE GENERATION

The generation and management of wastes are of global import and concern. All societies are faced with similar challenges: what to do with wastes produced by human activities such as industrialization, agriculture, and food acquisition. These challenges have given rise to regional, national, state/provincial, and local waste management policies that are tailored to waste conditions that present themselves to policymakers. On a global scale three wastes are of contemporary importance and impactful on human and ecosystem health: food, plastics, and electronics. All three will be described in this section.

12.8.1 Food Waste

As noted in Chapter 10 (Food Safety and Security), an important aspect of food security is food wastage. The seminal study on this subject was conducted in 2013 by FAO, which estimated that annually, approximately one-third of all food produced globally for human consumption is lost or wasted. This food wastage represents a missed opportunity to improve global food security and also to mitigate environmental impacts [67a].

On a national scale, researchers estimated that annually about 40% of all food in the U.S. goes uneaten, which represented the equivalent of $165 billion each year from food wastage. For comparison, this amount is approximately equal to the 2016–2017 total budget for the State of California. The top three food groups in terms of the value of food loss at these levels were the following: meat, poultry, and fish (41%); vegetables (17%); and dairy products (14%). These estimates at the U.S. consumer level translate into almost 124 kg (273 lb) of food lost from human consumption, per capita, in 2008 at an estimated retail price of $390/capita/year [68].

On a national scale, researchers estimated that annually about 40% of all food in the U.S. goes uneaten, which represented the equivalent of $165 billion each year from food wastage.

Similarly, a study by the UK government found that UK households waste 7 million tons of food—worth £700 per family—every year at a total cost of £12.5 billion. This is just less than half the 15 million tons of food wasted annually in the UK—the rest by supermarkets, restaurants, and elsewhere in the supply chain. Within these totals, UK householders throw away 34,000 tons of beef annually, wasting about £260 million worth of raw and cooked beef annually [69].

These numbers relating to food wastage must be understood in terms of the policy issue of lack of an international standard on how to define food waste. As observed by one group of researchers, agreement on how to define food wastage is lacking on a global scale. For instance, some consider any food not consumed by humans as being waste; however, some other sources do not consider discarded food that is fed to livestock (e.g., swine) as food wastage. In recognition of the lack of an international standard, an expert group has put forth a proposed set of guidelines that national and other organizations can use when accounting for food wastage, but adoption of the guidelines awaits [70].

* * *

Because food is one of the three necessities of life (i.e., air, water, and food), food wastage is a misuse of a vital resource. One might propose two paths to reduce food waste: (a) prevention of waste generation and/or (b) reuse/recycle generated food waste. Stated in different words, to reduce food wastage, simply don't generate food waste, or if it is generated, find ways to make use of the waste. For several reasons, the former path is preferable to the latter path. For instance, food

waste not generated does not require energy and economic resources necessary for dealing with generated food waste. Some exempts of each path follow.

Denmark has become a hallmark country in terms of reducing food waste. Celebrity chefs proselytize on entertainment media the virtues and methods to reduce food waste. Contemporaneously, social media campaigns also promote the message, "don't waste food." These efforts have resulted in Danes' increasing willingness to buy and consume items like just-expired dairy products and produce. According to a recent report from the Danish government, Danes now discard 25% less food than they did 5 years ago. Danes today discard 104 pounds of food per year on average compared to an estimated 273 pounds per person per year in the U.S. [71]. A similar resolve to reduce food waste is exemplified by efforts in South Korea. Seoul's city government requires residents to deposit their food waste in bins, where the amount of food they discard is weighed per household using a key-card system. Dispose of too much food and a fee is charged by municipal officials. Trial districts in Seoul have succeeded in reducing household food waste by 30% and restaurant food waste by 40%. Such programs are now underway in 90 localities nationwide in South Korea [72].

Food waste is an environmental hazard and is a threat to the health of ecosystems. In a 2007 report, FAO estimated that the global carbon footprint of wasted food was about 3.3 billion tons of CO_2-equivalents, which equates to about 7% of all global emissions in 2007 [74].

On the other path to waste reduction is reuse/recycling of generated food waste. In Colorado, a facility takes wasted food from Colorado's most populous areas and turns it into electricity. Through anaerobic digestion, spoiled milk, old pet food, and vats of grease combine with helpful bacteria in massive tanks to generate methane gas. The gas is transferred via a pipeline as fuel to use with electric power generators [73]. In California a company has developed a process that transforms truckloads of supermarket food waste into farm-ready fertilizer. The company developed an aerobic digestion method that accelerates the composting process, turning food waste into liquid fertilizer in 3 h. The company claims that since its launch in 2012, it has diverted more than 2.2 million pounds of food waste from a landfill, preventing the emissions of 3.2 million pounds of greenhouse gases (GHSs) and preventing the need for more than 1.1 million pounds of nitrogen fertilizers [75]. In Hong Kong, scientists at the City University of Hong Kong have found a method to turn coffee grounds and stale bakery goods into a sugary solution that can be used to manufacture plastic. The food waste is mixed with bacteria and fermented to produce succinic acid, a substance usually made from petrochemicals, and which can be found in a range of fibers, fabrics, and plastics [76].

Food waste is an environmental hazard and is a threat to the health of ecosystems. In a 2007 report, the FAO estimated that the global carbon footprint of wasted food was about 3.3 billion tons of CO_2-equivalents, which equates to about 7% of all global emissions in 2007. As perspective, this is more carbon than most countries emit in a year, with only China and the U.S. exceeding this amount in nationwide carbon emissions in 2007 [74]. GHSs, especially methane, released from landfills containing food waste are a significant contributor to climate change, as noted in the FAO study. Further, food waste can serve to unbalance the mix of wildlife within an ecosystem. And a growing body of evidence suggests that food waste may be reshaping the way the natural world functions globally, inadvertently food subsidizing some opportunistic predators and thus contributing to the decline of other species. For example, gulls with access to food waste in landfills have increased in numbers, resulting in fewer juvenile fish, a consequence of increased populations of gulls. Similarly, bears, coyotes, and wolves with access to food waste can increase in numbers and then pose a threat to domestic animals such as dogs and cats. Access to food waste serves to unbalance the normal mix of predators and prey [77].

12.8.2 Plastics Waste

Plastics are omnipresent in modern society. They are used to contain food, beverages, and retail products in general. As a contribution to public health, meat and other food products sealed in plastic wrappers inhibit contaminants from entering the food. Plastics are also used in construction of products as diverse as clothing and aircraft parts. They have become companions to humankind, but at a cost of their safe disposal. The total amount of plastic produced since the mid-twentieth century is approximately 5.51 billion tons, which is projected to rise to 33 billion tons by the end of the twenty-first century [78]. The sheer volume of plastic material is a challenge to waste managers and a threat to human and ecosystem health. As background, plastic is the general common term for a wide range of synthetic or semisynthetic materials used in a huge, and growing, range of applications. Plastics are organic; the same as wood, paper, or wool. The raw materials for plastics production include cellulose, coal, natural gas, salt, and crude oil. This section will describe some of the environmental health implications of plastics in waste streams.

The total amount of plastic produced since the mid-twentieth century is approximately 5.51 billion tons, which is projected to rise to 33 billion tons by the end of the twenty-first century. The sheer volume of plastic material is a challenge to waste managers and a threat to human and ecosystem health [78].

12.8.2.1 Plastics as Solid Waste

Plastics in the solid waste stream constitute a major challenge to waste managers. Two plastic products, beverage bottles and bags used in retailing, are the principal challenges, given the sheer volume of both plastic products, together with the longevity of plastics in general. Although recycling of plastics

is a commercial enterprise in some areas of the world, much plastic remains for dumping in landfills or by incineration. The volume of plastic waste, particularly bottles and bags, has stimulated some policymakers to limit or ban their use. This section will detail the plastic waste challenge presented by plastic bottles and bags.

According to EcoWatch, an NGO, the following items provide a picture of the impact of plastic waste [79]:

- Enough plastic is discarded annually to circle Earth four times.
- Only 5% of the plastics produced are currently recovered.
- The average American discards approximately 185 pounds of plastic per year.
- Plastic accounts for around 10% of the total waste generated.
- Americans discard 35 billion plastic water bottles annually.
- Approximately 500 billion plastic bags are used annually worldwide. More than one million bags are used every minute.
- It takes 500–1000 years for plastic to degrade.
- Virtually every piece of plastic that was ever made still exists in some shape or form (with the exception of the small amount that has been incinerated).

These statistics indicate that the presence of plastic products, especially bottles and bags, is significant in terms of waste disposal. In reaction, policymakers in several countries have instituted bans or other controls on the production and use of plastic bags and bottles. For example, California is the first U.S. state to ban single-use plastic bags. Large grocery stores and smaller businesses, like liquor and convenience stores, are prohibited from using plastic bags. Businesses are permitted to charge customers for use of paper bags [80]. France has apparently become the first country in the world to ban plastic plates, cups, and utensils, passing a law that will go into effect in 2020. The new law is a part of the country's Energy Transition for Green Growth Act, the same legislation that outlawed plastic bags in grocery stores and markets beginning in July 2016 [81].

Americans discard 35 billion plastic water bottles annually and discard approximately 185 pounds of plastic annually [79].

Several cities globally have implemented policies to ban the sale of plastic water bottles. In 2009 residents of Bundanoon, a town of 2500 residents about 100 miles south of Sydney, Australia, voted to ban the sale of bottled water, in part due to litter concerns. They were possibly the first community in the world to take such a step [82]. In 2013 Concord, Massachusetts, became the first U.S. city to enact a bylaw prohibiting the use of plastic water bottles [83]. Similarly, in 2014 San Francisco banned the sale of plastic water bottles. In 2011, the National Park Service of the U.S. issued Policy Memorandum 11-03 regarding the "recycling and reduction of disposable plastic bottles in parks." Regional directors of national parks could review and approve "a disposable plastic water bottle recycling and reduction policy, with an option to eliminate sales on a park-by-park basis." To date, prestigious parks including Arches, Bryce Canyon, Grand Canyon, Mount Rushmore, and Zion have banned bottled water sales [84].

Policymakers in some jurisdictions have taken alternative routes to outright banning of plastic bags and bottles for purpose of reducing the prevalence of plastic waste. For example, some jurisdictions such as New York City have enacted a bill that requires certain retailers to collect a 5-cent fee on each carryout bag, paper or plastic, with some exceptions [85]. Similarly, since 2014 retailers in Great Britain must charge customers five pence (8 U.S. cents) for plastic bags in an effort to wean the population off plastic shopping bags. The fee is estimated to reduce the garbage cleaning cost by £60 million ($80 million) over the next 10 years. In Wales, since 2001 when a similar measure was instituted, the use of plastic bags has decreased 79%. Rwanda banned plastic bags in 2008, and Bangladesh removed them in 2002 [86]. All these bans or restrictions on use of plastic bags are policies implemented for reduction of plastic waste in landfills, incinerators, and water sources.

12.8.2.2 Plastics in Oceans

There are two major threats to the security of oceans and the life they contain. One threat is climate change, as described in Chapter 6. Climate change is warming ocean waters and contributing to their acidification, resulting in ecosystem damage that may be irreversible. For instance, some coral reefs are dying and some fish populations are threatened by warmer ocean waters. The second major threat to ocean security is plastic waste, as described in this section.

As preface, according to EcoWatch, the following items provide an overview of the impact of plastic waste in ocean waters [79]:

- Billions of pounds of plastic can be found in swirling convergences in the oceans making up about 40% of Earth's ocean surfaces. Eighty percent of pollution enters the ocean from the land.
- Plastic constitutes approximately 90% of all trash floating on the oceans' surface, with 46,000 pieces of plastic per square mile.
- Plastic in the ocean decays into such small segments that pieces of plastic from a 1-L bottle could end up on every mile of beach throughout the world.
- 46% of plastics float (EPA 2006) and they can drift for years before eventually concentrating in the ocean gyres.*
- It takes 500–1000 years for plastic to degrade.
- The Great Pacific Garbage Patch is located in the North Pacific Gyre off the coast of California and

* Gyre: Oceanography: a ringlike system of ocean currents rotating clockwise in the Northern Hemisphere and counterclockwise in the Southern Hemisphere.

is the largest ocean garbage site in the world. This floating mass of plastic is twice the area of Texas, with plastic pieces outnumbering sea life six to one.
- One million sea birds and 100,000 marine mammals are killed annually from plastic in Earth's oceans.
- 44% of all seabird species, 22% of cetaceans, all sea turtle species, and a growing list of fish species have been documented with plastic in or around their bodies.
- In samples collected in Lake Erie, 85% of the plastic particles were smaller than 0.2 in., and much of that was microscopic. Researchers found 1500 and 1.7 million of these particles per square mile [79].

The Great Pacific Garbage Patch is located in the North Pacific Gyre off the coast of California and is the largest ocean garbage site in the world. This floating mass of plastic is twice the area of Texas, with plastic pieces outnumbering sea life six to one.

The quantity and prevalence of ocean plastics was estimated by a team of researchers from six nations who conducted 24 garbage-collecting ocean expeditions between 2007 and 2013. Based on their calculations, at least 5.25 trillion pieces of plastic—weighing nearly 269,000 tons—are currently present in Earth's oceans [87]. A different study linked worldwide data on solid waste, population density, and economic status in order to estimate the mass of land-based plastic waste entering the ocean. Investigators calculated that 275 million MT of plastic waste were generated in 192 coastal countries in 2010, with 4.8–12.7 million MT entering the ocean. The research also lists the world's 20 worst plastic polluters. According to the estimate, China tops the list, producing as much as 3.5 million MT of marine debris annually. The U.S., which generates as much as 110,000 MT of marine debris a year, ranked 20th [88].

12.8.2.3 Microbeads in Waste

Microbeads are a special form of plastic waste that is a hazard to the health of ecosystems. These are tiny bits of plastic used as ingredients in exfoliating body washes and facial scrubs. Since their introduction in 1972, they have made their way into more than 100 personal care products. Microbeads are used in soaps because exfoliating products need small, hard particles to rub debris from the skin [89]. Microbeads range in diameter from 5 μm to 1 mm. They are made from synthetic polymers including polyethylene, polylactic acid, polypropylenepolystyrene, or polyethylene terephthalate. One group of researchers calculated that 8 trillion microbeads per day are emitted into aquatic habitats in the U.S. Further, the investigators estimate that the 8 trillion beads that make it into aquatic habitats are only 1% of the total release, which would amount to 800 trillion microbeads ending up in the sludgy runoff from sewage plants [90]. A study by Japanese investigators found the concentration of microplastics, defined as plastic particles up to 5 mm in diameter, is higher in sediment than in sea water, raising concerns that it could affect organisms living in and on the bottom of the ocean. The study examined samples of sediment collected from the sea floor and elsewhere in area that included Tokyo, Southeast Asia, and Africa [91]. As will be described in the next section, microbeads present a serious threat to the health of ecosystems.

Because of concerns that microbeads can deleteriously affect aquatic life and ecosystems in general, several policymakers have enacted polices to prevent microbeads from entering environmental media. Of particular note, the U.S. Congress enacted the Microbead-Free Waters Act of 2015, which was signed into law by President Obama on December 28, 2015. The act requires the manufacturing of products containing microbeads to end by July 1, 2017, and their sale to cease by July 1, 2018 [92]. This action by Congress was stimulated by concern that microbeads were polluting the Great Lakes. Similarly, the UK government has announced plans to ban microbeads used in cosmetics and cleaning products by 2017 [93]. Further, the federal government of Canada has announced that it intends to ban microbeads used in personal care products. The Canadian federal government intends to develop regulations to prohibit the manufacture, import, and sale of microbead-containing care products [94].

12.8.2.4 Human Health and Ecological Effects of Plastics Waste

Any implications of plastics waste affecting human health seem undocumented. In contrast, the effects of plastic waste on ecosystems, particularly in regard to aquatic systems, are consequential and have led to considerable policy efforts to prevent or reduce releases of plastics waste into environmental media. A sample of investigations of the effects of microparticles on marine life is given in Table 12.9. While the presence of microparticles in tissues of fish and other marine animals is well documented, the health consequences are a subject of research, with the investigations shown in the table raising concern for the implications.

Perspective: Plastics are a boon to retailers and grocers, but a bane to waste managers. As related in this chapter, the sheer volume of plastic products presents a challenge to their

TABLE 12.9
Effects of Microparticles on Marine Life

Effect of Exposure	Reference
Fish eggs had a lower hatch rate; fish were smaller and less physically active; predator avoidance impaired	[113]
Stunted growth of creatures near the bottom of the food chain such as worms, plankton, mussels, and oysters	[114]
Exposed oysters produced fewer larvae, which grew at a slower rate, and ultimately reached a smaller size than larvae unexposed to microplastics	[115]
Microplastics found in the skin of both farmed and wild fish; unknown effect	[116]
Strong inflammatory response in blue mussels demonstrated by the formation of granulocytomas and lysosomal membrane destabilization	[117]

waste disposal. Unfortunately, plastic waste in oceans has become a global threat to marine life and coastal ecosystems. The presence of microplastics, e.g., microbeads, in environmental media and in marine life has led to policies of outright bans on them. But one must ask why microbeads placed in soaps, cosmetics, and similar products became product ingredients without any apparent consideration given to the consequences of microbead waste added to the environment. Another observation is to ask why biodegradable plastics have yet to become a reality.

12.8.3 Electronic Products Waste

Consumer products that contain electronics now abound globally. These products include vehicles with engine computers; kitchen equipment; entertainment devices such as flat screen TVs, computers, telephones, and many more. Electronics represent the global digital world upon which social media and modern day commerce rely. The variety and volume of electronic products is enormous. But as with other products of popular commerce, popularity equates to volume of production, accompanied by challenges of waste disposal when the products become passé or inoperative. Modern societies find themselves facing the nitty-gritty reality of what has become known as electronic waste or e-waste, which is defined as any device with an electric cord or battery—from refrigerators to smartphones [95]. And as with other environmental health issues, e-waste is a global problem.

A study conducted by researchers at the United Nations University found that the U.S. and China contributed most to record mountains of electronic waste in 2014; the study also found that worldwide less than a sixth was recycled [95]. Overall, 41.8 million tons of e-waste were discarded globally in 2014, with only an estimated 6.5 million tons recycled. The researchers estimated that the discarded materials, including Au, Ag, Fe, and Cu, were worth some $52 billion.

The U.S led e-waste dumping with 7.1 million tons in 2014, ahead of China at 6.0 million, followed by Japan, Germany, and India. The U.S., where individual U.S. states enforce e-waste laws, reported collection of 1 million tons for 2012 while China said it collected 1.3 million tons of e-waste in 2013. Norway led per capita waste generation, with 28 kg (62 lbs) dumped per inhabitant, followed by Switzerland, Iceland, Denmark, and Britain. On a per capita ranking, the U.S. was ninth and China was not among a list of the top 40 [95].

The study's researchers said that in many cases it made economic sense to recover metals that included 16.5 million tons of Fe, 1.9 million tons of Cu as well as 300 tons of Au. The gold alone was valued at $11.2 billion. Global volumes of e-waste were likely to rise by more than 20% to 50 million tons in 2018, according to the researchers' estimates.

The huge volume of e-waste has implications for human and ecosystem health. As noted by WHO, recycling of e-waste to retrieve metals—for example, Cu and Ag—has become a source of income in developing or emerging industrialized countries [96]. E-waste-connected health risks may result from direct contact with harmful materials such as Pb, Cd, Cr, brominated flame retardants, or PCBs, from inhalation of toxic fumes (e.g., from burning electric cable to reclaiming Cu), as well as from accumulation of chemicals in soil, water, and food. Children are especially vulnerable to the health risks that may result from e-waste exposure and, therefore, need more specific protection. As they are still growing, children's intake of air, water, and food in proportion to their weight is significantly increased compared to adults [96]. Journalists who visited two of the world's largest e-waste dumps reported children were at risk of exposure to e-waste contaminants during recycling processes. At one e-waste dump, many of the workers at the Agbogbloshie site in Nigeria were middle school-age boys who smash electronics to get their metals, thereby exposing themselves to toxic metals such as Cu, Cd, and Cr [97]. Similarly, the Chinese city of Guiyu, Guangdong Province, receives some 15,000 MT of waste every day. Most of the city's residents work in the recycling industry. Research by a Chinese university found abnormally high levels of lead in the city's children's blood [98].

12.9 WASTE REDUCTION: RECYCLING OF WASTE

What to do about waste has been a perplexing challenge to humankind from the time that small societies began to form. As human experience accrued, generation of waste, especially that produced by industrialization of national economie, became a societal issue. Landfills and waste dumps became sources of vermin, environmental pollution, and a burdensome economic impact. Gradually, twentieth-century policymakers, urban planners, environmental groups, and public health advocates came to the realization that waste reduction should become a societal policy.

The importance of waste reduction is fueled by knowledge that the volume of waste generated globally will continue to increase. This is according to World Bank researchers, who estimated that global solid waste generation would rise from more than 3.5 million tons per day in 2010 to more than 6 million tons per day in 2025. The researchers further predicted that by 2100 solid waste generation rates will exceed 11 million tons per day—more than three times the 2010 rate. Although these predictions come with uncertainty due to data limitations, the researchers aver that waste generation will significantly increase unless policy interventions are implemented [1,99].

One way to limit the impact of increased volumes of waste is to implement waste reduction strategies, as exemplified by the four Rs in Table 12.1. Recycling, one of the four Rs, is the process of collecting and processing materials that would otherwise be thrown away as trash and then turning the materials into new products. The EPA cites several benefits of waste recycling [100]:

- Reduces the amount of waste sent to landfills and incinerators
- Conserves natural resources such as timber, water, and minerals

- Prevents pollution by reducing the need to collect new raw materials
- Saves energy
- Reduces GHS emissions that contribute to global climate change
- Helps sustain the environment for future generations
- Helps create new jobs in the recycling and manufacturing industries.

Americans recycle 34% of all the waste they create, according to the EPA. In total, Americans generated 254 million tons of trash in 2013, which is about 4.4 pounds per person per day [101]. Many European countries have developed more successful recycling programs, with Austria and Germany executing the highest recycling rates at 63% and 62%, respectively [102]. There are numerous examples of recycling of waste materials that are familiar to residents of the industrialized countries. Perhaps the premier example is recycling of aluminum products, particularly containers of beverages. In 2016 nearly $1 billion worth of aluminum cans were discarded in the U.S. The aluminum industry spends more than $800 million annually for recycled cans. The U.S. aluminum can recycling rate is approximately 67%, yielding nearly a billion dollars of recycling profit annually [103].

12.9.1 Recycling Issues

There are some policy-relevant issues in recycling of waste. One issue is the fact that recycling itself is often a commercial enterprise, a desirable outcome whereby waste is converted into something useful and concurrently provides jobs and income for individuals and businesses. Additionally, recycling can be the genesis of creative processes for managing waste reduction. However, commercial recycling can suffer the same kinds of problems as any other business endeavor. For example, creation of products that lack customer appeal can lead to loss of revenues and present business sustainability challenges. Recycling of plastic products is a case in point. In 2016, global oil prices decreased to new lows due in part to a glut of oil placed in global markets. One consequence was to hinder recycling of plastic materials, since it became less expensive to produce a plastic product using cheaper oil supplies than to purchase a recycled plastic product that cost more to manufacture [104].

Further, commercial recycling is sometimes subsidized by governments anxious to comply with ordinance or local policies for waste reduction. Recycling industry sources assert that 2000 U.S. municipalities are paying to dispose of their recyclables instead of the other way around. Once a profitable business for cities and private employers alike, in recent years the recycling industry has become a negative income business due to multiple factors. These factors include decreased demand for commodities produced through recycling, a change in waste from paper to glass to plastics, both of which are less attractive for recycling, and more waste that requires sorting prior to recycling. The diminished profitability of waste recycling has resulted in more pressure on municipalities to increase their subsidies [105]. This kind of economic pressure ultimately translates into strain on decision-making by policymakers.

12.9.2 Innovative Technology for Waste Reduction

Economic and sociopolitical forces have contributed to a larger recognition of the benefits of waste reduction. Economic benefits can accrue from converting waste into commercial commodities. Sociopolitical forces include government policies developed for purpose of waste control and environmental groups are active in promoting waste reduction policies. A consequence of these kinds of forces can be innovative efforts forged for waste reduction. Two examples of innovation in waste reduction are exemplified by recycling of cigarette butts and changes underway in the global garment industry.

Cigarette butts are the most numerous form of trash that volunteers collect from the world's beaches on the Ocean Conservancy's cleanup days. More than 2 million cigarette parts were recently collected in a single year worldwide. Other sources present the same data. For instance, New York State experiences an estimated 1.5 million tons of cigarette butts a year. In Texas, butts account for about 13% of the litter accumulated on the state's highways, equaling 130 million butts a year. However, cigarette filters are made from wood-based plastic fibers that can be recycled. There are now a handful of companies working to collect and recycle spent cigarette butts and recycle them into plastic lumber that can be used for benches, pallets, and other uses [106].

As shown in Figure 12.2, textiles are a significant item in the waste stream. Some critics point out the damage being caused by a throwaway culture that is fueled by inexpensive clothing, which has seen a sharp rise in the number of garments annually sold around the world [107]. In a nascent effort to reduce the volume of textile waste, some fashion firms are turning to recycling of textile material for conversion into new fashions and for other uses. For instance, a company in Sweden launched a line of jeans containing recycled cotton and will offer an annual €1-million ($1.16 million) prize for new techniques to recycle clothes. On a smaller scale, Finnish entrepreneurs have managed to produce sweat shirts from 100% recycled cotton after improving existing recycling techniques and by recycling offcuts from clothes factories. However, others believe that recycling is just a distraction from the real challenge of the fashion industry: persuading customers to keep wearing their clothes for longer. To that end, a British designer is offering a 30-year guarantee on a range of T-shirts [107].

Of special promise are findings from a team of Japanese researchers who discovered a species of bacteria that can break the molecular bonds of one of the world's most-used plastics—polyethylene terephthalate, also known as PET or polyester. The Japanese research team sifted through hundreds of samples of PET pollution before finding a colony of organisms using the plastic as a food source. Further tests found the bacteria almost completely degraded low-quality plastic within six weeks. Use of this process to biodegrade plastics waste would be a most remarkable contribution to waste management [108].

12.9.3 The Circular Economy

An economic model that promotes waste prevention is the circular economy, a generic term for an industrial economy that is producing no waste and pollution, by design or intention, and in which material flows are of two types: biological nutrients, designed to reenter the biosphere safely, and technical nutrients. The latter are designed to circulate at high quality in the production system without entering the biosphere as well as being restorative and regenerative by design. This is contrast to a Linear Economy which is a "take, make, dispose" model of production [109].

As an example of adoption of the circular economy model, the EU has developed and begun to implement an enabling strategy [110]. In 2015, the European Commission adopted its Circular Economy Package, which includes revised legislative proposals on waste to stimulate Europe's transition toward a circular economy, which will boost global competitiveness, foster sustainable economic growth and generate new jobs.

The revised EU legislative proposals on waste set clear targets for reduction of waste and establish a long-term path for waste management and recycling. "Key elements of the revised waste proposal include:

- A common EU target for recycling 65% of municipal waste by 2030,
- A common EU target for recycling 75% of packaging waste by 2030,
- A binding landfill target to reduce landfill to maximum of 10% of municipal waste by 2030,
- A ban on landfilling of separately collected waste,
- Promotion of economic instruments to discourage landfilling,
- Simplified and improved definitions and harmonised calculation methods for recycling rates throughout the EU,
- Concrete measures to promote re-use and stimulate industrial symbiosis—turning one industry's by-product into another industry's raw material,
- Economic incentives for producers to put greener products on the market and support recovery and recycling schemes (e.g., for packaging, batteries, electric and electronic equipments, vehicles)" [110].

Some other countries (e.g., Australia) are considering or already implementing circular economy programs. It is worthy of mentioning that some persons prefer the term "regenerative economy," one in which, from beginning to end, the parts of a product can be reused over and over again. Regeneration is also about finding new ways of conceiving what a business, a building, or a product can be [111].

12.10 HAZARD INTERVENTIONS

This chapter is about waste generation and management. Some waste is inevitable, such as bodily wastes, agricultural and industrial wastes, and household wastes. And with waste generation comes the equally inevitable problem of waste management. Improperly managed waste disposal can be a hazard to human and ecosystem health, especially the latter. Interventions to mitigate or eliminate such hazards are therefore in the spirit of environmental health prevention policies. Some hazard interventions could include the following:

- Waste management policies at all levels of society, including individual members, must include elements of waste prevention and methods of proper waste management.
- Commercial products while in the design phase should include considerations of the implications of product waste. Waste management should be part of engineering education regardless of engineering specialty.
- Education of the public about waste management should be a subject of public service announcements on communication systems, e.g., television and social media.
- Commercial enterprises should be cognizant of the generation and management of waste during their operations and implement policies of waste minimization.
- Agricultural operations should implement waste minimization policies and methods, utilizing educational material available from local and national agricultural authorities.
- Individuals can make a positive impact on reducing waste by adopting personal policies such as avoiding using plastic bags and bottles through use of alternative products.
- Individuals should support policymakers whose agenda includes environmental health concerns.
- Individuals should encourage environmental and commercial organizations that promote waste reduction policies.
- The power of the purse is a forceful impetus in policymaking. In that vein, purchasing products made in whole or part from recycled materials will increase recycling of wastes.

12.11 SUMMARY

The two major statutes discussed in this chapter are the SWAct, which upon amendment became known as the Resource Conservation and Recovery Act (RCRAct), and the Compressive Environmental Response and Liability Act (CERCLAct, or Superfund). Both statutes contain a number of important environmental health policies of relevance to public health. From the RCRAct, open dumps were prohibited in the U.S., thereby eliminating places where disease-carrying vermin prospered, and placed upon states the responsibility for solid waste management, which is an example of federalism at work. The RCRAct also requires permits for those facilities that conduct hazardous waste management activities. The act also authorizes the EPA to inspect hazardous waste facilities

and issue corrective action orders when standards are not being met by facility operators. The policies of establishing national standards, issuance of permits for control of environmental hazards and inspection of facilities, in concept, are the same found in some other environmental statutes, e.g., the Clean Air Act, as amended. These policies' purpose is to control releases of potentially hazardous environmental substances into the environment.

The CERCLAct also contains several important policies of relevance to public health. The act identifies uncontrolled HWS and ranks those that are the most hazardous to human health and the environment (i.e., the NPL sites). The highest ranked sites are remediated preferentially before those of lesser hazard, a policy that comports with the public health practice of addressing first those hazards of greatest threat to human health. The CERCLAct also contains the policy of "the polluter pays for the costs of their pollution," which is a statement of accountability to the public. Lastly, the CERCLAct is unique among federal environmental statutes in its creation of a federal public health agency, ATSDR, for the purpose of addressing a specific environmental hazard—in this case, human exposure to uncontrolled hazardous substances.

Other acts discussed in this chapter consisted of the OPAct, the ODAct, Act to Prevent Pollution from Ships, and the PPAct. All four acts are intended to prevent or reduce the amount of pollution released into the environment. Reduced pollution levels are commensurate with improved public health protection, since the opportunity for human exposure is lessened.

Mismanagement of waste is a global issue and challenge. Described in this chapter are environmental health problems associated with disposal of plastics waste, electronics waste, and food waste. All three forms of waste are huge in volume and each represents a threat to ecosystem health. Global treaties have been developed (e.g., London Convention) for purpose of controlling waste generation and its mismanagement.

12.12 POLICY QUESTIONS

1. Contact your county or municipal waste management department to obtain the amount of household waste collected per week. Does your county or municipality operate one or more incinerators for disposal of waste? How many landfills are present in your survey? What is the average cost to households of waste removal and disposal?
2. Plastic waste is discussed in this chapter as a major global hazard to ocean and other water-based ecosystems. In your review of this chapter and other information resources, are there any policies that should be adopted as U.S. federal policies for purpose of controlling the amount of plastic waste left in the environment?
3. E-waste is an increasingly important burden for waste managers. Survey your personal possession of devices that could contribute in time to e-waste. Discuss each device's potential for recycling or reuse. Be specific. Ascertain if the locale in which you reside has capacity for management of e-wastes.
4. The RCRAct, as amended, covers the management of MSW and other wastes. Discuss five actions that you personally can take to reduce the volume of your household waste. Estimate in pounds the annual volume of waste reduction that you can achieve.
5. Using Internet resources, ascertain your state's programs and policies that pertain to the management of hazardous waste. Discuss what you consider to be the single most effective policy.
6. The CERCLAct (also called the Superfund Act), as amended, requires the EPA to rank uncontrolled HWS and place the most hazardous sites on the NPL. Using EPA resources, ascertain the number of NPL sites in your state. Discuss the status of any site's remediation. If there are no NPL sites in your state, select an adjacent state that contains one or more NPL sites.
7. Many states have state-based CERCLA programs. Ascertain if your state has such a program. If so, how many "state-lead" uncontrolled HWS are being remediated in your state. Select the site nearest to your residence and describe its remediation status.
8. In your opinion, do the successes of the federal CERCLA statute, as amended, outweigh its criticisms when considered in a public health context (Tables 12.5, 12.6)? Why? Be specific.
9. Discuss the essential public health differences between the RCRAct and the CERCLAct. Be specific.
10. What U.S. Public Health Service agency was created by the CERCLAct? Why?
11. Love Canal, New York, was found to be an uncontrolled hazardous waste, which became the impetus for Congress enacting the Superfund Act. Using Internet resources, discuss the actions taken by the federal government in mediating the Love Canal site. Discuss the current condition of the site.
12. As a person concerned about environmental health, keep a log for one week of the items and their estimated weight that you discard. For each item, discuss the potential for its recyclability. Discuss any methods that you use to reduce your personal amount of household waste.
13. Contact the county or municipal waste management department and ascertain if and how they use waste recycling for municipal waste reduction. Given the department's reply, discuss in your opinion, any gaps in the department's waste reduction programs.
14. You have been asked by a local community group to advise them on the efficacy of doubling the size of the county's solid waste landfill. The community group is especially concerned about public health implications. Discuss your response to the group.
15. Children in many developing countries are exposed to hazardous substances dumped in landfills. Discuss

the ways that children in these countries can come into contact with landfill waste. Describe five substances in municipal landfills that be a health hazard to children.

16. Assume that your county or province or parish or tribe is considering an ordinance that would require household waste to be separated into categories of paper/paper products, glass, metals, hazardous chemicals, and miscellaneous. Your neighborhood's residents have organized into two disparate camps: one group supports the ordinance; the other group opposes. Which group will you join and why? Does your answer change, assuming you are a senior public health specialist? Elaborate your answers.
17. Give five examples of commercial products derived from recycled waste. Are any of these products those that you personally use? Assume all five products cost 10% more than products made without use of recycled materials. Will you purchase them? If so, why? If not, why?
18. Some cities or other governed entities have banned the use of plastic bags by retailers such as grocery stores, apparel shops, and such. Assuming that you reside in such a locale, what steps will you take, if any, in compliance with the ban on plastic bags?
19. As a design engineer with a Fortune 500 company, you are head of a group that has been asked to update a product that historically ends its life wholly deposited in a landfill. Led by the engineer genius that you claim to be, your group has invented a product update that produces 50% less waste, but will cost 15% more than the current version of the product. What arguments will you make to "the suits" in support of your group's proposed design? Will environmental ethics be an element of your argument?
20. Well done! You have completed another chapter. We trust you don't consider this effort to have been a waste. Discuss the three most important lessons you learned from your study of this chapter's material. Was your personal environmental health behavior or policymaking changed by the content of this chapter? If so, how? If not, why not?

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13 Environment-Related Infectious Diseases

13.1 INTRODUCTION

Prior chapters of this book have addressed chemical hazards in the environment (e.g., air, water, and food) that had led to policymaking to control the effects on human and ecological health. This chapter describes a different kind of environmental-related outcome, infectious diseases. These diseases are caused by organisms or pathogens (such as viruses, bacteria, fungi, parasites, or protozoa) that can be transmitted through physical contact with or exposure to bodily fluids of an infected person. These causal agents are collectively called *vectors*, which are defined as living organisms that can transmit infectious diseases between humans or from animals to humans. A particularly hazardous disease agent is shown in Figure 13.1. Infectious diseases are constantly circulating within a population. However, when an infectious disease causes an increased, or unexpected, number of cases, it can be classified as an *outbreak*. Health departments at federal, state, tribal, and local levels monitor cases of infectious diseases and implement actions to control emerging and reemerging pathogens within their populations. This chapter describes various infectious agents in the environment and policies and public health actions taken to mitigate the adverse human and ecological health effects.

13.2 INFECTIOUS DISEASES: A GLOBAL PERSPECTIVE

In high-income countries, medical and public health advances and sound environmental policies created a shift toward noncommunicable, chronic conditions. Infectious diseases, however, still significantly contribute to the global burden of disease, in particular in developing countries. The U.S. recognizes that infectious diseases remain a problem worldwide. The U.S. commitment to combat the spread of infectious diseases is visible through global programs and funds. In the U.S., the Centers for Disease Control and Prevention (CDC) is the leading national public health agency in charge of early detection, control, prevention, and preparedness. A National Notifiable Diseases Surveillance System (NNDSS) collects, analyzes, and shares health data on notifiable diseases among local, state, territorial, federal, and international public health departments.

The World Health Organization (WHO) is the UN's public health agency and the leading international health organization, supported by 193 member states. WHO has established a disease surveillance network comprised of national and international medical laboratories in its member states. The CDC, the UK Public Health Laboratory Service, the French Pasteur Institute, and schools of public health globally report to WHO on a series of infectious diseases [1]. Under WHO's International Health Regulations (IHR), member states are legally required to report infectious diseases of international importance. WHO also provides operational support to response efforts during an epidemic and strengthens national core capacities to prevent, prepare, and recover for and from emergencies [2]. Furthermore, WHO environmental guidelines and policies on drinking water, sanitation and hygiene, and use of chemicals such as insecticides, directly and indirectly contribute to the prevention of infectious diseases.

13.3 THE ENVIRONMENT AND INFECTIOUS DISEASES

The primary determinant of infectious diseases is the pathogen (the infectious agent). A *pathogen* is any organism (usually a microbe) that can cause disease in a host. The host, the second determinant of infectious disease, is exposed to the pathogen and either harbors the disease, or becomes ill [3]. Public health is concerned mostly with human hosts; however, animal hosts can have an impact on human health. The environment is necessary for the exposure to and the spread of the infectious agent and is therefore the third determinant of infectious disease. As depicted in Figure 13.2, the three vertices of the triangle connect the pathogen, host, and environment to allow the transmission of infectious diseases. This chapter describes the role of the environment in transmission and control of infectious diseases [4].

13.3.1 Cholera

Cholera is caused by the bacterium *Vibrio cholerae*. During the 1800s, cholera outbreaks occurred frequently in the U.S. Cholera is transmitted by ingestion of water or food that has been contaminated with human feces. Upon infection, the cholera bacterium releases a toxin (classified as O1 or O139) that can cause severe diarrhea and dehydration [5,6]. If left untreated, it can be fatal. Currently, cholera is mostly travel-associated [7,8]. The CDCs' Cholera and Other Vibrio Illness Surveillance System was created in 1988 in partnership with the Food and Drug Administration (FDA) and Gulf Coast States to obtain information on any Vibrionaceae-associated illness and provide information about risk groups and exposure risk [9]. Other systems that conduct surveillance on *Vibrio*-associated illness include the NNDSS, the National Antimicrobial Resistance Monitoring System, and the National Outbreak Reporting System. All cholera cases also have to be reported to WHO in compliance with international health regulations.

Cholera is endemic in more than 50 countries worldwide. The last endemic cholera outbreak in the U.S. occurred in

FIGURE 13.1 The female Aedes aegypti mosquito that carries the Zika virus. (From Centers for Disease Control and Prevention, Zika virus. https://www.cdc.gov/zika/symptoms/symptoms.html, 2017.

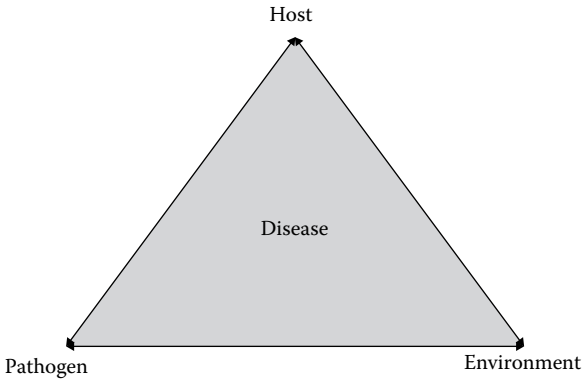

FIGURE 13.2 Epidemiological triangle of disease. An illustration of the relationship between pathogen (or agent), host and, environment. (From CDC, *Principles of Epidemiology in Public Health Practice—An Introduction to Applied Epidemiology and Biostatistics*, 3rd ed., Atlanta, GA, 1–511, 2006, https://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson1/section8.html.)

1911. Most cases occur in African and Asian countries where populations do not have access to improved drinking water sources. WHO maintains and publishes weekly reports of aggregate national cholera data. The 1969 WHO IHRs and the 2005 ratification require WHO notification of all cholera cases. Cholera, however, is estimated to be heavily underreported, with official estimates representing 5%–10% of all annual cases. It is estimated that an annual one to four million cholera infections occur worldwide, resulting in an estimated 21,000–143,000 annual deaths [10].

Cholera disease is particularly fatal to children. A simple scientific advancement known as Oral Rehydration Therapy replaces essential salts and body fluids through a sodium glucose mixture known as oral rehydration salts (ORS). ORS are cheap, globally distributed, and credited for reducing cholera as well as other diarrheal disease mortality in children by more than 54% from 1.3 million in 2000 to fewer than 600,000 in 2013 [11]. However, even with an inexpensive and effective solution to decrease cholera morbidity, cholera prevention is based entirely on providing clean water supplies for human consumption [12]. Many people in developing countries do not have access to safe drinking water on a daily basis [13] (Chapter 9). Recent epidemics have demonstrated poor infrastructure accelerates the spread of water-borne diseases during a natural disaster [10]. An example of an inadequate public health infrastructure follows.

On January 12, 2010, a 7.0-magnitude earthquake struck Haiti. The country was already the poorest country in the Western Hemisphere. The Haitian population largely depended on the agricultural sector, residents lived in poverty in overcrowded slums, and Haitians had limited access to sanitation and clean water. Despite a severely limited public health infrastructure, there had never been a case of cholera reported in Haiti [14]. The earthquake and its aftermath killed an estimated 230,000 people and displaced most of the nation's population. The international community was quick to respond and large-scale search and rescue missions began within days. On October 17, 2010, the first case of cholera was reported to international agencies [15]. Investigations by WHO found that cholera had been introduced into Haiti by the UN's Nepalese peacekeepers. The Nepalese UN base was located upstream of the Artibonite River, which supplied most of the country with fresh drinking water. Improper sanitation practices at the base, including open dump pits and leaky latrine pipes, allowed human feces infected with *V. cholerae* O1, serotype Ogawa, a strain found in cholera cases in Nepal to enter the river. By March 2011, more than 500,000 cholera infections were reported with approximately 5000 deaths. Since its introduction, several subsequent cholera outbreaks have been reported in Haiti [16].

13.3.2 Typhus

Mites, lice, and fleas are as ubiquitous as ticks. Mites can live freely in the environment or as parasites feeding on mammalian blood and keratin (nails and hair). Due to their parasitic nature, mites can cause common diseases such as scabies (*Sarcoptes scabiei*) or transmit bacterial diseases such as scrub typhus [17]. Scrub typhus bacteria (*Orientia tsutsugamushi*) is transmitted by mites throughout Asia and Australia. This wide ecological distribution is due to geographic spread of the vector and a high population density. Scrub typhus presents as a febrile illness with headaches and rash. Even though it is not endemic in the U.S., the global burden of disease is high with scrub typhus infections accounting for more than 20% of febrile illness hospitalizations in some Asian countries [18,19].

Fleas are parasites that live on birds or mammals and exclusively feed on host blood. Rat and cat fleas (*Xenopsylla cheopis* and *Ctenocephalides felis*) can transmit *Rickettsia typhi*, a bacterium that can cause human illness when infected flea feces are rubbed into scraps or bites in the skin. In the U.S., cases of murine typhus have been reported in Hawaii, California, and Texas. Murine typhus infections include common symptoms such as fever, rash, and headache; when left untreated can lead to organ damage [19].

Lastly, body lice can transmit *Rickettsia prowazekii*, the typhus fever causative agent. Typhus fever bacteria is spread by lice through contaminated feces similarly to murine typhus. When left untreated, typhus fever can cause common symptoms

and a distinct upper trunk rash. Typhus fever is not endemic in the U.S. but is present in colder regions of South America, Africa, and Asia. When left untreated, the case fatality rate is 40% [20].

The wide range and variety of ticks, mites, fleas and lice; the number of specific diseases; and the different hosts from which they can feed make these arthropod-borne diseases impossible to eradicate. Control and prevention strategies target personal protection to avoid coming in contact with and using repellents containing 20%–30% DEET (*N*,*N*-diethyl-*m*-toluamide) when going into wooded areas [21]. Personal hygiene and sanitation are also essential in combating mites, fleas, and lice. Currently, some of the mite- and lice-borne diseases discussed are not endemic in the U.S.; however, globalization and population movement, combined with an increase in population density, increase the likelihood of these arthropods to disseminate across a larger geographic range.

13.3.3 Implications for Environmental Health Policy: Clean Water and Sanitation

The U.S. federal government's involvement in preventing and controlling the spread of infectious diseases is a recent occurrence in the nation's history. Toward the end of the nineteenth century, industrialization of the disparate, rural, agrarian towns that made up most of the U.S. forced the migration and concentration of people into cities. This made infectious disease outbreaks larger in magnitude, more difficult to control, and more costly to society. State and local governments were in charge of combating disease and illness, but this task was still viewed as a personal responsibility. However, as national outbreaks of cholera occurred, the U.S. federal government was forced to establish clean water and waste disposal systems in the U.S. The Public Health Service Act (PHSAct) of 1912 implemented the first federal policies to dispose of human waste. The modern water and sewage treatment systems that emerged in the U.S. and other Western countries during the twentieth century made it possible to adequately dispose and treat sanitary waste (Chapter 12). The separation of water and sewage eliminated many water-borne diseases, including cholera in the U.S. [22]. However, water-borne diseases such as cholera remain a problem in the world mostly due to limited access to potable drinking water. In response, WHO has issued guidelines for drinking water quality [23]. As previously noted, the introduction of cholera during natural disasters, such as the 2010 Haiti Earthquake, is an example of the importance robust water and sewage infrastructure have on the elimination of communicable diseases.

13.4 ZOONOTIC DISEASES AND HUMAN HEALTH

Zoonotic diseases are caused by a pathogen that is transmitted from vertebrate animals to humans. The vertebrate animal is the pathogen's "reservoir host" or "intermediate host" in which it can multiply and develop when there is no active transmission to humans. The CDC has adopted the One Health approach presented during the 2012 Global Risk Forum One Health Summit [24]. One Health recognizes the interdependence of human health and that of animals and the environment [25]. Even though the concept of multi-sectoral and multi-stakeholder public health cooperation to manage public health threats, food safety, and food security are not new, three global causes have advanced the One Health strategy: (1) over the past 50 years, human populations have grown exponentially and expanded into new habitats, (2) land use practices, such as deforestation and farming, combined with climate change, have disrupted habitat conditions allowing for new human-animal interactions, and (3) the increase of international travel due to globalization allows infectious diseases to quickly spread across the globe [26]. Therefore, public health surveillance, public education on how to handle animals and pets, and treatment and vaccination research are essential to prevent the transmission and control zoonotic diseases.

Zoonotic diseases can be transmitted from animals to humans through consumption of contaminated water (as described before in the case of cholera) and through direct contact with infected animals. Animal husbandry practices in the U.S. are closely monitored and regulated to prevent the transmission of disease between animals and to humans. The U.S. Department of Agriculture (USDA) collaborates in the One Health initiative with the CDC, FDA, and EPA, amongst others, to ensure safety of national and imported animal commodities [27]. Through surveillance and research the USDA monitors animals and animal products in the U.S. to help control and eliminate conditions that can lead to the spread of disease. A healthy livestock and sound livestock practices can prevent economic loss as well as the emergence of new microbial diseases. Influenza, or the "flu", illustrates the case of a naturally occurring virus that circulates among livestock and has the potential of causing severe human disease.

13.4.1 H1N1 Global Pandemic

Influenza, or the seasonal flu, is a contagious respiratory illness that spreads in the U.S. through human contact, particularly in the winter. During the twentieth century, four flu pandemics were recorded. The most catastrophic one happened between 1918 and 1919 and was known as the "Spanish Flu"; it affected 20%–40% of the global population and resulted in the death of approximately 50 million people. The Spanish Flu was caused by the H1N1 influenza virus [28]. Influenza viruses are of the genus *Orthomyxoviridae*, consisting of three types: influenza A, B, and C. Influenza A is the most common type. Different influenza viruses express different hemagglutinin ("H") and neuraminidase ("N") proteins on the outer envelope of the virus and these are used to classify the virus. There are 18 and 11 known "H" and "N" variants, respectively [29].

In 2009, the H1N1 influenza virus was detected in the U.S. population. By June 2009, WHO had declared a H1N1 pandemic [30]. H1N1 is also known as the "swine flu" due to genetic characteristics previously isolated in swine. H1N1

had circulated in swine in the U.S. for years, causing sporadic human infections since 2005. Phylogenetic analysis determined that the epidemic causing H1N1 was a combination of swine, avian, and human viral lineages. Originally thought to have begun in Mexico, Mexican government officials closed private and public facilities to prevent the spread of H1N1. The international community responded by scanning people arriving from Mexico and cancelling many aircraft flights, heavily affecting Mexican tourism. Even though the virus was less lethal compared to the 1918 epidemic, millions fell ill due to ease of transmission and short supply of the H1N1 vaccine [31]. Furthermore, the term "swine flu" was heavily used in mass media leading countries to ban livestock or livestock-related products from North America, halt importation of all swine, or in the case of Egypt, slaughter all the swine in the country [32].

The H1N1 influenza threat led to an aggressive vaccination campaign in the U.S. It is estimated that the campaign prevented one million illnesses and 300 deaths. The H1N1 pandemic was declared over in August 2010 [33]. The CDC recommends all adults get the annual flu vaccine which is developed through surveillance of the most frequently circulated influenza strains, and in collaboration of the five WHO Collaborating Centers for Reference and Research on Influenza [34]. The CDC maintains FluView, a weekly influenza surveillance report, to inform health departments and practitioners across the U.S. [35]. USDA's Animal and Plant Health Inspection Service monitors avian and swine influenza, providing updated information on reportable animal diseases for public safety [36]. The 2009 H1N1 demonstrated how a novel flu variant can affect even the most prepared countries. The interaction between poultry, livestock, and humans allowed genetic recombination of flu virus lineages that are able to mutate and transfer from animals to humans. Such recombination is ongoing, prompting public health departments to be constantly vigilant of any influenza case in the U.S. and abroad.

13.4.2 West Africa Ebola Epidemic

Ebola virus disease (EVD) was first documented in 1976 when two simultaneous outbreaks erupted in what is now South Sudan and the Democratic Republic of Congo, near the Ebola River. The Ebola virus (family: Filoviridae, genus: *Ebolavirus*) can cause hemorrhagic fever in humans and is often fatal. The virus is highly contagious and spreads from human to human. Treatment consists of supportive care with rehydration; no vaccine exists. Five outbreaks have occurred in Africa since 1976. Laboratory infections of EVD have taken place in Reston, Virginia, England, and Russia, each with one or fewer infected cases [37].

The EVD natural reservoir host has not been identified. However, recent studies point to a small insect-eating bat as the EVD reservoir, yet EVD has never been isolated from a bat or any other mammal [38]. It is believed that human contact with this bat began the worst EVD outbreak in 2013. EVD outbreaks had never been reported in West Africa, but the first case appeared in Guinea and quickly spread quickly to neighboring countries Sierra Leone and Liberia. The CDC collaborated with WHO, Ministries of Health, and other international partners to establish rapid control strategies in response to mounting cases of EVD. The CDC activated the EOC to coordinate technical assistance, deploying more than 900 CDC personnel to provide logistics, communication, management, and support functions to the response activities. At the end of the outbreak, more than 27,000 infections and 11,000 deaths were reported. In addition, the already struggling healthcare infrastructure in these countries was left depleted as numerous health practitioners were among the dead [39].

Questions remain about how the Ebola virus was introduced into West Africa, far from its origins in Central Africa [40]. It is possible that the Ebola Virus was circulating in Guinea in mammal reservoirs with which humans have limited contact. Such reservoirs are suspected to be either a fruit- or an insect-eating bat. In 2015, Guinea was ranked 182 out of 188 countries on the Human Development Index [41]. Civil conflict and failed economic development decimated its public health infrastructure, forcing many persons into unexplored habitats to seek food for survival. This encroachment could have exposed humans to the Ebola virus's reservoir host. The socioeconomic conditions and lack of public health infrastructure and surveillance contributed to the EVD rate of transmission [42]. The EVD was also introduced in Nigeria and Senegal, two African countries with robust public health systems. In Nigeria, health authorities traced all contacts of the EVD index case, and more than 800 people were identified, interviewed, and/or tested. A total of 20 EVD cases as well as eight deaths were confirmed [43].

In September 2014, the U.S. diagnosed the first confirmed EVD infection in a traveler from Liberia. The incubation period (from infection to initial symptoms) is 2–21 days during which the infected person is contagious. Therefore, complete isolation of the infected individual is necessary to prevent the spread of EVD [44]. The index patient was isolated and treated, but died from the infection. A healthcare worker caring for the index case also became infected with EVD, developing symptoms by October 10th and a second health-care worker tested positive for Ebola virus 5 days later. Both fully recovered from the disease. A third medical aid worker who had returned from Guinea tested positive for EVD. The patient was isolated and fully recovered. These cases prompted a U.S. national debate on how to prevent the spread of EVD by returning aid workers.

The debate led governors in Illinois, New York, and New Jersey to issue home quarantine for 21 days for all aid workers returning from Guinea, Sierra Leone, or Liberia [45]. The CDC and other health organizations opposed such recommendations because they would prevent health practitioners from traveling to these countries where much effort was needed to curtail the EVD epidemic. The U.S. federal, state, and local public health departments and the vast network of medical centers throughout the country made the spread of EVD among local populations unfeasible. CDC issued an *Interim US Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure* to address public concerns

related to the EVD epidemic in West Africa [46]. Two years after the index case appeared in Guinea, WHO declared the last affected country, Guinea, free of Ebola virus transmission [47]. The CDC *Guidance* was retired the same day.

Such a humanitarian catastrophe is unlikely in the U.S. or other Western countries. The 2014 West Africa EVD epidemic illustrated how lack of economic development can affect human health in a twofold fashion: (1) people venture into unknown habitats hunting for food exposing them to unknown pathogens and (2) the lack of economic development implies a public health system not capable of serving the population's health needs and unable to respond to a humanitarian health crisis.

13.4.3 Implications for Environmental Health Policy: Quarantine and Public Health

At the end of the 1700s, mariners were disproportionately afflicted by illness and disability. At sea, they were confined to small places aboard ship and unsanitary conditions, which were detrimental to their health and also spread disease to the locals in port cities. The need to establish Federal regulation to govern retention of vessels with cases of or coming from ports with infectious diseases led to the adoption of The National Quarantine Act (NQA) of 1878. The act gave the U.S. federal government the authority to establish rules and regulations on incoming vessels. The following year Congress enacted the Act to Prevent the Introduction of Infectious or Contagious Disease into the U.S. and to establish the National Board of Health (NBH). The NBH was charged with collecting information on all public health matters, advising state governments on public health preservation and improvement, and creating a national public health organization. Currently, there are 20 quarantine stations across the U.S. to stop the introduction and spread of infectious diseases. The Department of Health and Human Services and the CDC have statutory authority to regulate quarantine practices in the U.S. The final rule for Control of Communicable Diseases: Interstate and Foreign became effective on March 21, 2017. The Ebola Virus outbreak of 2014 prompted the update of this final rule in order to increase transparency of such practices in the U.S. [48].

13.5 EMERGENCE OF VECTOR-BORNE DISEASES

As depicted in Figure 13.3, there are three determinants that are necessary for disease transmission—the pathogen, the host, and the environment. Vector-borne diseases are zoonotic infectious diseases that have an additional determinant, the vector, necessary for transmission of disease. The vector transmits the pathogen to the host by bite or through exposure of a bodily fluid, such a saliva or urine. As noted in the figure, the vector is connected to the three triangle vertices. The environment plays a crucial role in the transmission of vector borne diseases. The vector needs a supportive environment in which it can thrive and interact with both the pathogen and the host. Vectors include different arthropod species

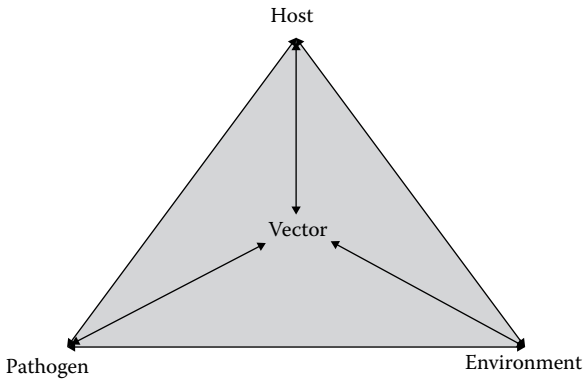

FIGURE 13.3 Epidemiological triangle of vector-borne disease. An illustration of the relationship between pathogen (or agent), host and, environment and the vector necessary for disease causation (Modified from CDC, *Principles of Epidemiology in Public Health Practice—An Introduction to Applied Epidemiology and Biostatistics*, 3rd ed., Atlanta, GA, 1–511, 2006, https://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson1/section8.html.)

such as mosquitos, ticks, mites, sandflies, and triatome bugs; mammal species such as livestock, rodents, cats and dogs; and other species such as turtles and birds.

In the U.S., 14 vector-borne diseases of national public health concern are reportable to the NNDSS [49]. Within the CDC, the National Center for Emerging and Zoonotic Infectious Diseases [50] is tasked with the prevention and reduction of illness and death caused by these diseases as well as to limit the spread of vector-borne diseases. Worldwide, vector-borne diseases account for 17% of all infectious diseases and more than one billion infections and one million deaths [51]. Following is a brief summary of selected vector-borne diseases that highlight the importance of the environment in the transmission of infectious diseases.

13.5.1 Mosquito-Borne Diseases

Similar to the Ebola virus, mosquito-borne viruses have jumped from feral animals to humans due to activities that increase the interactions between them. These activities include deforestation, human encroachment on animal habitats, and bush meat hunting. Deforestation and bush meat hunting are a direct consequence of expanding populations, and logging and mining activities can indirectly lead to the emergence of new infectious diseases. This section describes the principal infectious diseases caused by transmission of viruses and parasites via mosquitoes.

13.5.1.1 Malaria

Malaria is an ancient disease with records of a malaria-like disease described in ancient Chinese medical textbooks dating back to 2700 BCE [52,53]. Malaria is transmitted mostly by mosquito species of the *Anopheles* genus. All *Plasmodium* species have a similar life cycle involving the mosquito vector and the human host [54,55]. Malaria transmission also depends on the *Anopheles* mosquito. The intensity

of malaria transmission is dependent on the numbers and types of *Anopheles* mosquitoes present. Furthermore, some *Anopheles* species prefer human blood meals (anthrophilic) and others preferentially feed on animals (zoophilic). Most *Anopheles* species are active between dusk and dawn but some feed indoors (endophagic) while others prefer to feed outdoors (exophagic). In contrast to *Aedes aegypti*, *Anopheles* lays its eggs in muddied or dirty waters and is not reliant on clean standing water. *Anopheles* can therefore lay its eggs on any makeshift water container from ponds and lakes to deep tire tracks on dirt roads. Hence, unlike *Ae. aegypti*, the *Anopheles* mosquito does not concentrate in urban areas but can be found in all types of habitats. The *Anopheles* species feeding preferences have implications for vector control strategies [56].

Unlike other mosquito-borne diseases discussed in this chapter, malaria is a parasitic disease transmitted to humans by infected female *Anopheles* mosquitoes. A malaria infection is characterized by high fever, headache, sweating, and or moderate to severe shaking chills. These symptoms can last a few weeks or the parasite can remain dormant in the body for years. Complications can arise from malaria infections including cerebral malaria, which can lead to a coma, anemia, low blood sugar, organ failure, and even death. The persons most at risk of malaria complications are infants and young children, travelers to endemic regions, and pregnant women and the fetus. In addition to the *Anopheles* mosquito, malaria can be transmitted through blood transfusions and from mother to child during pregnancy [57].

Because malaria was disrupting construction of the Panama Canal, a vector-control campaign at the time was undertaken to reduce both yellow fever and malaria infections. This campaign was the first in many efforts by the U.S. to eradicate malaria from its population. The discovery of the insecticide properties of DDT in the 1940s accelerated the efforts to decrease malaria transmission after World War II. In the U.S., DDT was used to prevent the reintroduction of malaria by soldiers returning from training in endemic areas. These efforts, paired with the U.S. Public Health Service's malaria water level control and insecticide spraying campaigns, eliminated endemic malaria from the continental U.S. by 1947 [52]. Currently, about 1500 cases of malaria are diagnosed in the U.S. annually, mostly in travelers and immigrants returning from malaria-endemic countries.

Historically, malaria was endemic in the tropical and subtropical region of the world but currently is mostly a problem in Sub-Saharan African countries, South Asia, and Papua New Guinea, Solomon Islands, and Haiti. These areas accounted for an estimated 600,000 deaths worldwide in 2012. Even though mortality and morbidity are still extremely high, successful campaigns have significantly reduced the mortality by 45% and saved more than three million lives since 1990. In 1998, WHO, UNICEF, the World Bank, and the United Nations Development Program founded the Roll Back Malaria partnership. Roll Back Malaria focused on strengthening endemic and non-endemic malaria countries' health systems for sustainable health improvement by partnering with governments and civil society (NGOs, academia, etc.). Countries that committed to the Roll Back Malaria initiative took the lead in identifying strategies to intensify malaria control efforts, understanding how their population viewed, prevented, and treated malaria, and considered the context in which private and public care was offered in the country. WHO provided the support for Roll Back Malaria partner countries by endorsing the technical malaria strategy approach, advising on technical and financial assistance, and encouraging partners to stay engaged in the partnership [58]. By 2010, global malaria deaths were reduced by 26% and 24 malaria-eliminating countries had decreased annual malaria cases by 85% [59].

13.5.1.2 Yellow Fever

The Yellow fever virus was first introduced into the Americas during the 1600s slave trade. The first documented yellow fever outbreak occurred in 1648 in the Yucatan Peninsula. Within years, outbreaks were reported in Boston, Charleston, and New York City. Over the course of the years, yellow fever outbreaks were relegated to southern U.S. port cities, where the subtropical climate sustained a mosquito population year round [60]. At the turn of the twentieth century, U.S. efforts to build the Panama Canal were being halted due to the vast number of workers falling ill with yellow fever. The construction of the canal involved deforestation of tropical forest. Workers aggregated in shift camps where stagnant water and humid conditions increased mosquito breeding sites and transmission of the yellow fever virus as well as other parasitic diseases. A large yellow fever outbreak in 1905 reduced the Panama Canal work force, threatening significant production delays. As a result of this outbreak, President Theodore Roosevelt authorized the U.S. Army's chief sanitation officer, Dr. William Gorgas, to implement the largest fumigation effort in history. The mosquito populations significantly declined and as a result yellow fever cases were reduced in half within 1 year [61,62].

Efforts to find a vaccine against yellow fever began as early as the *Ae. aegypti* fumigation campaigns. In 1937, Max Theiler at the Rockefeller Foundation, developed a more efficacious strain of a previous vaccine called 17D. The first mass vaccination campaign with 17D occurred in Brazil in 1939 when more than one million people were vaccinated. An effective vaccine and aggressive vector-control campaigns reduced yellow fever infectious to certain tropical regions in the South American continent [63]. Currently, the 17D strain is still part of the WHO's List of Essential Medicines and in the U.S. it is given to travelers to countries with endemic yellow fever [64,65]. However, in 2015, a yellow fever outbreak in Angola and the Democratic Republic of Congo exhausted the world's emergency stock pile [66,67]. A large yellow fever outbreak occurred in the urban center in Minas Gerais, Brazil, in 2017 [68]. These two recent outbreaks illustrate the importance of mosquito control and environmental manipulation to prevent the spread of vector-borne diseases even when an effective vaccine against the disease exists.

13.5.1.3 Dengue

In the 1950s, a new virus was introduced into the Americas. The dengue virus (DENV) was first isolated from an infected patient in Trinidad in 1953 [69]. Dengue or severe dengue is caused by DENV of which there are four types (DENV1-4). Like the yellow fever virus, DENV has a sylvatic cycle in Africa but is maintained in the Americas through the domestic cycle by *Ae. aegypti*. Upon a second infection with a different DENV type, the infected person can develop much more severe illness, including hemorrhagic presentations, hypovolemia, shock, and even death. Dengue, or severe dengue, has a mortality rate of 20% if untreated. Treatment is primarily supportive therapy, which reduces mortality of severe dengue to less than 1% [70]. Research is also under way to develop a vaccine to prevent dengue [71,72]. By the 1980s, all four DENV types had been introduced and were in circulation in the Americas [69].

Most cases of dengue in the U.S. are not endemic. However, a small outbreak in Brownsville, Texas, in 2005 demonstrated the ease with which the disease can become endemic when the vector is abundant in the region [73]. Similarly, endemic dengue cases surfaced in south Florida in 2009. Florida had not documented an autochthonous dengue case since 1934 and investigations led to the confirmation of a dengue outbreak in Monroe and Miami-Dade Counties. The outbreak ended in 2011 [74]. Despite continuous surveillance and vector-control efforts in Florida, locally acquired cases of dengue were reported in 2014 and 2016.

13.5.1.4 West Nile Virus

The West Nile Virus (WNV), a *flavivirus*, was introduced to the U.S. in 1999. It was first isolated in 1937 in the West Nile District of Uganda. For years, WNV circulated in Africa, Asia, and the Middle East, arriving in Europe in the 1990s. Like many other viral illnesses, WNV infection can remain asymptomatic or infected people develop mild symptoms including fever, headache, body aches, and a rash. However, 1 in 150 infected people develop severe symptoms characteristic of a neuroinvasive diseases such as encephalitis or meningitis [75]. In 1999, the WNV was isolated from an infected patient in New York. It remains uncertain how this virus came to the U.S., through an infected person, a WNV vector or intermediate host, but it is clear the virus was introduced from Israel. By 2002, WNV had established itself in 44 U.S. states and spread to five Canadian provinces [76]. The accelerated spread across North America was possible due to two reasons: the ubiquitous distribution of the intermediate host and variety of potential vectors. WNV is maintained in nature in avian hosts and ornithophilic (avian feeding) mosquitos. A large variety of birds act as a reservoir host for WNV and both ornithophilic and antropophilic (human feeding) mosquitos transmit the virus to humans. The main vector of transmission to humans are mosquitos of the *Culex* genus but WNV has also been detected in species of mosquitos in the *Aedes, Anopheles*, and *Culiseta* genus amongst others [77,78].

13.5.1.5 Chikungunya Virus

The failure to eliminate and eradicate the *Ae. aegypti* mosquito has also led to the recent introduction of new zoonotic viruses to the Americas. Unlike DENV and yellow fever viruses, the chikungunya virus (CHIKV) belongs to the family Togaviridae; but similar to the other two mosquito viruses, it has a sylvatic, semidomestic, and domestic cycle. It was first identified in 1953 in West Africa and is now found throughout Africa, south and southeast Asia, and the Pacific Islands. Chikungunya means "the bend walker" due to the arthralgia (joint pain) and flu-like symptoms experienced upon infection [79]. People infected with CHIKV can remain asymptomatic or experience mild disease, but severe infections can cause arthralgia and sequelae that can last for months or years. Currently, there is no available antiviral therapy or vaccine against CHIKV.

The most common vectors of CHIKV are *Ae. aegypti* and *Ae. albopictus*, both of which are distributed along the tropics [80]. For years, low levels of human CHIKV infections had been reported in African and Asian countries, where the virus is endemic. Chikungunya outbreaks from Indian Ocean islands and countries were reported between 2005 and 2007. Subsequently, a small outbreak in southern Italy was confirmed in 2007 where the CHIKV was being transmitted and became endemic due to *Ae. albopictus*. By 2013, the CHIKV reached the Caribbean when in December two autochthonous cases were confirmed in the French island of St. Martin. Within months, the CHIKV had spread to the Caribbean countries, all countries in Central America, South America (except for Chile and Uruguay), Mexico, and the U.S. By mid-2016, more than 1.7 million suspected cases were reported by the Pan-American Health Organization (PAHO) in 45 countries throughout the Americas [81,82].

13.5.1.6 Zika Virus

Similar to other mosquito-borne viruses, the Zika virus (ZIKV) was first discovered in West Africa in 1947 in rhesus monkeys; the first reported human cases occurred in Uganda in 1952 [83]. Through the 1980s, ZIKV spread throughout equatorial Asia, causing sporadic cases of mild disease. Until 2007, no outbreaks of ZIKV disease had ever been documented. In 2007, a ZIKV outbreak was identified in Yap Island. Most of the cases showed mild disease with symptoms including rash, fever, and arthralgia [84]. The next reported outbreak identifying ZIKV as the causative agent was in French Polynesia in 2013 with 5895 suspected cases and 294 confirmed cases [85]. Two years later, 7000 cases of an unknown illness were reported between February and April 2015 in northwest Brazil. Retrospectively, this outbreak was linked to the introduction of the ZIKV to Brazil from the South Pacific during a major sporting event in either 2013 or 2014 [83,86]. By 2017, ZIKV had spread to all countries in the Americas except for Chile, Uruguay, the U.S., and Canada.

Zika, like yellow fever and dengue, is caused by a *flavivirus* transmitted by *Ae. aegypti* and *Ae. albopictus*. The continental distribution of *Ae. aegypti* is one of the primary

reasons for the rapid spread of ZIKV in the Americas along with an immunologically-naïve population and high levels of travel [87]. In a majority of cases, ZIKV infection causes mild symptoms associated with other viral diseases. This includes fever, rash, headache, joint and muscle pain, and conjunctivitis. More severe symptoms including Guillain–Barré syndrome (GBS), a rare immune disorder that affects the peripheral nervous system, have been linked to ZIKV infections [88,89]. The most concerning consequence of ZIKV infection is the association with adverse fetal outcomes, including fetal loss for maternal ZIKV infections between 6 and 32 weeks of gestation and microcephaly for maternal ZIKV infections between 7 and 13 weeks of gestation [89,90]. A study by CDC found that about 1 in 10 U.S. pregnant women with confirmed Zika infections gave birth in 2016 to a baby or had a fetus with Zika-related defects. About 1300 pregnant women in 44 states showed evidence of possible Zika infection. The problems included undersized heads and brain damage (microcephaly), but also seizures, difficulties with vision, hearing and movement, and developmental delays, such as trouble sitting up and eating [90a].

Furthermore, substantial evidence exists that the ZIKV can be transmitted from mother to fetus, and, unlike any other mosquito-borne arbovirus, through sexual intercourse [89]. The unprecedented speed of ZIKV transmission across the Americas, combined with the modes of transmission and severe consequences of infection (such as GBS and congenital defects), prompted WHO to declare a Public Health Emergency of International Concern [91].

Following the initial clusters of GBS and microcephaly following ZIKV outbreaks in Brazil, experts expected an increase in the incidence of GBS and microcephaly during the next seasonal cycle. However, fewer cases than expected of microcephaly were reported in 2016. ZIKV infection could be necessary but not sufficient to cause congenital abnormalities during pregnancy and other cofactors, such as environmental agents, could be at play [92]. Therefore, medical and epidemiological research is needed to determine the drivers of the current GBS and congenital abnormalities clusters in countries that have experienced ZIKV epidemics. As of 2017, clinical vaccine trials are under development for dengue [93], chikungunya [94], and Zika [95]. However, as demonstrated by the yellow fever vaccine, even an effective vaccine cannot substitute for sound vector control and environmental practices in the prevention of disease. Control of *Ae. aegypti* and *Ae. albopictus* populations in the Americas is crucial to prevent future arbovirus outbreaks and stop the geographic spread of these mosquitoes.

13.5.1.7 Implications for Environmental Health Policy: Vector Control and Pesticides

One of the most characteristic features of *Ae. aegypti* is its adaptation to live in urban areas, where it breeds in clean-water containers and feeds during the day. In 1947, an intensive *Ae. aegypti* Pan-American eradication campaign heavily reliant on the use of DDT, succeeded in reducing the mosquito to undetectable levels and 17 countries in South and Central America were declared *Ae. aegypti* free by 1961. The U.S. did not participate in eradication efforts [96]. Over the years, the eradication campaigns lost political support and funding, and over the next 10 years only three more countries achieved eradication of this mosquito. The decrease in surveillance and mosquito resistance to DDT and other insecticides also contributed to the continental infestation of *Ae. aegypti*.

Yellow fever, dengue, chikungunya, and Zika viral diseases illustrate the importance of vector-control strategies. However, DDT is banned and misuse and overuse of other chemicals have led to larvacide- and insecticide-resistant mosquitos. A reduction in mosquito breeding sites, insecticides and larvacides, and education on personal protection have contributed to the reduction of yellow fever and dengue. However, endemic seasonal outbreaks still exist. To halt transmission of yellow fever, dengue, chikungunya, and Zika, environmental control of the breeding sites, and mosquito surveillance campaigns need to occur year round. To date, no disease spread by a vector (or intermediate host) has ever been eradicated, although one disease, Guinea worm disease (dracunculiasis), is nearing global eradication due to a cooperative effort by WHO, the Carter Center in Atlanta, Georgia, and various national ministries of health. Prior to the global eradication effort, which began in earnest in the 1990s, Guinea worm was spread all across the midsection of Africa, parts of the Middle East and South Asia. From more than three million cases of Guinea worm disease a year in the 1980s, the world tally in 2016 stood at just two confirmed cases [97].

Other insecticides and larvacides have been developed and used to control mosquito breeding sites. The Roll Back Malaria Initiative demonstrates the importance of a comprehensive approach to malaria elimination that requires political and financial commitment. Much of this campaign's success is due to large financial support and Roll Back Malaria Partner efforts that focused mostly on four large scale interventions: (1) large-scale, countrywide insecticide-treated bed nets to people in malaria endemic areas; (2) user-friendly drug packages to increase medication compliance and slow down *Plasmodium* drug resistance; (3) access to early treatment to reduce childhood mortality; and (4) residual house spraying of insecticide and environmental management [58]. However, as successful as this global campaign has been, many challenges remain. Both *Plasmodium* and *Anopheles* have developed resistance to treatment and insecticides, respectively. Similar to the *Ae. aegypti* eradication campaigns, dwindling financial support, political instability, war, and climate change threaten to reverse some of the progress made in the combat of malaria.

To date, no disease spread by a vector (or intermediate host) has ever been eradicated, although one disease, guinea worm disease (dracunculiasis), is nearing global eradication.

13.5.2 Tick-Borne Diseases

Ticks are the second most common vector of human disease in the U.S. Ticks are small hematophagous (blood-feeding)

arthropods that live in foliage globally but prefer warm, moist climates. Over the past 20 years, tick-borne diseases have become a serious problem in the U.S., mostly due to human migration into wilderness areas [98]. Ticks feed on the blood of different mammals, including humans, and can transmit a variety of diseases caused by bacteria, parasites, or viruses. In North America, the most common diseases transmitted by tick bites are: Lyme diseases (spirochete *Borrelia burgdorferi*), ehrlichiosis (bacteria *Ehrlichia chaffeensis*, *E. ewingii*, and *E. muris*-like), babesiosis (different protozoan of the *Babesia* species), Rocky Mountain Spotted Fever (bacteria *R. rickettsia*), Tularemia (bacteria *Francisella tularensis*), and Q fever (bacteria *Coxiella burnetii*). Powassan (POW) virus is transmitted to humans by infected ticks. Approximately 75 cases of POW virus disease were reported to the CDC in the U.S. over the past 10 years. Most cases have occurred in the Northeast and Great Lakes region, but climate change could enlarge the area of infected ticks. There is no specific treatment, but people with severe POW virus illnesses often need to be hospitalized to receive respiratory support, intravenous fluids, or medications to reduce swelling in the brain [98a].

Different human-biting tick species are distributed around the U.S., each transmitting a specific tick-borne disease. The known ticks in North America are: American Dog tick (*Dermacentor variabilis*), which transmits tularemia and Rocky Mountain spotted fever east of the Rocky Mountains and the Pacific Coast; Blacklegged tick (*Ixodes scapularis*) transmits anaplasmosis, babesiosis, Lyme disease, and Powassan disease in the Northeast and upper Midwest; Brown Dog tick (*Rhipicephalus sanguineus*), which transmits Rocky Mountain spotted fever with a countrywide distribution; Gulf Coast tick (*Amblyomma maculatum*), which transmits a form of spotted fever known as *R. parkeri* rickettsiosis along the Atlantic and Gulf of Mexico coastal areas; Lone star tick (*A. americanum*), which transmits erhlichiosis in the Southeast and East of the U.S.; Rocky Mountain wood tick (*D. andersoni*), which transmits Rocky Mountain spotted fever, Colorado tick fever and tularemia in Rocky Mountain states; and Western Blacklegged tick (*I. pacificus*), which transmits Anaplasmosis and Lyme disease along the U.S. Pacific Coast [99].

Most tick species feed on feral animals including birds, rodents, deer, and lizards, but ticks are also found on domesticated animals such as dogs. The variety of tick species and tick-borne pathogens in the U.S. combined with human encroachment in wilderness areas and close proximity to domesticated animals have made tick-borne illnesses a serious, difficult to control problem. The CDC's Division of Vector-Borne Diseases (DVBD) leads a federal effort to prevent and control tick-borne diseases. Three of the four DVBD branches, Arboviral Diseases Branch, Bacterial Diseases Branch, and Rickettsial Zoonoses Branch focus on research that targets the control of tick-borne diseases at multiple levels, from animal health and prevention to vaccination. In addition, NIH's National Institute of Allergy and Infectious Diseases (NIAID) has a tick-borne disease-specific research program that focuses on basic biological research, vaccine development, and diagnosis, treatment, and prevention strategies.

The wide range and variety of ticks, the number of tick-specific diseases, and the different hosts from which ticks feed make tick-borne diseases impossible to eradicate. Control and prevention strategies target personal protection to avoid coming in contact with ticks and using repellents containing 20%–30% DEET when going into wooded areas [100,21].

13.5.3 Rodent-Borne Diseases

Hantavirus pulmonary syndrome and bubonic plague: Although hantavirus pulmonary syndrome is caused by a virus (hantavirus; family Bunyaviridae) and the bubonic plague by a bacterium (*Yersinia pestis*), both infectious diseases are transmitted by rodents. The bubonic plague, also known as the Plague or Black Death, arrived in Europe from Asia during the fourteenth century by ships infested with infected rats. *Yersinia pestis* can be transmitted to humans by infected flea or rat bite, or pneumonically from person to person. Due to its high case-fatality rate of 30%–60%, the Plague killed approximately 50 million people in Europe within 4 years of becoming endemic, reducing the population by 60%. Large epidemics of the Plague occurred throughout the centuries but the impact of the disease was greatly mitigated in the nineteenth century due to modern sanitation, public health practices, and medical advances and antibiotics which reduced its mortality rate to 11% [101]. Nowadays, small outbreaks or single cases of infections of the bubonic plague are still reported worldwide. In the U.S., 1006 human plague cases occurred between 1900 and 2012. Most of the bubonic plague cases occur in rural or semi-rural areas in the southwestern states of New Mexico, Arizona, and Colorado. Transmission occurs mostly through flea or rodent (including squirrels, chipmunks, or rats) bites, and are rarely due to person to person contact [102]. All cases of bubonic plague must be reported to the CDC and WHO.

13.5.4 Implications for Environmental Health Policy

The rodents and small mammals that harbor disease-causing viruses and bacteria are as ubiquitous as the ticks, mites, and fleas that spread them to humans. The first line of defense against tick-borne diseases is personal protection. In the developing world, human encroachment into uninhabited areas and deforestation for economic reasons have exposed people to new diseases as previously discussed in this chapter. However, in the U.S., encroachment into uninhabited areas happens mostly for recreational purposes. Prevention efforts have included area-wide pesticide spraying and targeting the mammalian reservoir through vaccination and inoculation [103]. Multiple factors have accelerated the spread of these diseases. These include potential ecological changes due to climate change, which could expand the geographical distribution of the reservoir and the vector, closer proximity between wildlife and human populations, and human behavior for social or recreational purposes. The complex dynamic

between the reservoir, the vector, and the host requires an integrated pest management approach to preventing tick-borne diseases [104]. This approach includes monitoring and controlling vector and reservoir populations and public education on personal protection and prevention.

13.6 TROPICAL INFECTIOUS DISEASES

Tropical diseases encompass all diseases that occur solely, or principally, in the tropics. In practice, the term is often taken to refer to infectious diseases that thrive in hot, humid conditions, such as malaria, leishmaniasis, schistosomiasis, onchocerciasis, lymphatic filariasis, Chagas disease, African trypanosomiasis, and dengue. Several of these infectious diseases have already been discussed in this chapter. It is beyond the scope of this chapter to discuss other tropical infectious diseases, but additional details can be found in WHO publications.

13.7 IMPLICATIONS FOR ENVIRONMENTAL POLICY: CLIMATE CHANGE

Vector-borne diseases are the best studied diseases associated with climate change. As described in Chapter 6, the amount of CO_2 released into the atmosphere has exponentially increased since the 1800s Industrial Revolution. Since the 1800s, global temperature has increased by 1.7°F; artic ice and land ice have decreased at a rate of 13.3% per decade and 281.0 Gt/year, respectively; and sea level is increasing 3.4 mm per year [105]. These changes in the planet's composition have led to increased evaporation and precipitation overall, increasing sea levels, and shifting climate patterns, resulting in a more extreme and less predictable climate.

Warmer temperatures: An increase in global temperatures can drastically affect the geographic distribution of known vectors of disease. Historically, the geographic range of a species is determined by climatologic conditions. Mosquitoes and arthropods thrive in warm and humid weather. As annual average temperatures increase, so has the altitude of freezing points and glacier melting in the tropics. The tropical range is also expanding longitudinally. Thus, mosquitoes can now thrive at higher altitudes over a larger geographic range, exposing nonimmune populations to vector-borne diseases. The introduction of mosquito and arthropod-borne viruses into non-endemic regions can trigger large outbreaks and are difficult to control due to the lack of population immunity.

Furthermore, extreme climate change conditions, such as El Niño, which is associated with warmer average temperatures in the tropics, can positively affect the biting rate and reduce the mortality rate of mosquitoes, leading to an increase in the severity of vector-borne disease epidemics once a new virus is introduced. This effect was modeled by Caminade et al. highlighting the amplified effect the 2015 climatological conditions had on the ZIKV outbreak in South America [106].

Changes in precipitation/seasonal weather patterns: Warmer temperatures increase the rate of evaporation and precipitation, triggering more rainfall in tropical regions. Vectors such as *Aedes* and *Anopheles* need standing bodies of water in which to lay eggs. More rainfall, and consequential flooding, creates more mosquito breeding sites and presents a challenge to vector control strategies. Furthermore, the unpredictability of rainfall and longer wet seasons increase the duration with which mosquitoes can thrive within a population. Seasonal variations make it difficult to predict potential outbreaks or periods of active disease transmission, limiting the accuracy of current vector-borne disease prediction models.

Extreme weather events: Similar to changes in weather patterns, extreme weather events, such as droughts, hurricanes, and large floods make predictions and disease transmission models less accurate. As extreme weather events increase in severity and frequency, non-endemic vectors or pathogens are more likely to become endemic.

In 1997, the UN's Framework Convention on Climate Change (UNFCCC) adopted the international treaty known as the Kyoto Protocol (Chapter 6). Under the belief that climate change is due to human activity, mostly CO_2 emissions, the Kyoto Protocol aimed to reduce international greenhouse gas (GHG) emissions by all participating member nations [107,108]. The U.S., however, has never ratified the Kyoto Protocol. During President Obama's tenure, the UNFCCC adopted the Paris Agreement that aims to reduce GHG emissions to limit the temperature to 1.5°C of preindustrial levels [109]. The Agreement went into effect November 2016. The largest GHG emitters, the U.S. and China, were among the 141 parties that ratified the Paris Agreement. To adhere to the standards of the Agreement, EPA implemented the Clean Power Plan rule to redress climate change by focusing on cleaner and renewable energy [110]. However, implementation was held up by the Supreme Court in 2016, and the Trump administration announced in 2017 its disapproval of the Clean Power Plan and its intention to withdraw as a party to the Paris Agreement.

Perspective: The Obama administration's policies to reduce the U.S. carbon footprint on global climate change are opposed by the Trump administration. This change in U.S. environmental policy could impair global efforts to combat climate change domestically and internationally. As noted in Chapter 6, at the current rate of GHG emissions, the U.S. significantly contributes to global carbon output. The Trump administration's stance against climate change policies and emphasis on strengthening the coal and fossil fuel economy could amplify and accelerate the effects of global warming. And as discussed in this chapter, one major consequence to humankind's well-being will be an increase in environment-related infectious diseases.

13.8 IMPLICATIONS FOR ECOSYSTEM HEALTH

While this chapter has focused on the impact of specific environmental hazards and associated infectious diseases, these same hazards also portent adverse effects on ecosystem health. Although the ecological effects are less well known and researched, the vectors listed in this chapter can adversely affect the health of organisms that reside in ecosystems. For example, some mosquito-borne and tick-borne diseases can

be transmitted to domesticated animals and livestock with adverse health and economic consequences. Pesticides used in public health programs for mosquito and tick control can become contaminants in runoff water that reaches local water supplies and any resident marine life. Rodent infestation of a geographic area can adversely affect infrastructures such as municipal sewers that in turn indirectly supply water to support ecosystems. Additionally, instances of pandemics of infectious disease can reduce the human workforce required to service and maintain local ecosystems, for example, water quality monitoring.

13.9 HAZARD INTERVENTIONS

Interventions to mitigate the environmental hazards that cause infectious diseases were discussed throughout the chapter and can be capsulized here. As implied by the content of Figure 13.3, infectious diseases can be prevented by elimination of causative vectors. This, of course, is more easily stated than accomplished, given the complexities of mitigation of associated environmental vectors; for example, programs of rodent control. What can be stated with certainty is the fundamental essential implementation of traditional public health programs of surveillance, laboratory science, behavioral science, and epidemic investigations, as was illustrated in Figure 1.1. Further, public support of local programs of public health is vital for controlling environment-related infectious diseases.

13.10 SUMMARY

Humans occupy planet Earth with a host of other living organisms and creations of nature. As described in this chapter, some of our partners in life can be a source of infectious disease. Discussed herein are several kinds of infectious diseases and their causes that are linked to environmentally-relevant sources. Infectious diseases such as cholera and typhus contribute to mortality and morbidity in millions of people in tropical environments and in countries with limited public health resources. As summarized in this chapter, vector-borne diseases have a strong link to environmental conditions. Mosquitoes, ticks, rodents and other pests are significant vectors of infectious diseases that include malaria, yellow fever, dengue, West Nile fever and encephalitis, Ebola outbreak, Zika infection, and others.

Changes in environmental conditions, for example, global and regional temperature increases, can increase the range of domain of vectors such as mosquitoes. Policies on mitigating climate change are therefore highly relevant for protection against the spread of infectious disease vectors. Public health interventions include education of populations at potential health risk, surveillance programs that monitors outbreaks of infectious diseases, personnel trained in vector eradication, available vaccines that immunize persons at risk of infection, and researchers who can develop a body of science about causal factors of an infectious disease outbreak and use the knowledge for treatment regimens. In the U.S. the PHSAct contains federal policies and authorizations for public health agencies for purpose of preventing and responding to infectious diseases. On a global scale, WHO administers resources that are directed to infectious disease prevention and control. Policies that support WHO's efforts are vital if highly infectious diseases such as malaria, Ebola, and Zika are to be prevented or contained.

13.11 POLICY QUESTIONS

1. As presented in this chapter, some varieties of mosquito can transmit viruses and/or parasites that can cause human infectious diseases. In your opinion, should all forms of mosquito be eradicated from planet Earth? Present your opinion in an essay of appropriate depth and include pros and cons for your opinion.
2. Humankind has eradicated smallpox as a threat to humanity and is nearing the eradication of polio and Guinea worm disease. Will humankind ever rid itself of malaria? Justify your opinion by providing an analysis of the challenges facing eradication.
3. Discuss how climate change could affect the prevalence of tick-borne disease in the community in which you reside. Using Internet resources, assess whether your local and state health departments have made preparations for dealing with climate change's impact on infectious diseases.
4. Using Internet resources assess and prepare a report of appropriate depth that describes various global programs that focus on malaria control. Include material in your report that describes the purpose and degree of success of each program.
5. Contact a local pest control company and ascertain their level of effort in containing rodent populations in the area in which you reside.
6. Research why Dr. John Snow is often championed as the father of modern epidemiology. Discuss his place in your pantheon of public health heroes.
7. Access the CDC website and locate the agency's principal programs for prevention of environment-related infectious diseases. Capsulize each program and analyze its principal accomplishments in prevention of these diseases.
8. Access the NIAID website and locate the agency's principal programs for prevention of environment-related infectious diseases. Capsulize each program and analyze its principal accomplishments in prevention of these diseases.
9. Discuss the etiology, illness symptoms, treatment, and prevalence of persons who've contracted cholera. What is the primary tool to prevent the occurrence of cholera?
10. Discuss the etiology, illness symptoms, treatment, and prevalence of persons who've contracted typhus. What is the primary tool to prevent the occurrence of typhus?

11. Assume you are a seasoned wildlife biologist. Would you be concerned about programs of mosquito and tick control? What concerns, if any, might you have? List the pros and cons of such vector control programs.
12. As presented in the chapter, several infectious diseases can have tick-borne origins. Using Internet and other resources ascertain which tick-borne diseases are prevalent in your state of residence. Cite data and evaluate any public health prevention programs.
13. Explore whether your university has any ongoing research that is directed to the study of environment-related infectious diseases. Discuss the purpose and extent of any such research and forecast the potential contribution of the identified research. If your university has no such research, explore other universities in your state or adjacent states.
14. Following a hasty, tasty review of Chapter 6, together with this chapter's content on climate change, discuss your primary human health concerns about whether climate change could affect your well-being and that of your family members.
15. Some Members of Congress have advocated for a reduction in the funds from the U.S. that support activities and programs of the United Nations. Do you agree with this funding policy? If so, why? If not, why not? In your opinion should any particular UN programs be excluded from funding cuts by the U.S.?
16. Assume your local health department has proposed to utilize area-wide spraying of pesticides for purpose of mosquito control. Assuming that you are the leader of a local environmental group, what actions would your organization take in regard to the proposed spraying? Be specific and provide an analysis of your actions.
17. Assume that you are the director of a local health department that has proposed to utilize area-wide spraying of pesticides for purpose of mosquito control. What actions would you take in regard to the proposed spraying? Be specific and provide a critical thinking analysis of your actions.
18. Assume that you are a pediatrician who works for PAHO. The organization's director has come to your office and asked that you undertake a review of environment-related infectious diseases that can cause birth defects in babies born to mothers who reside in the areas covered by PAHO. Provide a copy of the report that you prepared in response.
19. Using Internet and other resources, research the life and work of Drs. Walter Reed and Ronald Ross. In an essay of appropriate depth, discuss how their work relates to the content of this chapter. In particular, describe why the public health work of Dr. Ross could be classified as heroic. Were you familiar with these two medical doctors' public health contributions?
20. Well done! You have completed another chapter. We trust your effort did not produce any health distress. Discuss the three most important lessons you learned from your study of this chapter's material. Was your personal environmental health behavior or policymaking changed by the content of this chapter? If so, how? If not, why not?

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Section III

Emerging Areas Impacting Environmental Health

14 Energy Production and Associated Policies

14.1 INTRODUCTION

Before proceeding, it is important to define *energy* as "power derived from the utilization of physical or chemical resources, especially to provide light and heat or to work machines." The need for energy to match daily demands of products and services has historically shaped much of modern society. Few activities are so necessary for life, yet so potentially threatening to our sustainability. Each of the following issues is determined by a complicated nexus of economic and geopolitical factors: what energy source to use, how to acquire it, how to transport it to homes and businesses, how to process a source into energy, and how to manage any negative by-products of that source. The energy production cycle has a significant impact on the health and wellness of our population and our ecosystem, yet these considerations have historically been an afterthought in the political decision-making process, as exemplified by the energy source in Figure 1.

Examined in this chapter are the complex policies associated with the energy production cycle and the many environmental health impacts of key energy sources. Figure 14.1 shows an example of an U.S. energy source, hydraulic fracturing of shale. An assessment of U.S. policies surrounding energy production is augmented with a characterization of comparable policies in Europe and Asia. The U.S. has one of the largest demands for energy and correspondingly ranks among the highest energy polluters. Concern exists that other economically fast growing countries may replicate this trend.

14.2 PRÉCIS HISTORY OF U.S. ENERGY PRODUCTION POLICIES

The U.S. has no national energy policy, although as will be described, states and some limited federal involvement in energy policymaking has occurred. This section provides a short summary of the involvement of government in energy policy.

14.2.1 Early History

The U.S. has long benefited from having access to the abundant natural resources necessary for growth and development. Ample wood supply fueled the early years of the country. In the late nineteenth century, the country was able to transition from wood to coal, which was also in great supply across the country. Decades later, as the country transitioned from coal to oil, large reservoirs of petroleum were accessible within its borders. Transitions in energy sources were accompanied by a shift from local and state markets to regional, national, and global markets. Market globalization resulted in commensurate amendments of existing U.S. energy policy.

Energy policy history in the U.S. dates back to the 1887 U.S. Supreme Court decision of Munn v. Illinois, where the court held that certain suppliers and providers of energy had "natural monopolies." In exchange for the benefits of having monopolies, the court's decision was to regulate those industries. Early regulation of energy suppliers sought to encourage energy production, making sure the public had access to reliable, abundant, and inexpensive energy. In exchange for providing ample supply, regulators aimed to promote interests of the energy sector by restricting competition, and ensuring a "fair" return on investments for its investors [1].

For most of the country's history, energy was produced locally and was traded within states. As a result, initial energy policies were developed and enforced at local and state levels. Since there was no dominant, coherent national energy policy, each region and state developed its own policy strategy for each specific energy source, often independent of each other [2]. Each source of energy, in turn, had unique factors that influenced how it was regulated. Policies for natural gas are considered to have been developed with consumer support, while industry is considered a key driver of oil-related policies, and workers were seen as the drivers of coal-related policies [3].

As the twentieth century progressed, the U.S. federal government regulated energy in three areas: First, the federal government settled a long dispute among regional stakeholders by defining a federal responsibility for managing mineral resources on public land. With the Mineral Leasing Act of 1920, the U.S. Secretary of the Interior was given the authority to grant and administer leases for energy companies (oil and coal) to have mineral rights. It also created a system to distribute the profits of the leases. A majority (52.5%) of revenue would be earmarked for the federal reclamation fund, with 37.5% going to state governments and the rest staying with the U.S. Treasury [4]. Second, the federal government became involved through the tax system. The Revenue Act of 1916 set up a set of policy subsidies designed to promote oil and gas exploration [4]. Third, the federal government became more involved in the management of energy markets. By the 1920s, excessive supplies of oil and coal led to an unstable market for prices, which further led to concern about waste of energy supplies. A cabinet level committee was created in 1924 called the Federal Oil Conservation Board. The Board

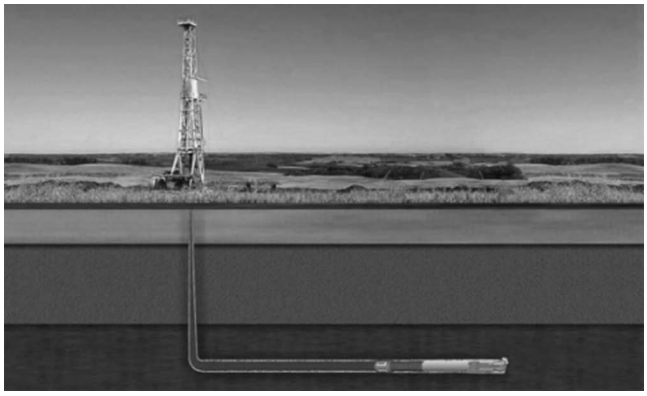

FIGURE 14.1 Hydraulic fracturing of shale for release of methane gas. (From U.S. Department of Energy, Shale Gas 101, 2016.)

was tasked with reporting on conditions of physical waste in the oil industry. Stabilizing production became a major challenge in oil-producing states, since state and regional advisory committees tried to control production, which only led to attempts by some to sell off-market oil, referred to as "hot oil." The Connelly Hot Oil Act of 1935 eventually was passed by congress to create a federal authority to enforce market control set by regional boards [4].

The growing influence of the federal government during the Great Depression and the geopolitical fallout from World War II contributed to the modern age of energy policy. During the depression, the coal industry steadily decreased. Approximately 84% of coal companies reported no net income, and coal industry employment declined by 42% and wages by 38%. At the same time, coal mining—which had long been seen as a hazardous occupation—came under increasing scrutiny. Starting in 1941, Congress passed a series of laws to set standards aimed at improving safety conditions and occupational health of mine workers. Decades later, this culminated in the Coal Mine Health and Safety Act of 1969, which established health standards (noise, dust, safety) for miners [4].

The high demand for more transportable fuels such as oil and natural gas resulted in a rapid shift in priority toward the production of these two fuels. The U.S. produced and refined the oil for all of the Allied military campaigns in World War II, and the rapid growth in infrastructure bolstered post-war production. With much of the global capacity decimated in the late 1940s, the U.S. became even more oil-centered, further negatively impacting the price of coal [4].

14.2.2 Postwar Changes

The U.S. goal of ample, affordable energy took a more central role in the development of policy in the 1950s and 1960s for the purpose of maintaining a national surplus of oil, coal, and gas. However, by the late 1960s, population and economic growth, combined with stagnated production, slowly drained energy reserves. The 1960s also introduced unprecedented environmental and public health pressures into the energy policy decision-making process. Several high profile cases emerged in the late 1960s, such as the Santa Barbara oil spill in 1969, increasing dissatisfaction with the safety of nuclear energy, and concerns over the negative byproducts of the energy process on the nation's air and water supplies. In response, the National Environmental Policy Act (NEPAct) of 1969 established a standard for considering environmental effects of any federal policy, and offered a paradigm shift in the policy-making process. All future energy policy decisions had to consider—either directly or indirectly—the role of environmental concerns, as the environment was "both the source of raw materials needed to generate energy and as the depository of the pollution stemming from the production and use of energy" [5].

The NEPAct contributed to the creation of the EPA and the environmental statutes of the 1970s. The EPA's regulations developed under the Clean Air Act (CAAct) increasingly put pressure on U.S. industries to move away from coal. The technologies needed to ensure minimum emission standards made coal an expensive source for utilities to use. Additionally, the use of environmental impact statements (EIS) through NEPA was used as a tool to delay the mining of coal. As shown by the data in Figure 14.2, U.S. coal production began to decrease circa 1985 due to environmental concerns and cost issues. Similarly, coal used for electric power generation began to decline circa 2005. The CAAct discouraged the use of coal with high sulfur content (to prevent the release of sulfur dioxides), resulting in increased mining of low-sulfur containing coal. There were large quantities present in federal land in the Powder River Basin of Wyoming and Montana. Yet, because of the public ownership of that land, and the policy laid out in the NEPAct, the Sierra Club was able to obtain a court injunction to block any coal development until an EIS was completed to examine potential adverse environmental effects [3].

Political and economic changes domestically, combined with global growth, resulted in national readjustments of energy priorities. In the early 1970s, energy consumption had grown 3.5% a year for 15 years following 1950 and then increased to 4.5% from 1965 to 1973. While the ample surplus of oil and natural gas generally satisfied the U.S. demand, more inexpensive imported oil was playing an increasingly important role. Approximately 30% of that oil was coming from suppliers that were geopolitically insecure, yet no policy was in place to address the possibility of those sources becoming suddenly inaccessible [4]. Global demand for oil was growing, and the creation of the Organization of Petroleum Exporting Countries and its resulting decisions to raise prices 1700% (in 1984 dollars) across the 1970s, diminished national oil supply and produced widespread gas shortages. The shortages in gasoline supplies were a key factor in the failure of President Jimmy Carter to get re-elected in 1980 [3].

In response to the energy crisis, the U.S. curbed demand, invested in new fuels (synthetic fuels), utilized coal resources, and improved redistribution of oil revenues. Most

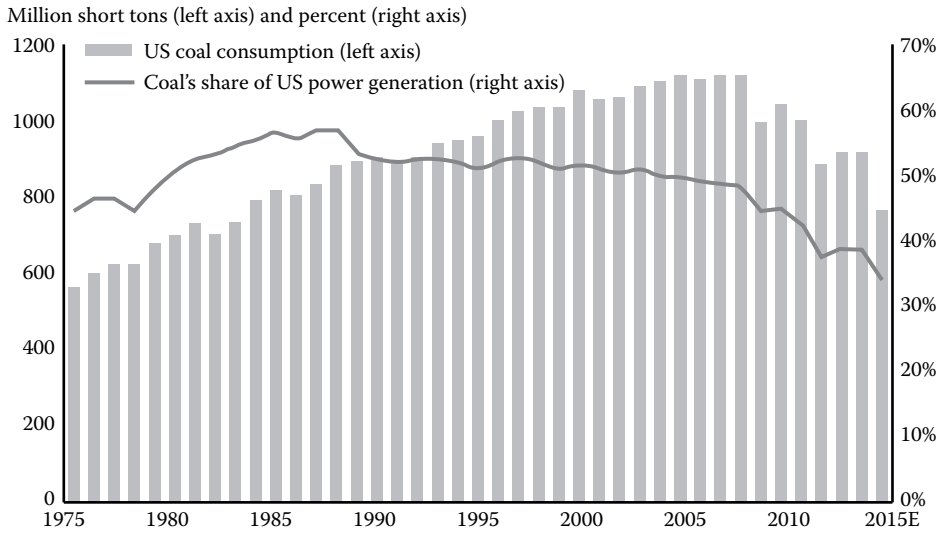

FIGURE 14.2 U S. coal production and share of power generation. (From U.S. Energy Information Administration (EIA), and Rhodium Group estimates, U.S. Department of Energy, Washington, DC, 2016.)

importantly, the energy crisis created a national conversation regarding oil substitutes and long-term planning to coordinate the entire energy cycle, including research, exploration, production, and transportation. Additionally, the crisis created an unprecedented political pressure at the national level to manage energy policy, changing the political center of gravity in deciding energy policy within the U.S. However, once the answer to the question of "is there a problem?" was unanimously agreed upon by federal stakeholders, the next question of "what do we do about it?" uncovered the reality that there was very little agreement on the basic priorities of energy policy [3]. This impasse continues to frustrate political movement in developing comprehensive energy policies.

Following the energy crisis and the shortages in the 1970s there was pressure to scale back regulation of most energy sources. For example, the Natural Gas Policy Act of 1978 encouraged exploration of new sources by eliminating some regulatory oversight. This led to utilities becoming unbundled in the 1980s allowing them to sell energy with greater flexibility [4].

Deregulation resulted in two significant trends: First, renewable energies became a key stakeholder in shaping national energy policies with the rise of wind and solar as energy sources. This greatly expanded the role of the federal government in energy markets, promulgating policies aimed at growing these new industries. Second, the rise of hydraulic fracturing as a new technology generating inexpensive natural gas changed the scope of the U.S. energy market. Specifically, hydraulic fracturing dramatically increased natural gas production and collaterally growing domestic oil production, actions that negatively impacted the coal industry.

14.3 U.S. ENERGY PRODUCTION

The volume of U.S. energy production and the magnitude of energy demand in the U.S. are described in this section.

14.3.1 Introduction

To contextualize the impact of energy in the U.S., it is important to appreciate the magnitude of the demand. Energy is the amount of heat or work that can be obtained by combusting a fuel. Energy is measured as a British Thermal Unit (BTU) or a kilowatt-hour (kWh), with 1 kWh equaling 3412.14 BTUs. One BTU approximates the energy expended when lighting a match. A homeowner in the U.S. may need more than 10 million BTUs for home heating over the winter. In 2015, the total U.S. consumption was 97,349.577 trillion BTUs, compared to 73,099 trillion BTUs in 1981, and 31,981 trillion BTUs in 1949. Peak monthly demand occurred in January 2014, when the monthly use was 9597 trillion BTUs. The 11-month (January–November) total energy consumption in the U.S. in 2016 across sectors was 88,344 trillion BTUs.

While policies exist that try to reduce this demand, most energy policies target the energy production cycle: exploration, extraction, transportation, storage, and disposal of hazardous byproducts. Most energy production processes result in negative trade-offs that potentially impact ecosystem and/or human health, requiring public health vigilance to assure priority is given to the cleanest and most sustainable energies [6].

Evaluating energy policies should take into account the complex nature of how a specific energy reaches consumers. Most of the nation's energy goes to electricity generation, and factors influencing the energy grid and electric utilities strongly influence which sources are (1) viable and (2) desired by relevant stakeholders.

The U.S. electrical industry consists of more than 300 utilities, 1000 generators, and more than 700,000 homes and businesses with on-site solar generating systems. Managing these systems are regional power grids, councils, and thousands of regulatory authorities [7]. Most of the U.S population is served by investor-owned utilities that are private companies. They are financed by bonds and shares but subject to

state regulations. A minority (25%) of the population is served by a consumer-owned utility. These are commonly seen as either municipal utilities managed by the public or cooperatives, which are nonprofit entities governed by a board elected by the customers of the cooperative.

While utilities are mostly regulated by local (e.g., environmental impacts) and state (e.g., retail rates) laws, some aspects (e.g., interstate transmission) are regulated by federal laws. The Federal Energy Regulatory Commission directs the federal regulation in this area. Additionally, the EPA manages some aspects that fall under the agency's scope of environmental protection.

U.S. states manage energy production through regulatory commissions. These governing entities set standards that affect the cost to consumers. Most relevant to public health, commissions increasingly use a tool called *integrated resource planning*. This is a long-term plan that is completed by the utility as part of evaluating future energy efficiency goals. Additionally, many states have environmental standards that require the regulator to evaluate environmental costs in determining the most sustainable long-term energy resource to the ratepayers.

Delivery of produced energy may pose environmental and public health concerns. For example, in North America the grid carries 1 million MW via more than 100,000 thousand miles of high-voltage transmission lines. Yet, logistics make it difficult to efficiently transport energy from where it is produced to where it is consumed. For example, renewable energies, such as wind and solar, tend to be produced in remote areas of the U.S. But without high cost batteries for storage of electricity, reaching population centers is challenging, since 10% of electricity is lost in transmission. Standards to improve efficiencies would help to provide more future energy needs, and make renewable energies more feasible. Through the Energy Independence and Security Act of 2007, $100 million was provided to utilities to implement smart grid systems. However, what is needed is a national high-voltage grid, yet due to the balkanized nature of the energy sector, the U.S. federal government must navigate hundreds of overlapping authorities [7].

Harmonizing supply and demand is critical. For example, utilities that rely more on solar energy risk the over-generation in the afternoon when solar plants are producing the most, yet people need the least amount of energy, and an increased need for energy, just as solar drops off in the late afternoon [8]. In addition, solar power plants at peak output may only represent 20% of capacity [9]. Promising efforts linking energy efficiency and performance to public health benchmarks will inform the development of holistic energy policies [10,11].

14.3.2 Influences on U.S. Production and Policy

Three factors drive the types of energy used to address the U.S. energy demand. First, despite technological advances, after once easily accessible reserves are extracted, fossil fuel energy must be derived from less concentrated, more remote reserves, making the production of fossil fuels a rising-cost enterprise. Second, the price of energy cannot be ignored. The central policy of the U.S. has been to provide ample, low-cost energy to its citizens. As prices of oil rose, so did the promulgation of hydraulic fracturing to derive much more inexpensive natural gas. Third, considerations of employment are a major influence. The energy system in the U.S. has evolved to multiple, overlapping authorities: local, regional, state, and federal, which makes federal coordination of a holistic energy plan difficult. Specifically, regional preferences for energy production are directly linked to local resources, which in turn influence local employment and economic development and inform promulgation of policy. Consequently, the resulting policy landscape is fragmented and thereby can perpetuate social and health disparities.

14.3.3 Policy Instruments

Five policy tools are available to the government in managing energy and protecting the environmental and public health. First, policies can develop performance and environmental standards. While many standards were developed in response to adverse environmental or community health impact, this policy lever has especially been used as a way to encourage the production of energy from cleaner sources. Second, policies can also provide energy subsidies to make more preferable sources more economically viable to energy producers. For instance, renewable energy is driven by two key federal tax credits: the production tax credit (PTC), supporting the production of wind energy, and the investment tax credit, strengthening solar energy production. As a third strategy, policies can also make a source more economically viable for the consumer. Specifically, economic sanctions can influence energy-use behavior by guiding where and how companies can produce. In addition, renewable portfolio standards (RPS) can be used to specify a minimum share of electricity to be supplied from renewable sources.

The fourth policy tool indirectly affects energy use by examining the impact on human health. The Environmental Impact Assessment (EIA) identifies environmental effects, and the Health Impact Assessment (HIA) process identifies, quantifies, and communicates potential adverse health effects to decision-makers. Both assessments allow public health professionals the opportunity to ensure health concerns are being considered by energy decision-makers. The EIA/HIA is a structured approach to estimate the impact of a proposed project on the health of a specific population or geographic area. Illustrative examples include addressing built environment concerns and energy projects, such as examining coal and clean energy options in Kentucky.

The fifth policy tool that indirectly affects energy use by prioritizing potential environmental and public health effects is the Precautionary Principle (Chapter 2). This methodology helps to ensure that new technologies do not impose unexpected health and environmental costs.

14.3.4 Sources of U.S. Energy

This section describes the two main sources of energy produced in the U.S.: various forms of fossil fuel and sources of renewable energy. Of particular importance are the trends in U.S. energy production and policies attending the changes from fossil fuels to renewable sources.

14.3.4.1 Fossil Fuels

Humankind came to rely on fossil fuels as an easily obtainable, abundant natural resource as a means to meet energy needs. While wood and other forms of fibres remained in use for many household heating supplies, coal and oil gradually became the primary energy sources for industrial and transportation purposes. This section presents data on the production and policies bearing on fossil fuels in the U.S. For purposes of this chapter, fossil fuels are defined as any combustible organic material, such as oil, coal, or natural gas, derived from the remains of former life.

14.3.4.1.1 Coal

Unlike the other fossil fuels, the U.S. coal industry is privately owned, and besides land leasing, its production has minimal connections to the U.S. federal government [3]. As a result, up until a few decades ago, the industry was able to produce, distribute, and dispose of coal with relatively little government oversight. Over time, policies were promulgated aimed at reducing the impact of the industry on ecosystem and human health. Several standards address coal mining workplace safety, specifically noise and air quality (such as the Federal Mine Safety and Health Act). Further, it strictly regulated how the coal production can modify the surrounding environment [Safe Drinking Water Act (SDWAct)], and how waste is stored (Resource Conservation and Recovery Act).

Coal is almost exclusively used as fuel for the electric utility industry. In 2008, 1.2 billion tons of coal was produced (supplying 50% of U.S. electricity). As previously noted, U.S. coal production has steadily decreased since 1985. In 2015, 900 million tons were produced (supplying 33% of U.S. electricity) [12]. The four largest mining companies that account for 50% of all coal production were collectively worth $34 billion in 2011. In 2015, they were worth $150 million [13]. This decrease in value of U.S. coal is due to the exponential growth of hydro-fracking-generated natural gas and the movement of several U.S. states to curb greenhouse gas (GHG) emissions [14].

Due to strict emission standards for sulfur dioxide, low-sulfur coal is in high demand (found mostly in public lands in Wyoming and Montana). Currently, 40% of U.S. coal is mined from public lands, leased to companies by the federal government. However, opposition to such practices has grown [15].

The production of coal in the U.S. may be to some extent affected by the Trump administration's issuance of an executive order on March 28, 2017 entitled "Energy Independence," which is targeted at revoking the Obama administration's Clean Power Plan. The Obama plan would have discouraged coal production in order to reduce the emission of GHGs emitted when fossil fuels are combusted. Whether electric utilities will increase their use of coal, however, is uncertain, given the alternative of less expensive natural gas supplies [15a].

14.3.4.1.2 Oil

Similar to coal, U.S. oil production is mostly privately owned with limited linkages to the federal government. While no agency regulates the prices, there are a coordinated set of commissions that regulate production. At an early stage, the oil industry was tailored to serve the U.S. transportation interest. As a result, oil production and use tend not to engage electricity generation. The U.S. uses approximately 19 million barrels of oil per day, primarily to support automobiles and mobile sources. As illustrated by the data in Figure 14.3, U.S. oil production peaked and began to decline circa 1970, but commenced to increase circa 2005 due to increased used of fracking operations in the U.S., as illustrated in Figure 14.1. In 2010, 5.4 million

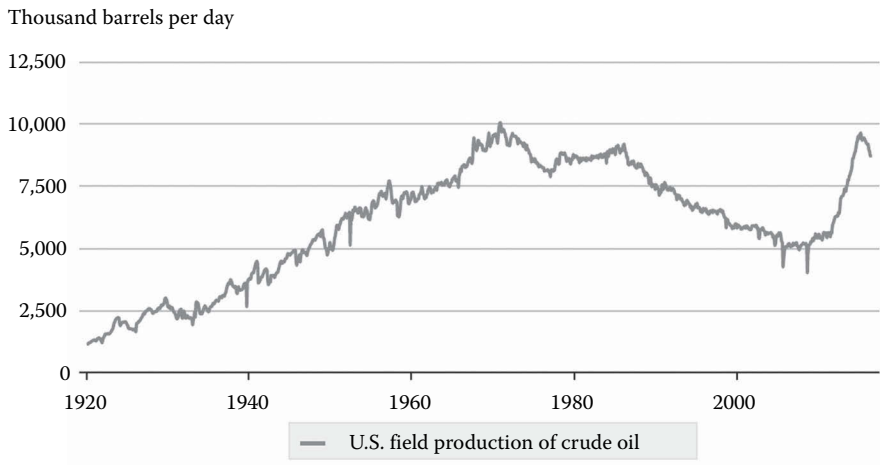

FIGURE 14.3 U.S. field production of crude oil. (From U.S. Energy Information Administration, Crude oil and lease condensate production at highest volume since 1986, U.S. Department of Energy, Washington, DC, 2014.)

barrels of crude oil were produced in the U.S. per day. In April 2015, production peaked at 9.6 million/day. As a result of tax incentives for oil exploration and the use of hydraulic fracturing to find oil in harder-to-reach areas, the U.S. is now producing more oil than it has since 1986 [16,12].

Oil drilling has become a policy issue increasingly influenced by environmental and public health concerns. For decades, the oil industry relied on drilling off the coast of the U.S. The 1969 Santa Barbara oil spill was a widely publicized disaster that helped launch the modern-day environmental movement and changed the policy framework for offshore drilling. In that spill, 4.2 million gallons of crude oil were released. After the disaster, California placed a moratorium on all new offshore drilling. Congress later passed a law that effectively banned all new offshore drilling in California, though still leaving 23 oil and gas leases in the state's waters [17]. The 2010 Gulf Oil Spill further put pressure to limit offshore drilling in the U.S., but after a short moratorium, drilling was brought back to the Gulf of Mexico [18]. Although in the later years of the Obama administration, officials considered a plan to open the Atlantic coast for oil and gas exploration, the U.S. Department of Interior announced an existing Atlantic Ocean moratorium would continue until 2022 [19].

Although a major network of pipelines and rail terminals exist across the U.S. to transport oil to refineries, this complex infrastructure has not kept up with oil production. For example, the Keystone XL pipeline proposed to transport oil drilled in the tar sands of Alberta, Canada, to refineries on the Gulf Coast, has provoked both interest and opposition [20]. Since it crosses national borders, the State Department has authority to approve it, partly based on its environmental impact [21]. In 2016, following comprehensive environmental impact assessments and public concerns especially from tribal nations, permission to build the pipeline was not granted by the Obama administration [22]. This decision was reversed by the Trump administration in 2017.

14.3.4.1.3 Natural Gas

Natural gas is 90% methane but also contains high levels of ethane, propane, butane, and pentane [23]. As a result of processing, the volatile organic compounds except for methane, as well as hydrocarbons, sulfur, helium, and nitrogen are released into the environment. Electricity is generated by combining gas turbines with a steam turbine [23]. Natural gas can only be efficiently distributed through pipelines. The low density of natural gas requires several transportation and storage precautions, and leaks are common. To help track leaks, a small amount of odorant is added to the colorless and odorless gas. Ownership of natural gas is private industry, but price, production, sales are regulated.

Natural gas has surged in recent years, now serving as the fuel of choice for producing 30% of U.S. electricity [12]. Much of this growth is likely attributable to the price difference with coal. Unlike other electric power plants (coal and nuclear, in particular) natural gas plants are often smaller, less expensive to build, and as a result, better designed to scale up or down depending on market prices. Natural gas is also considered environmentally friendlier than coal. When compared with coal, it tends to emit fewer particulates into ambient air, less smog, and less CO_2. On the other hand, the process of hydraulic fracturing has been associated with unique by-products. Additionally, the methane leaks are a contributor to climate change.

14.3.4.1.4 Hydraulic Fracturing of Shale

Hydraulic fracturing of shale (called "fracking") is a process that has revolutionized the energy economy, yet may have produced a series of new environmental and public health threats. The process involves the injection of water, sand, and chemicals at high pressures to crack open rock layers and thereby release the oil or gas within the shale (Figure 14.1). While the process has existed since the 1940s, in the mid-2000s companies developed methods to combine fracturing with horizontal drilling at a reasonable cost. The high gasoline prices in the early 2000s also made the process more financially attractive. Fracking was initially considered a preferable alternative to nuclear and coal. However, the process came under increasing scrutiny as concerns of environmental and public health effects increased. Concerns include contamination of nearby drinking water supplies, especially because of the presence of undisclosed compounds used in the process.

Environmentally, the methane leaks from the fracturing of shale could counteract any climate benefits through the switch from coal to gas. In 2016, the EPA finalized a rule to decrease methane leaks from oil and gas production. Methane is a potent contributor to global warming, accounting for 11% of emitted GHGs, and there has been rising concern about these leaks as fracking operations expand geographically. Leaks often occur in faulty drilling operations. Many companies already use infrared cameras to detect accidental methane releases. However, these requirements mainly apply to new or modified sources and not to most of the existing wells responsible for 90% of methane emissions from oil and gas.

Initially, fracturing was able to grow partly unregulated. The Energy Policy Act of 2005 specifically exempted fracturing from any underground injection control provisions related to the SDWAct. With time, public pressure produced policies to better regulate its use. First, states such as New York and Illinois passed stringent standards on use and storage of waste. In 2015, the federal government created the first major regulatory standards for hydraulic fracturing in more than 30 years. The policies require any operation on federal land to disclose the chemicals that are in use. The requirements also tighten standards on how wells are constructed, and waste disposal. However, the rules only apply to hydraulic fracturing operating on public lands, which represents just 11% of gas drilling in the U.S. [24]. The Trump administration supports fracking, making adherence to these policies uncertain.

14.3.4.2 Renewable Energy Sources

As described elsewhere in this book, global reliance on fossil fuels as a primary source of energy production comes with an environmental and human health consequence. In particular,

combustion of coal and oil for energy delivery results in emissions of air contaminants that can be injurious to human and ecosystem health and contribute to climate change. Because of these consequences, policies to limit or replace fossil fuels have promoted the development and application of renewable energy sources. For the purposes of this chapter, renewable energy is energy that is collected from renewable resources, which are naturally replenished on a human timescale, such as sunlight, wind, rain, tides, waves, and geothermal heat. The nature of these sources and attendant policies are described in this section.

14.3.4.2.1 Wind

Wind power has been the fastest growing source of energy in the U.S. In 2008, it provided just 1% of the country's electricity. By early 2015, that had risen to 4.9%. However, national adoption has not yet been achieved since 80% of generated wind power comes from just 12 U.S. states. One-fourth of all wind energy is produced in Texas [12,25]. Globally, the U.S. is the second biggest producer in wind power (in 2013, the U.S. produced 61 GW of wind capacity). However, other countries are outpacing U.S. production. For example, Germany built three times as many wind power plants as the U.S. in 2013 [26].

Most of the growth of wind energy in the U.S. can be attributed to policy incentives. Wind is heavily subsidized through tax credits. Figure 14.4 shows the impact of production of tax credits on the U.S. generation of wind-based energy. In the 1990s the market for wind-generated energy was nonexistent until Congress created a PTC that would subsidize wind producers (in 2014 it was 2.3 cents per kWh) [25]. The industry relies heavily on government support, which can decrease turbine construction costs by 33%. However, when it was created, it required Congressional renewal. Several times Congress has failed to extend this subsidy, which led to canceled investments or bankruptcy. Subsequently, long-term investment projects supported by Congress allowed for a more robust footprint of wind production [27,28]. However, the Trump administration has chosen to emphasize coal and hydro fracking as energy sources, a decision that may again endanger the sustained development of wind energy in the U.S.

Another impediment to expanding the use of wind is the difficulty of transporting the power to more populated areas since there is no direct current transmission. The "not in my backyard" syndrome also impacts the growth of this energy source when construction projects of wind turbines are rejected by local stakeholders due to aesthetics [26]. Finally, wind needs a backup source of power, since wind turbines historically generated just 20% of their capacity [25].

14.3.4.2.2 Solar

Solar power is still a marginal player in the U.S., producing only 0.6% of U.S. electrical output. Solar power comes from individual panels on rooftops and utility-scale solar power plants (defined as a solar array larger than 5 MW) [12]. Most new solar power plants use photovoltaic panels. Between 2007 and 2016, the number of solar power plants grew from zero to hundreds. Decreased pricing of solar panels, a 30% federal tax credit that subsidizes solar production, and incentives such as "net metering" laws where customers who use solar power have the option to sell excess solar electricity back to the utility, significantly increased the use of solar energy. However, these incentives vary greatly by state, leading to regional disparities. The cost of a solar system installation as of 2016 was $4 per watt. While these favorable circumstances may result in an increase in solar energy use, recent federal government policy priorities may interfere with the projected growth [29].

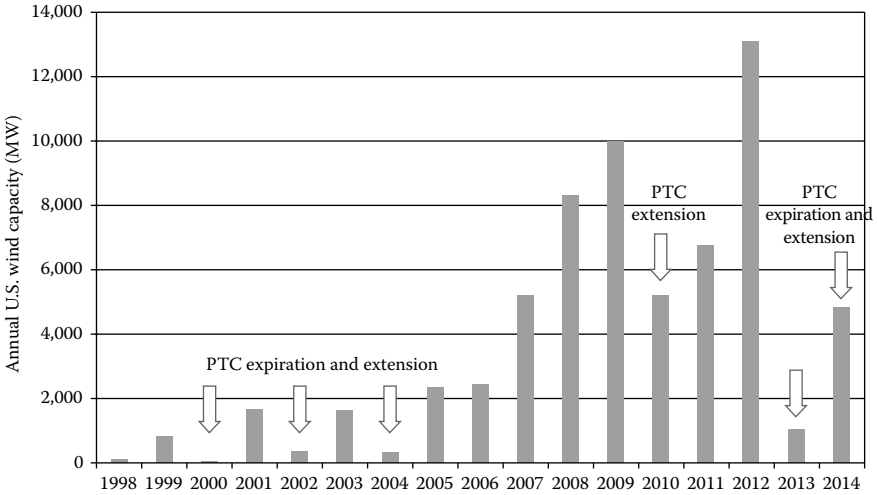

FIGURE 14.4 Impact of production tax credit expiration and extension on U.S. annual installed wind capacity. (From Union of Concerned Scientists, Production tax credit for renewable energy, http://www.ucsusa.org/clean-energy/increase-renewable-energy/production-tax-credit#.WIJ86vkrLmY, 2015.)

14.3.4.2.3 Water/Geothermal

Hydroelectric power is generated when falling water passes electricity-generating turbines. This source of power creates no combustion products. The costs of dam construction are initially very high. However, afterward, energy production costs remain low. While wind is the fastest growing renewable source, water remains the largest, providing 7% of electricity [12]. As of 2015, there were more than 1420 hydroelectric dams in the U.S. They tend to be regionally concentrated, with the western U.S. states providing the most hydropower. The state of Washington alone produces one-third of U.S. hydropower. Unlike solar and wind energy generation, hydropower is likely capped, since untapped river sites are rare and the political will is lacking in the U.S. to construct another large dam. In addition, there is growing local pressure to demolish existing dams, given the resulting damage caused to ecological systems. In 2013, Congress passed the Hydropower Regulatory Efficiency Act, which added generating capacity to existing dams in an effort to increase production from this energy source [30].

Geothermal energy is similar to water-generated energy but far less developed in the U.S. The process taps into the earth's bedrock by drilling three or more miles underground into areas with certain types of rock. High water pressure is applied inside rock fractures. Injection wells are then drilled that allow water to circulate in the newly-made reservoir, and draw out steam. This steam is then used to supply power to electrical turbines [31]. Geothermal energy can now be harnessed at lower temperatures than required for boiling water by using closed circuits and liquid compounds with lower boiling temperatures. In 2013, 20 countries produced a total of 70 billion kWh of electricity. Indonesia was the second largest producer following the U.S. The Obama administration offered a first test of geothermal energy as a significant alternative energy source by financing projects through the Department of Energy [12]. It is uncertain whether this incentive portfolio will be sustained by the Trump administration.

14.3.4.2.4 Biomass

Biomass fuels are combustible organic materials that can include wood, peat, crop residues (corn husks and coconut shells), and animal excrements (which derives from nondigestible plant components in the animal diet). The materials contain stored energy from the Sun, and when combusted, chemical energy is released. Biomass can be burned directly, or in modern processes, it can be converted first into other combustible materials, such as ethanol or methanol, or even gasified. The most well-known biomass is wood converted to charcoal through oxygen-poor combustion.

In 2015, biomass produced a small proportion (5%) of the energy used in the U.S. Wood and wood-derived biomass constituted 43% of the production, and 46% represented biofuels (mostly ethanol). Ethanol is a popular biofuel in the U.S. The primary feedstock for U.S. ethanol is corn, and most ethanol plants are concentrated in the Midwest. Biodiesel, on the other hand, comes from soybean oil. Biodiesel contains no sulfur and its combustion emits 47% less particulate matter than ethanol.

Driven by the environmental benefits, domestic supply, and concern over gas prices, political pressure grew in the first few years of the twenty-first century to prioritize biomass in automobiles. The Energy Act of 2007 set a production minimum, mandating refiners to produce 16 billion gallon of biofuels. There is also a 51 cent per gallon tax allowance given to blenders who mix ethanol with petrol. The same year, Congress passed the Renewable Fuel Standard policy, which requires the U.S. to use a higher raw amount of ethanol each year. The 2013 target was 16.55 billion gallons of ethanol–gasoline mixture. The goal was to strive for 36 billion gallons ethanol mixed with gasoline by 2022.

This standard was established under the assumption that gas consumption would increase, keeping the ethanol-gasoline mixture proportionately the same. However, unexpectedly, gasoline use peaked in 2007, and as a result biofuels are making up a larger percentage of gasoline. Manufacturers are concerned about there being a tipping point of ethanol proportion (~10%) in the gasoline where damage can occur to the automobile. Producers and refiners disagree over the safe level.

Landfill gas or biogas that forms after decomposition of organic wastes can be converted to methane gas through digesters and thereby serve for energy usage [32].

14.3.4.2.5 Fuel Cells

Hydrogen fuel cells produce electricity by combining hydrogen and oxygen atoms. Using steam, methane can be converted to hydrogen and CO_2. This creates an electrical current, and releases no byproducts except water and waste heat. Fuel cells are clean, renewable, extremely efficient, but expensive. Fuel cells serve as an electric power source for some outer space vehicles and to power some hydrogen-fueled vehicles, mostly buses. Fuel cells are also used in backup electricity generators for large sites.

14.3.4.3 Nuclear Energy

Nuclear energy is neither a fossil fuel nor renewable source of energy production. Nuclear fission uses uranium as a fuel and must be mined from the Earth similarly to coal. The uranium atoms are split and the controlled chain reaction produces heat and radioactive material. The heat is used to generate steam that turns turbines for electricity generation. Nuclear power is environmentally attractive to some energy stakeholders since it does not produce CO_2, and minimizes air pollution locally.

Nuclear energy has a mix of ownership and is operated much differently than fossil fuels. The federal government has monopoly ownership of radioactive fuel that powers the reactors and strictly regulates use. In 1956, control of nuclear energy was transferred to a civilian organization,

the Atomic Energy Commission. Because of national security concerns, however, the federal government remains a dominant and pervasive force in the development of this energy source.

Nuclear power produces 20% of the U.S.'s electricity. In raw numbers, the U.S. produces more power from nuclear energy than any other country (twice as much as the next closest country). Globally, the use of nuclear power as an energy source is decreasing. In 1996, nuclear power produced 17.6% of the world's electricity, but today that is 10.8% [12,33]. Electricity generation derived from nuclear energy increased in the 1990s, reaching a peak of 2660 TWh in 2006, but decreased by 2013 to 2369 TWh of electricity [12,34]. The 2011 Fukishima disaster resulted in a decrease in nuclear power use. After the disaster, Japan closed 48 of its reactors. Since 2012, actions in the U.S. resulted in early closure of five nuclear reactors, and several more are targeted for closure [33]. The high operating costs of nuclear power, compared to natural gas, or with wind and solar, further impacts the demand for nuclear energy.

14.4 U.S. ENERGY POLICIES

The U.S. has no national energy policy. Rather, U.S. states have individually promulgated polices that bear on energy production, workplace safety, and transportation issues. The limited involvement of the U.S. federal government is described in this section.

14.4.1 Pipeline and Hazardous Materials Safety Administration

This agency was created in 2004 as a component of the U.S. Department of Transportation. It is tasked with creating and enforcing standards for the country's pipeline infrastructure. While the number of accidents has fallen, some critics have raised doubts about the Pipeline and Hazardous Materials Safety Administration (PHMSA)'s ability to properly carry out its charge [35]. Through October 2016, 3032 pipeline spills had occurred since 2006. The cost of these leaks since 2006 amounted to $4.7 billion [35]. Another source notes, "There are 2.7 million miles of pipeline snaked across the US. Some of the pipes carry hazardous chemicals, others carry crude oil, and still others carry highly pressurized natural gas. And when it comes to safety, all of them are under the care of 528 government inspectors." […] "PHMSA has 188 federal inspectors. States have another 340 inspectors, all of whom go through PHMSA-certified training. According to the agency's website, those two forces combined are "responsible for regulating nearly 3000 companies that operate 2.7 million miles of pipelines, 148 liquefied natural gas plants, and 7574 hazardous liquid breakout tanks" [36]. According to the same source, much of the regulatory control is left to the pipeline operators, with fines being rarely levied against offending organizations.

14.4.2 Energy Policy Act, 2005

This policy was the first major U.S. energy act since the early 1990s and affected tax incentives, regulations, and loan guarantees for virtually every type of energy source:

- Ethanol: The law established a national renewable field standard that requires gasoline in the country to contain an increasingly amount of biofuel.
- RPS: A growing proportion of the federal government's purchases of energy had to come from renewable sources.
- Energy Demand: The law passed more than a dozen new product energy efficient standards.
- Hydropower: The law revamps how hydroelectric dams were licensed, and set incentives for the dams to improve efficiency.
- Oil and Gas Exploration: The act encouraged the production on federal lands through royalty reductions.
- Coal: The law set standards for a new clean coal technology program, which gave funds for research, and subsidies for experimental clean-coal plants.
- Electric: This became the most significant provision of the bill. It gave new federal authority to oversee the reliability of the nation's electrical grid [39].

14.4.3 State Renewable Portfolio Standards (RPS)

RPS were initiated in California, and since the late 1990s have been adopted by many states. At its core, RPS require electricity suppliers, generators, or consumers to source a certain quantity of renewable energy. To determine if utilities and retail suppliers have complied with RPS, it is necessary to track the amount of renewable energy a specific state sells. To implement RPS, several states use a renewable energy certificate tracking system, which is a uniquely numbered electronic certificate that is associated with the renewable attributes of one megawatt-hour (MWh) of generation from a registered facility. RECs can be traded, bought, and sold. Net Metering: the Energy Policy Act of 2005 added a net metering ratemaking standard to the original list of Public Utility Regulatory Policies Act of 1978 ratemaking standards. States were required to consider and make a timely determination considering whether to implement each ratemaking standards [41].

14.5 ENERGY PRODUCTION AND CLIMATE CHANGE

Climate change policies are intertwined with energy policies, as much of the production of GHGs comes from the extraction, production, and use of fossil fuels. Countries go into two directions to institute primary prevention of GHGs; both of which limit the options for energy policies. First, countries reduce the demand for fossil fuels by instituting a carbon tax. This puts a set amount on any product

or service for every ton of carbon it produces. Economists tend to prefer carbon taxes as an effective way to address pollution, since it makes people and companies pay for the damage that they cause by directly (or indirectly) emitting carbon. Further, making fossil fuels more expensive would make consumers and companies seek out cleaner (renewable) alternatives.

Another strategy to discourage the use of fossil fuels is by implementing a cap and trade system. Similar to the acid rain program under the Clean Air Act in the U.S., this would set a limit on carbon to be emitted in a region, state, or country (Chapter 8). Companies would buy (or be given) permits to emit carbon. As the cap on carbon is lowered in subsequent years, the market price for carbon permits would theoretically increase. This would create an incentive for companies to choose cleaner alternatives for their production and sell their permits to other companies for the higher market prices. Eventually, the government would be able to slowly lower the cap on emissions while incentivizing companies to redesign or alter their production to use cleaner fuels.

A second set of options available to countries is to use other typical environmental policy tools. This can include incentives such as tax credits and production credits for solar and wind energy. Other options are regulations aimed at fossil fuels by making production more difficult, reducing negative externalities, and making the end cost of fossil fuels more expensive. As will be discussed in the global section at the end of the chapter, policy decisions made to address climate change heavily influence what types of energy sources are feasible and profitable. Also, the same political forces that make energy policy so difficult–such as jobs, national security, and consumer prices– make aggressive climate change action equally contentious.

14.6 GLOBAL IMPLICATIONS

The same principles that have affected the U.S. in pursuing energy policies that balance low costs with clean environment also exist for other countries. The policy choices of large countries such as China and India reciprocally impact options in the U.S.

14.6.1 China's Energy Policies

Over the past few decades, China has placed a heavy emphasis on industry development, often pursuing growth over protecting environmental and human health. China burns more coal than the rest of the world combined; coal represents 75% of the total energy required for China's growth. Between 2000 and 2013 annual coal consumption increased from 1.36 billion tons to more than 4.24 billion, an average annual growth rate of 12%. However, that reliance has led to unprecedented environmental pollution. As noted in Chapter 8 (Air Quality), by itself, coal accounts for 40% of $PM_{2.5}$ levels in China's atmosphere [37]. This reliance on coal has slowly subsided. In 2014, China's coal use was 4.12 billion tons (a decrease of 2.9 billion tons. This was driven by a slowing economy, a shift from heavy industry to services, and a growth in public pressure to address environmental pollution [37].

The Chinese government has attempted to modify its use of coal, and address environmental effects from energy use in several ways: An Energy Development Strategic Action Plan outlines its transition from coal aiming by 2020 to decrease the proportion of energy coming from coal from 66% to 62%, and grow renewable energy from 11% to 15% [37]. To help this, China is also expanding a cap-and-trade system that had been tested in several of China's cities for several years. This would start with carbon emissions, but it is planned to expand to other industries in the country [38].

To cushion the move from coal, China is rapidly developing several other energy sources. Following a summit with the U.S., the Chinese government vowed to improve renewable sources, and seek to lower emissions of air pollutants [38]. New plants in western provinces are planned to produce cleaner synthetic natural gas. The government is proposing several coal-to-gas (CTG) plants. The aim is to ship gas to population centers in the east, where it would burn much more cleanly in power plants and detoxify the air in cities. However, the plants are highly energy intensive and can create far more CO_2 overall than coal alone. As of 2016, China had three CTG plants operating, four under construction, three newly approved, and plans for 17 more in the future [38].

China is also considered to become the largest developer of new nuclear reactors. As of 2014, China was planning to build 28 new units by 2018. China also is by far the largest wind producer. In 2013, it built 16,088 MW in annual capacity (compared with the next country, Germany at 3237 MW). In wind capacity, China had 91 GW of wind power, compared with 61 GW in the U.S. Additionally, China is also considering combining solar and biomass plants. Plans include increasing production to 2000 MW of solar and thermal power. Construction of dual plants that convert to biomass power at night are expected to decrease costs and improve capacity [39].

The Chinese highly centralized governance structure allows the country to mandate the creation of ultra-high voltage lines capable of carrying a significant amount of more electricity, allowing for much more efficient national transportation. Unlike China, the U.S. decentralized governing system requires a multi-stakeholder collaborative approach to creating a national energy grid [40,41].

14.6.2 India's Energy Policies

India faces energy demands similar to China's. However, differences in governmental structure, resource availability, and political system influence India in ways different from China's. There are more than 300 million people in the country without electricity. As a result, the government has heavily prioritized energy growth through use of coal. The Indian government expects coal consumption to triple by 2040. The goal to double coal production by 2020 is hampered by financially strapped electricity distribution companies, difficulty in increasing mining of domestic coal, and the high costs of coal imports. The

reliance on coal as a power source also brings issues of environmental degradation and adverse effects on public health and impacts on climate change.

India's Shift to a Sustainable Energy Future program was launched in 2007 to explore other more sustainable energy sources, including solar power and biomass. The country produces vast amounts of biomass. Rice straw is burned in Punjab's biomass plant to generate 12 MW of electricity. In 2013, the country set a goal of doubling its nonconventional energy supply from 25,000 to 55,000 MW by 2017. A large portion of this is planned to come from biomass. India produces approximately 600 million tons of "agro-waste." Biomass by itself is believed to potentially add 18,000 MW of electricity, while also serving as a source of energy for farmers [42].

14.6.3 Europe's Energy Policies

European countries face different energy demands than the U.S., and partly as a result, have created environmental policy frameworks driven more by the Precautionary Principle (Chapter 2). For Europe, two looming threats have shaped energy policy: climate change and nuclear plant-related disasters. For the latter, the nuclear disaster of Chernobyl in the 1980s dramatically reversed what had been a decade-long support for nuclear as an energy source. In the 1960s and 1970s, European countries overwhelmingly supported nuclear energy. In particular, after the 1970s oil crisis, while the U.S. reprioritized domestic oil and gas drilling, European countries turned toward nuclear energy. Countries such as France and Sweden shifted to primarily nuclear power as the energy source of choice. However, since the 1980s (after the Chernobyl disaster) the continent began to move away from nuclear power. This was further accelerated by the Fukushima nuclear disaster two decades later. Faced with similar financial pressures as the U.S., Europe's nuclear reactors are unprofitable, and increasing in age. Added to that is the public opposition of adding any new nuclear sites.

European energy policies emphasized the use of diesel fuel for automobiles in order to reduce GHGs and achieve climate change goals set in the 1990s. However, while diesel produces fewer GHGs, it emits much higher concentrations of air pollutants, especially particulates and nitrogen oxides, which are directly damaging to human health. Starting in 2000, the EU set strict emissions standards for diesel vehicles. However, the testing strategy used on vehicles was easily manipulated by car manufacturers. Some European automakers have been caught manufacturing diesel cars far exceeding the EU emission standards (Chapter 8). In 2014, Europe developed even stricter emissions standards, and put more rigorous vehicle testing procedures in place.

The EU implemented an aggressive permit system that attempted to reduce environmental emissions of GHGs. The European Emissions Trading System was established using similar principles as the acid rain permit system in the U.S. However, the program has faced difficulties as a result of the financial crisis of 2008 and the collapse of the natural gas and coal market drastically decreased the price of permits. In 2008, it cost \$50 to emit 1 ton of CO_2, after the crisis the permit could be purchased for \$7.

In the 1990s Germany set a goal of being fossil fuel free. The country gives very generous subsidies for renewables. Anyone who installs solar panels or wind turbines is guaranteed above-market price for electricity fed back into the grid. It also used portfolio standards by requiring utilities to draw on renewable sources for electricity before turning to fossil fuels. However, these subsidies make electricity very expensive, one of the most expensive in Europe. Complicating this process–similar to China and the U.S.–is the abundant supply of coal in Germany. Similar to the U.S., mining employment in Germany has collapsed (from around 300,000 in 1990 to about 40,000 in 2016), and many have used the high renewable energy prices as a reason to invest in old coal regions to produce inexpensive national energy.

14.7 ASSOCIATIONS BETWEEN ENERGY DEVELOPMENT AND HUMAN HEALTH

It is widely known that energy generation and use can threaten public health. Many energy production cycles pose a risk for catastrophic disasters, such as oil spills in the Pacific and Gulf Coast, and nuclear power failures in Japan, Three Mile Island, and Chernobyl. Coal mining creates tremendous workplace dangers to miners. Due to its reliance on dirty energies, such as coal, China provides a snapshot of the health challenges posed by energy and economic development. It was found that burning coal was the largest contributor to air pollution in China, which led to 366,000 premature deaths in 2013. Petroleum shares many of the common features with the impact of coal.

Direct health effects associated with the combustion of petroleum result from various air contaminants. Vehicle emissions of particulates and ozone-forming nitrogen oxides are an important cause of air pollution. In many countries lead is added to gasoline as an octane enhancer (to improve the efficiency of gasoline combustion in automobiles). When the leaded gasoline is burned, lead is released into the air as part of the exhaust. Lead can then be directly ingested as dust leading to cognitive issues, and overall health effects. Biomass can also cause adverse health effects. The burning of traditional biomass for household energy is a major cause of indoor air pollution in developing countries. Incomplete burning results in the release of particulates, carbon monoxide, and carbon dioxide.

Hydroelectric power can cause health risks through the increased methylation of mercury in the anaerobic conditions deep in reservoirs, which create methylmercury concentrates in the aquatic food chain and pose a risk of toxicity to humans. Dams can also affect the water ecosystem, raising risks of waterborne disease. As will be discussed with the ecosystem health, this wide range of health issues associated with the energy production cycle has influenced the choices the U.S has made regarding energy choices. Through tools

like the HIA, more deliberate considerations of human health have entered into the energy decision-making process.

14.8 ASSOCIATIONS BETWEEN ENERGY DEVELOPMENT AND ECOSYSTEM HEALTH

The extraction, transportation, use, and disposal of energy sources irreparably harm the ecosystems. Building dams to produce hydroelectric energy can alter local ecosystems, and are believed to produce harmful GHGs. The use of coal creates significant pollution to the nearby aquatic systems through open-pit mining. This dumping releases impurities in the coal (including sulfur and heavy metals) into the waterways, disrupting aquatic ecosystems and potentially contaminating drinking water. The burning of fossil fuels such as coal and oil results in the release of CO, CO_2, particulate matter, and polycyclic aromatic hydrocarbons. Biomass causes its own ecosystem issues. It puts pressure on forest and agriculture resources. In areas with high population densities or fragile forest ecosystem, fuelwood collection can devastate local forests, leading to erosion and reduced water quality and availability Nuclear raises concerns regarding the radioactive releases and storage of radioactive wastes. The by-products of the nuclear fission process are classified as high-levels wastes that can produce serious adverse health effects. Nearly every energy option produces some kind of negative environmental impacts. For example, hydraulic fracturing of shale has been associated with increased numbers of earthquakes, leading to some U.S. states developing regulations intended to reduce earthquakes [43]. This makes it so much more important to weight environment consequences (through tools like the EIA) to weigh the comparative environmental costs of any energy decision. One of the biggest developments in U.S. politics in the twentieth century was the development of a sizable stakeholder group that—seen recently through the Keystone XL pipeline dispute—mobilize through all energy policy deliberations to advocate for the least environmental harm.

14.9 HAZARD INTERVENTIONS

Unusually high environmental contaminant releases can occur at almost every stage of the energy cycle. While many of these releases happen with little attention, several environmental disasters have their root in the inherent risks created in the energy production process. Many policies work to mitigate risks at each stage of the cycle.

The use of coal as an energy source, as discussed, produces a range of environmental health effects. There also exists the risk of large-scale environmental contamination. One of the largest hazards associated with coal production is the safe disposal of coal ash and sludge. Often these waste disposal sites are not properly contained, and sometimes the containment structure can break causing a significant release of coal waste products. In 2008, an ash dike ruptured near the Tennessee Valley Authority's Kingston Fossil Plant, resulting in more than 1 billion gallons of coal fly ash slurry being released into the surrounding environment. The EPA struggled over the following months to stop the advancing spill and ensure potable water quality. Stricter regulations of coal ash disposal sites are still being debated by agencies and state legislatures. Coal miners work in deep underground mine shafts, which sometimes collapse. Several high profile coal mining disasters happened in China in 2016, where gas explosions and poor safety regulations led to the deaths of dozens of workers.

The use of petroleum creates unique hazards. Like coal, oil must be extracted underground, leading to workers in perilous workplace settings. Accidental releases and blowouts are common in oil drilling. While on land, these effects can be contained. However, with offshore drilling, the environmental health ramifications can be far-reaching, such as the Gulf of Mexico Oil Spill of 2010. Additionally, oil and natural gas must be transported by rail and pipelines for refining and use. Pipeline leaks and train derailments can put nearby ecosystems and populations at risk. This hazard makes the construction of pipelines increasingly politicized. An example was the battle in 2016 over construction of the Dakota Access pipeline. The pipeline was proposed to run just north of Sioux County and the Standing Rock Indian Reservation. Protesters asserted that a leak or spill could send oil directly into the tribe's main source of drinking water. The hazards related to the transportation of oil lead to massive protests throughout 2016, contributing to the Obama administration's decision to disapprove the pipeline. However the construction of the pipeline was approved in 2017 by the Trump administration as a means to increase the number of construction jobs.

One unique hazard of hydraulic fracturing is the risk of explosions and fires. As the ability to extract gas from the deep sediments expanded, companies have competed to create "recipes" for the fracking fluid used for injection. This fluid has traditionally been considered a company secret. However, right-to-know activists have been joined by many first responders in pushing for fracturing sites to release the chemicals stored on site. This helps the first responders know how best to respond to fires and explosions. However, many states still keep the full list from the public, only disclosing the ingredients to state agencies, such as a department of natural resources.

While nuclear energy produces no GHGs and relatively minor environmental emissions, a tremendous barrier to its broader inclusion is the public's acute fear of potential catastrophic failure. A multitude of policies exist to ensure redundancies in all nuclear reactors, yet as the Three Mile Island, Chernobyl, and Fukishima cases show small errors in design, preparation, training, or monitoring can result in significant environmental and public health concerns.

14.10 SUMMARY

Energy was defined in this chapter as "power derived from the utilization of physical or chemical resources, especially to provide light and heat or to work machines." The sources of energy have changed over the history of humankind from wood used to build fires for warmth and food preparation

to highly sophisticated utilization of fossil and nuclear fuels used for power generation delivered to mega-cities, personal dwellings, and transportation. And as described in this chapter these forms of energy are being supplemented or replaced by renewable sources of energy such as solar, wind, biomass, geothermal, and fuel cells. Public concerns about the global effects of climate change were presented and discussed as the basis for utilization of lesser reliance on fossil fuels and policy-encouraged development of renewable sources of energy.

Energy policies vary across the nations of the globe. The U.S. has no national energy policy, but the U.S. federal government funds research on development of renewable sources of energy and enforces the provisions of the Energy Policy Act of 2005, an act that affected tax incentives, regulations, and loan guarantees for virtually every type of U.S. energy source. However, U.S. states have implemented their own policies on energy production and use. For example, some states have enacted regulations on the development of fracking as a source of natural gas. Globally, the EU, China, and India have independently developed energy policies that collectively focus on improving energy efficiency and in compliance with international agreements on climate change.

As presented in this chapter, energy generation and use can threaten public health due to catastrophic disasters such as oil spills, nuclear power plant incidents, and workplace dangers to miners. Use of coal as a fuel for energy production is a public health concern. For example, burning coal in China led to 366,000 premature deaths in 2013 due to air pollution. Direct adverse health effects associated with the combustion of petroleum result from various air contaminants. Vehicle emissions of particulates and ozone-forming nitrogen oxides are an important cause of air pollution. As to ecological effects, wastes from energy sources can enter ecosystems and cause adverse effects on water quality and marine life.

14.11 POLICY QUESTIONS

1. What are the influences of how energy production, usage, and disposal are regulated? What events might change the importance of those influences?
2. How do you get your electricity? Investigate whether your local utility is mandated to use a certain proportion of renewable energy.
3. What are some ways that you could influence your local utility to choose more environmentally-friendly energy sources?
4. What are some current factors that make coal especially attractive to countries like China and India? What are some ways that the global community could influence these communities to choose less harmful sources?
5. The U.S. federal government uses a variety of incentives to manipulate the energy market. Are there good reasons why the public would like to influence what sources are used? Are there any negative effects of using this influence?
6. What would be your solution for green, sustainable energy? What generation source (nuclear, wind, solar, etc.) would you favor and why?
7. Contact your local power utility and assess to what extent the company is using renewable energy sources. In an essay of appropriate depth, discuss whether your power utility is adequately using renewable energy sources. State in your essay how you could influence the utility to use more or less renewables.
8. The Trump administration has issued policies that are purposed to overturn the Obama administration's Clean Power Plan (Chapter 6). Prepare an essay of appropriate depth that discusses the implications of this action. Include in your essay how your well-being could be affected or why you would be unaffected.
9. In your opinion should government provide subsidies to support the development of new energy sources? If so, why and how? If not, why not? Provide detailed justification for your response.
10. Do you or someone whom you know well drive an electric or hybrid vehicle? Discuss in an essay of appropriate depth your or their experience with the vehicle. Discuss the reasons for choosing the vehicle. If you have chosen to forego these kinds of vehicles, discuss your reasons.
11. It is asserted in this chapter that the U.S. lacks a national energy policy. In an essay of appropriate depth, discuss the pros and cons of this lack of a national policy. In your essay discuss whether climate change could force the U.S. to develop such a policy.
12. Prepare an essay of appropriate depth in which you discuss whether more large dams should be constructed in U.S. rivers for purpose of increasing the nation's supply of hydroelectric energy. Include in your essay the impact of large dams on regional ecological systems.
13. Perform an analysis of the number and extent of oil pipeline spills in the U.S. over a time span of your selection. Using Internet resources select one major oil spill and evaluate the spill's effect on human and ecological health.
14. Does your state or province of residence allow hydraulic fracturing of shale for purpose of producing natural gas and fossil fuel? If so, are any regulations that control some aspect of fracking? Discuss the purpose of any regulations. If not, why is there no fracking in your state or province?
15. In your opinion should solar and wind power replace all other forms of energy production globally? In an essay of appropriate depth, discuss the environmental and economic implications of this policy.
16. Prepare an analysis of the extent of landfills in your state or province that are tapped to produce methane gas as an energy source. In your opinion should this

source of methane be utilized as an energy source, given that methane is a powerful GHG?

17. Does your state or province house nuclear power plants? If so, analyze the numbers, ages, and amount of electricity they produce on an annual basis. What percentage of the state's or province's power supply is provided by nuclear power? Discuss any concerns you might have in regard to the nuclear plants in your state or province.
18. Using Internet resources, describe the Fukushima Daiichi nuclear disaster that occurred in Japan. In an essay of appropriate depth, discuss the human and ecological consequences of the disaster. Describe how this disaster might influence your personal policy in regard to nuclear power and an energy source.
19. Discuss the socioeconomic implications of a national policy that would mandate that all new construction of houses and office buildings must include a newly developed fuel cell system that would replace exterior sources of electricity.
20. Congratulations! You have expended some personal energy in digesting the content of this chapter. We trust that this has not produced excess fatigue or indigestion. Please discuss the three most important lessons you learned. Was your personal environmental health behavior changed by the content of this chapter? If so, how? If not, why not?

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15 Genetically Modified Organisms

15.1 INTRODUCTION

The subject of this chapter, genetically modified organisms (GMOs), is closely intertwined with issues of climate change, human global population increase, and human food insecurity. There are several policymaking issues related to GMOs, as discussed in this chapter. The policy issues include sociopolitical considerations such as international trade of GMO food products, cultural impacts of GMO agricultural products on traditional methods of farming, and freedom of information concerning food labeling of products containing GMO ingredients. In particular, the subject of product labeling has become a vigorous kerfuffle in the U.S. and Europe.

To begin, as defined by the World Health Organization (WHO), "Genetically modified organisms (GMOs) can be defined as organisms (i.e., plants, animals or microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination. The technology is often called 'modern biotechnology' or 'gene technology,' sometimes also 'recombinant DNA technology' or 'genetic engineering.' It allows selected individual genes to be transferred from one organism into another, also between nonrelated species. Foods produced from or using GM organisms are often referred to as GM foods" [1]. This definition from a global health agency was selected because GMOs have significant implications for global health issues, as will be discussed next. Examples of genetically modified crops are illustrated in Figure 15.1.

Genetic modification (GM) is the introduction of new traits to an organism by making changes directly to its genetic makeup (e.g., DNA) through intervention at the molecular level. The method is also called genetic engineering or GE. With GE, scientists can change the traits of plants and animals by inserting DNA pieces, whole genes, or long stretches of DNA segments from many different organisms. These sequences can also be taken from the same species or be newly made up. Scientists can also delete or swap DNA sequences in organisms or introduce genetic material to silence genes. Unlike conventional breeding and hybridization, GE is a laboratory technology that enables the direct transfer of genes between organisms in different species or kingdoms that would not breed in nature, and the introduction of new sequences that do not even exist in nature [2].

> WHO: Genetically modified organisms (GMOs) can be defined as organisms (i.e., plants, animals or microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination.

At the core of WHO's definition is "organisms" (i.e., plants, animals, or microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination. In other words, organisms are created via a method of DNA manipulation that would not have otherwise existed in nature. Further, it is important to know that genetic rearrangement or modification has always been a fact of nature, but as a consequence of mating of species and/or natural recombination. Examples abound of GM via methods of natural selection. Farmers, arborists, and zoologists, among others, have long practiced methods that combined the genetics of trees, fruits, and livestock in order to expedite growth in trees used for timber, grow larger fruit (e.g., apples, pears), yield seedless fruit (e.g., grapes, watermelons), grow hardier grain (e.g., hybrid maize), and more productive farm animals (e.g., mules). Using these kinds of natural selection, the Green Revolution became a touchstone example of this non-GMO method of species modification.

The Green Revolution was the notable increase in cereal grain production in Mexico, India, Pakistan, the Philippines, and other developing countries in the 1960s and 1970s. This trend resulted from the introduction of hybrid strains of wheat, rice, and corn (maize), and the adoption of modern agricultural technologies, including irrigation and heavy doses of chemical fertilizer. This effort resulted in more than doubling world food production between 1960 and 1990. Many experts credit the Green Revolution with averting global famine during the second half of the twentieth century and saving perhaps one billion human lives. The leader of a Mexican research term, U.S. agronomist Norman Borlaug, was instrumental in introducing a new short variety of wheat to India and Pakistan, helping to avert famines in both countries, for which he was awarded the Nobel Peace Prize in 1970.

The development and commercialization of GMOs commenced in the late twentieth century and became widespread for use in certain agricultural applications globally. As noted in a study conducted by the U.S. National Academy of Science, Engineering, and Medicine [3], "since the 1980s, biologists have used genetic engineering to produce particular characteristics in plants such as longer shelf life for fruit, higher vitamin content, and resistance to diseases. However, the only genetically engineered characteristics that have been put into widespread commercial use are those that allow a crop to withstand the application of an herbicide or to be toxic to insect pests." In general, GMOs are often promoted as a means to increase crop yields, thereby improving crop revenues and supplying more food to a hungry world. However, critics of the use of GMOs have expressed concern that new varieties of organisms were being imposed on the world, with

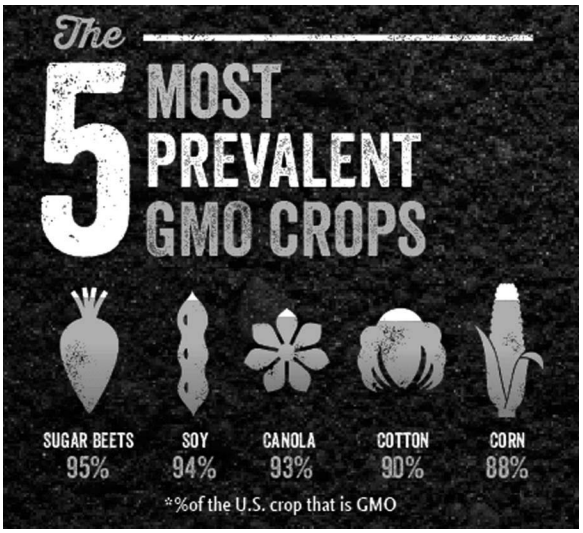

FIGURE 15.1 Examples of some genetically modified crops. (From Whole Foods 2016, Whole Foods Market, IP, L.P, Austin, TX. With copyright permission.)

uncertain, undocumented outcomes. These two harbors of thought: GMOs are needed now to increase food production versus fear of alien organisms, have led to serious, sometimes vigorous actions in regard to policymaking about the use of GMOs. This chapter will describe the state of policies pertaining to the use of GMOs.

15.2 HISTORY

A review of the history of genetically modified organisms by Randle [4] observes, "Humans have been genetically modifying organisms for over 30,000 years! Clearly, our ancestors had no scientific laboratories capable of directly manipulating DNA that long ago, so how did they do it, and how have GMOs become such a popular topic?

While our ancestors had no concept of genetics, they were still able to influence the DNA of other organisms by a process called 'selective breeding' or 'artificial selection.' These terms, coined by Charles Darwin, describe the process of choosing the organisms with the most desired traits and mating them with the intention of combining and propagating these traits through their offspring. Repeated use of this practice over many generations can result in dramatic genetic changes to a species. While artificial selection is not what we typically consider GMO technology today, it is still the precursor to the modern processes and the earliest example of our species influencing genetics.

The Birth of Modern Genetic Modification: An enormous breakthrough in GMO technology came in 1973, when Herbert Boyer and Stanley Cohen worked together to engineer the first successful genetically engineered (GE) organism. The two scientists developed a method to very specifically cut out a gene from one organism and paste it into another. Using this method, they transferred a gene that encodes antibiotic resistance from one strain of bacteria into another, bestowing antibiotic resistance upon the recipient. One year later, Rudolf Jaenisch and Beatrice Mintz utilized a similar procedure in animals, introducing foreign DNA into mouse embryos.

Although this new technology opened up countless avenues of research possibilities, immediately after its development, the media, government officials, and scientists began to worry about the potential ramifications on human health and Earth's ecosystems. By the middle of 1974, a moratorium on GE projects was universally observed, allowing time for experts to come together and consider the next steps during what has come to be known as the Asilomar Conference of 1975. At the conference, scientists, lawyers, and government officials debated the safety of GE experiments for 3 days. The attendees eventually concluded that the GE projects should be allowed to continue with certain guidelines in place. For instance, the conference defined safety and containment regulations to mitigate the risks of each experiment. Additionally, they charged the principal investigator of each lab with ensuring adequate safety for their researchers, as well as with educating the scientific community about important developments. Finally, the established guidelines were expected to be fluid, influenced by further knowledge as the scientific community advanced. Due to the unprecedented transparency and cooperation at the Asilomar Conference, government bodies around the world supported the move to continue with GE research, thus launching a new era of modern genetic modification."

GE isolates the gene for the desired trait, adds it to a single plant cell in a laboratory, and generates a new plant from that cell. By narrowing the introduction to only one desired gene from the donor organism, scientists can eliminate unwanted characteristics from the donor's other genes. GE is often used in conjunction with traditional breeding to produce the genetically engineered plant varieties on the market today. The first GM crops were planted in the U.S. in 1994. The current 10 most popular GM foods in the U.S. are soy, corn, canola oil, cotton oil, milk, sugar, aspartame, zucchini, yellow squash, and papaya [5].

GM corn, soy, and canola (and cottonseed oil) proliferate in our food system as ingredients in processed food and in animal feed, but there are very few GM crops—fruits and vegetables or GM grains—that are consumed as whole foods. The exceptions are some GM sweet corn grown in the U.S. and Canada, some GM squash varieties grown in the U.S., and GM papaya grown in the U.S. and China. There is also a very small amount of GM eggplant now grown in Bangladesh. However, all of these GM fruits and vegetables—along with some GM sugar beet (grown in Canada and the U.S.) and GM alfalfa (grown in the U.S.)—collectively account for only 1% of global GM crop hectares [2].

15.3 CURRENT GMO PREVALENCE AND PRACTICES IN THE U.S.

Foods from GE plants were introduced into the U.S. food supply in the 1990s. Cotton, corn and soybeans are the most common GE crops grown in the U.S. In 2012, GE soybeans accounted for 93% of all soybeans planted in the U.S., and GE corn accounted for 88% of corn planted. The majority of GE plants are used

FIGURE 15.2 Ears of maize, showing pest resistance in GMO top ear. (From Dr. Taylor Wallace, GMO—Dispelling the myths about GM food and crops, http://drtaylorwallace.com/gmo-dispelling-myths-gm-food-crops/, 2014. With copyright permission.)

to make ingredients that are then used in other food products. Such ingredients include: corn starch in soups and sauces, corn syrup used as a sweetener, corn oil, canola oil, and soybean oil in mayonnaise, salad dressings, breads, and snack foods, and sugar from sugar beets in various foods. Other major crops with GE varieties include potatoes, squash, apples, and papayas [5].

GM technology has traditionally been used to make crops resistant to certain insects or herbicides and to protect them from viral diseases. Genetically modified corn, like the unblemished ear in Figure 15.2, was genetically modified to reduce damage from insects seen damaging the bottom ear, thus raising yields by preventing loss while reducing the need for insecticide applications [6].

15.4 CURRENT GLOBAL PREVALENCE OF GMOS AND PRACTICES

In 2013, approximately 17 million farmers globally planted an estimated 420 million acres of GM crops (the size of the U.S. and Mexico combined). A survey by the Canadian Biotechnology Action Network [2] found there are primarily four GM crops—corn, soy, cotton, and canola—being grown anywhere in the world (Figure 15.3). Together, these four crops account for 99% of global GM acres. Almost 100% of GM crops on the market are genetically engineered with either one or both of just two GM traits: herbicide tolerance, and insect resistance. These two traits account for almost all of the GM crops grown commercially over the past 20 years. Just 10 countries account for almost all—98% of—the GM hectares globally. The top three countries that cultivate GM crops—Argentina, Brazil, and the U.S.—account for more than 75% of global GM hectares. GM crops are grown on approximately 3.7% of the world's total agricultural land, by less than 1% of the world's farmers [2].

Four GM crops account for 99% of global GM crop hectarage: soy, corn, cotton, and canola [2].

15.5 U.S. POLICIES ON GMOS AND PRACTICES

In contrast with most other countries, the U.S. has limited policies bearing on the development, use, and commerce of GMOs.

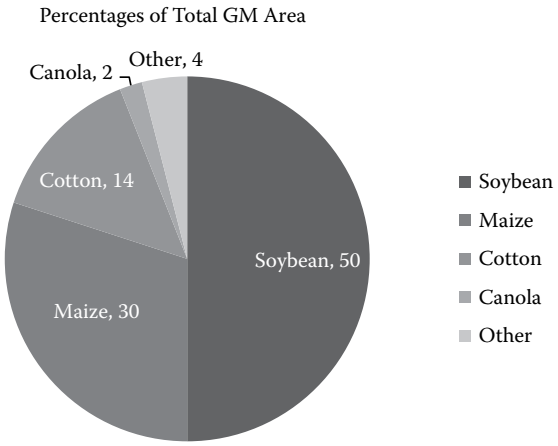

FIGURE 15.3 GM crops as percentage of total GM area. (From Canadian Biotechnology Action Center (CBAN), Report 1: Where in the world are GM crops and foods? http://gmoinquiry.ca/wp-content/uploads/2015/03/where-in-the-world-gm-crops-foods.pdf, 2015.)

This assertion may seem remarkable, perhaps ironic, given the widespread use of GMOs in U.S. agriculture and food production. However, as will be explained, the U.S. stance on GMOs policymaking was substantially shaped by two frameworks: one domestic and one international in origin. The following sections (15.5.1, 15.5.2) describe these two frameworks and their impact on GMO policymaking in the U.S.

15.5.1 U.S. Coordinated Framework for Regulation of Biotechnology, 1986

In response to public concern, Congressional interest, and encouragement from the business community, on June 26, 1986, President Ronald Reagan's White House Office of Science and Technology Policy (OSTP) published the final part of the Coordinated Framework for the Regulation of Biotechnology in the *Federal Register* (FR 51, No. 123, pp. 23302–93). The framework resulted from more than 2 years of work by persons representing more than 18 federal agencies and executive offices. The goal in developing the Coordinated Framework was stated to be an explanation to the American public that, for questions involving the products of "biotechnology" (more specifically, organisms derived from recombinant DNA technology), human health, and the health of the environment were of paramount concern and were adequately protected. The policy guidelines are based on widely accepted scientific principles and provide a stringent, yet rational, basis for regulation [7].

The Coordinated Framework is a broad and complex U.S. federal policy that explains the application of *existing statutes* (emphasis added) to the regulation of recombinant DNA and outlines the approach to interagency coordination by federal agencies. The framework observes that government regulation is not organized around technological processes, but rather the government tends to be structured around products, as developed by various technologies for specific intended purposes. Therefore, the framework comments that one critical element in a coordinated regulatory framework is the

common definition of the nature of the products subject to particular types of regulatory oversight.

The announced framework notes, "The principal focus of the policy is environmental release of new organisms. There has been general acceptance of the regulation of non-living products of biotechnology and, in fact, the 1986 policy reiterates that the past regulatory practices will be maintained. The new policy explained the application of certain statutes over genetically modified organisms, and in some cases even imposes an abbreviated review over unmodified organisms when applied to environmental uses. There is a clear policy established requiring review of genetically engineered microorganisms prior to release into the environment, with some organisms subject to an abbreviated review. In the unlikely event of a problem arising in this period of time EPA could use its authority under § 7 of TSCA to immediately limit or prohibit the manufacture, processing, distribution, or use of the product. In addition to the EPA activity, USDA will review all genetically engineered plant pests and animal pathogens" [7].

The Coordinated Framework for the Regulation of Biotechnology is a broad and complex U.S. federal policy that explains the application of existing statutes to the regulation of recombinant DNA and outlines the approach to interagency coordination by federal agencies.

Therefore, the Coordinated Framework for Regulation of Biotechnology of 1986 provided the policy platform for subsequent decisions by the U.S. federal government in regard to GMOs. Distilled to its essence, the Framework advocated that existing federal laws were sufficient for application to GMO issues. As a consequence, no legislation specific to GMOs was thought necessary for Congressed action. In 1992 the OSTP updated the Coordinated Framework, setting forth a risk-based approach (Chapter 19) for the oversight of activities that introduce biotechnology products into the environment. This update reaffirmed that federal oversight should focus on the characteristics of the biotechnology product and the environment into which it is being introduced, rather than the process by which the product is created. In 2015 the OSTP announced plans to further revise the Coordinated Framework. As announced by the OSTP, the update "aims to improve biotechnology regulation by reducing regulatory burdens and improving transparency, predictability, and coordination among regulatory agencies. The new regulatory approach will significantly impact the manner in which biotechnology products are approved, making this initiative an important one to follow" [8]. This update awaits completion as of 2017.

* * *

A comprehensive 2-year study by the U.S. National Academy of Science, Engineering, and Medicine evaluated the published literature on GMOs and GE [3]. As subsequently will be discussed, in 2016 the Academy released its findings on GMO issues of relevance to human and environmental health. The Academy's report contains recommendations in regard to current U.S. policies on GMOs. In particular, the Academy recommends using a tiered process for regulating new crop varieties that should focus on a plant's characteristics rather than the process by which it was developed. Further, new plant varieties that have intended or unintended novel characteristics that may present potential hazards should undergo safety testing—regardless of whether they were developed via GE or conventional breeding techniques.

The current policy in the U.S. on new plant varieties is in theory a "product"-based policy, but the USDA and the EPA determine which plants to regulate at least partially based on the process by which they are developed. The Academy's report notes that a process-based approach is becoming less and less technically defensible as the old approaches to GE become less novel and as emerging processes—such as genome editing and synthetic biology—fail to fit current regulatory categories of GE.

The Academy recommended that in determining whether a new plant variety should be subject to safety testing, regulators should focus on the extent to which the novel characteristics of the plant variety (both intended and unintended) are likely to pose a risk to human health or the environment, the extent of uncertainty about the severity of potential harm, and the potential for human exposure—regardless of whether the plant was developed using GE or conventional breeding processes. "-omics" technologies will be critical in enabling these regulatory approaches.

Of note, the Academy recommends that regulating authorities should be proactive in communicating information to the public about how emerging GE technologies or their products might be regulated and how new regulatory methods may be used. They should also proactively seek input from the public on these issues. Not all issues can be answered by science alone, the report says. Policy regarding GE crops has scientific, legal, and social dimensions [3].

15.5.2 Cartagena Protocol on Biosafety, 2003

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international treaty that aims to ensure the safe handling, transport, and use of living modified organisms that result from biotechnology that may have adverse effects on biological diversity, taking into account risks to human health. It was adopted on January 29, 2000, and entered into force on September 11, 2003. The first meeting of the Conference of the Parties for purpose of drafting a protocol on biosafety was opened on February 22, 1999, in Cartagena, Colombia, lending the city's name to the final Protocol.

The text of the Cartagena Protocol on Biosafety comprises 40 articles, with three annexes. The objective of the Protocol is stated in Article 1, "In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the Objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified

organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements" [9].

The Scope of the Protocol is stated in Article 4: "This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health." Other Articles specify terms and procedures specific to aspects of the Protocol's Objective. For example, Article 5 is specific to Pharmaceuticals: "Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations" [9].

As of June 2014, there were 170 countries that are Parties to the Protocol. The U.S. is not a Party.

15.5.3 U.S. GMO Policy and Authorities

As previously stated, GMOs are regulated in the U.S. under the Coordinated Framework for Regulation of Biotechnology, published in 1986, pursuant to previously existing statutory authority regulating conventional products, with a focus on the nature of the products rather than the process in which they are produced.

As overview, plant GMOs are regulated by the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) under the Plant Protection Act (PPA). GMOs in food, drugs, and biological products are regulated by the U.S. Food and Drug Administration (FDA) under the Food, Drug and Cosmetic Act (FDCAct) and the Public Health Service Act (PHSA). GMO pesticides and microorganisms are regulated by the EPA pursuant to Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCAct). The form of regulation varies depending on the type of GMO involved. A précis summary of each of these three federal agencies' GMO responsibilities follows.

15.5.3.1 U.S. Food and Drug Administration

As described in Chapter 10, FDA regulates the safety of all human and animal food products in the U.S. (other than meat, poultry, and eggs, which are regulated by USDA), as well as drugs and biological products [10].

Food: The FDA's primary statutory authority is the Federal FDCAct, which authorizes the agency to regulate, among other things, "adulterated food," defined as food that "contains any poisonous or deleterious substance that may render it deleterious to health," and "food additives," which include "any substance [that may] becom[e] a component or otherwise affect[] the characteristics of any food." The FDCAct prohibits the sale of adulterated or misbranded food [10].

Under the FDCAct, substances added to food can be classified as "food additives," which require approval from the FDA that they are safe before they can be marketed, and "generally recognized as safe" (GRAS), as to which preapproval is not needed [10].

In a 1992 policy statement, the FDA reaffirmed that in most cases it would treat foods derived from GMOs like those derived from conventionally bred plants, and that most foods derived from GM plants would be presumptively GRAS. However, with respect to a GMO product "that differs significantly in structure, function, or composition from substances found currently in food," premarket approval of the substance as a food additive would be required.

The FDA encourages developers of new plant varieties intended for food use, including GMOs, to engage in a consultation procedure with the FDA, in order "to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution" [10].

Animals: The FDA has jurisdiction over genetically engineered animals, pursuant to its authority to regulate "new animal drugs" (NADs) under the FDCAct. Under the FDCAct, NADs are deemed generally unsafe unless the FDA has approved a New Animal Drug Application (NADA) for the particular use of the drug. Except in cases in which the FDA exercises discretion to decline to require compliance, or where the drug is only for investigational use and thus need only conform to specified exemptions, the FDA requires a GE animal to be the subject of an approved NADA based on a demonstration that it is safe and effective for its intended use.

The FDA has jurisdiction over genetically engineered animals, pursuant to its authority to regulate "new animal drugs" (NADs) under the FDCAct.

Drugs: The FDA generally has regulatory authority over drugs (Chapter 10). Pharmaceutical companies interested in introducing a new drug into the U.S. market in most cases must submit a New Drug Application (NDA) to the FDA, which must include extensive information and data on the drug's safety and effectiveness, such as the drug's chemistry, manufacture, animal and *in vitro* studies, clinical data, and the like. Drugs developed through GE must go through the same NDA process as other types of drugs.

Biological products: The FDA regulates medical products classified as "biological products," which includes vaccines, serums, blood products, and such, under relevant provisions of the PHSA (Chapter 4). Biological products, whether involving GM, must be licensed by the FDA before they can be introduced into commerce. The licensing procedure for biological products requires submission to the FDA of detailed information on laboratory and clinical studies, manufacturing methods, and other information relevant to whether they are safe and effective for their intended purpose.

15.5.3.2 U.S. Department of Agriculture

The USDA has jurisdiction to regulate GMOs through authorities delegated to its Animal and Plant Health Inspection Service (APHIS), which regulates the planting, importation, or transportation of GM plants pursuant to its authority under the PPA. This act authorizes the Secretary of Agriculture to "prohibit or restrict the importation, entry, exportation, or movement in interstate

commerce of any plant, plant product [etc.] if the Secretary determines [it] is necessary to prevent the introduction … of a plant pest or noxious weed within the United States" [10]. By regulation, APHIS classifies most GM plants as plant pests or potential plant pests and as "regulated articles." Under the Plant Protection Act (PPA), a regulated article must receive prior approval from APHIS before it is introduced. APHIS grants authorization to use GM plants in three ways: through a notification process, a permitting process, or a determination of nonregulated status.

Notification procedure: The notification procedure is available to plants that are not classified as noxious weeds or weeds in the release area, if certain criteria and performance standards are met. The criteria include that the plant must be a species that APHIS has determined may be safely introduced; the genetic material must be stably integrated; the expression of the genetic material must not result in plant disease; etc. The performance standards govern shipment, storage, planting, and testing, and are intended to prevent the plant from being released from containment. When the applicant sends a notification to APHIS, APHIS will respond within a prescribed time with an acknowledgement or a denial. If the notification is denied, the applicant may apply for a permit.

USDA has jurisdiction to regulate GMO plants pursuant to its authority under the Plant Protection Act.

Permit procedure: The permit procedure requires an applicant to submit information concerning, among other things, the donor organism, the recipient organism, and the composition of the regulated article; the expression of altered genetic material in the regulated article and the molecular biology of the system used to produce the article; the locality where the donor and recipient organisms and the regulated article were developed; the purpose of the regulated article; the quantity to be introduced; the processes to prevent release; the intended destination, use, and distribution; and the final disposition of the regulated article. If APHIS grants the permit, it is subject to conditions designed to ensure both that the regulated article remains contained and that APHIS can maintain regulatory oversight. Failure to comply with the conditions can result in withdrawal of the permit.

Determination of nonregulated status: GM plants that have been tested and have been shown not to pose a risk may be eligible for a determination of nonregulated status. A petition for determination of nonregulated status must include detailed biological information on the regulated article and the recipient organism, published and unpublished scientific studies, data from field tests, and other information designed to assist APHIS in determining whether the plant constitutes a pest. Upon receipt of a petition, APHIS publishes a notice in the *Federal Register* and allows 60 days for public comment. APHIS has 180 days to approve in whole or part or deny the petition.

15.5.3.3 Environmental Protection Agency

The EPA regulates pesticides and microorganisms developed through GE, using authorities under two of the agency's base statutes.

Pesticides: The EPA regulates the manufacture, sale and use of pesticides under FIFRA. Under FIFRA, pesticides must not cause "unreasonable adverse effects on the environment," which is defined to include both safety to the environment and safety in food for consumption. FIFRA requires all pesticides to be registered with the EPA before they can be distributed commercially. Pesticides must be tested and shown to be safe before they can be registered. A registration application must include information regarding testing, identity of the product, draft labeling, information on tolerance of residues, and other safety-related information.

Pursuant to its authority under FIFRA, the EPA regulates plants that are genetically modified to produce substances intended to control pests as to both their environmental safety and their safety in food, termed plant-incorporated protectants (PIPs). The standard registration procedures for pesticides apply to PIPs, unless they are made exempt by regulation. PIPs are exempt from FIFRA registration if the PIP is used in a crop used in food and its residues are exempt from regulation under the FDCAct, if the PIP is an inert ingredient listed as exempt by EPA, or if the PIP is from a plant that is sexually compatible with the recipient plant. With respect to those PIPs that are exempt, if the producer of the PIP obtains information regarding adverse effects from the PIP on human health or the environment, it must share it with EPA [10].

EPA regulates pesticides and microorganisms developed through genetic engineering, using authorities under FIFRA and TSCA, respectively.

Microorganisms: The EPA also has authority to regulate GMOs under the TSCAct (TSCA). The TSCA authorizes the EPA to regulate chemical substances that may present an unreasonable risk of injury to health or the environment. Manufacturers of covered substances must submit a pre-manufacture notification to the EPA. The EPA has determined that GMO microorganisms are chemical substances subject to regulation under the TSCA. The EPA has established regulations specifically for microorganisms that require submission of a Microbial Commercial Activity Notice before they are used for commercial purposes. The Notice must include information describing the microorganism's characteristics and genetic construction; by-products of its manufacture, use, and disposal; health and environmental effects data; and other information [10].

15.5.3.4 U.S. National Environmental Policy Act

The U.S. National Environmental Policy Act (NEPAct) requires U.S. federal agencies in some cases to prepare Environmental Assessments (EAs) of federal actions, such as adopting a policy or approving a permit, to determine if they are likely to significantly impact the environment. If a federal action is likely to have a significant impact, the agency must prepare a more detailed evaluation called an Environmental Impact Statement (EIS). Federal agency approvals of GMOs may require an EA or an EIS in some circumstances.

15.5.3.5 U.S. State Laws

U.S. state laws generally play only a small role in the regulation of GMOs in the U.S. The federal preemption doctrine

FIGURE 15.4 Examples of voluntary GMO labels on fruit sold in the U.S. (From The Holistic Works. https://theholisticworks.com, 2016.)

(Chapter 1), which bars conflicting state regulations when Congress intends federal regulation to occupy a particular field, precludes many aspects of state regulation of GMOs.

A rare example in which one state's law is more stringent than federal law on GMOs involves a bioengineered tropical aquarium fish known as the GloFish, which is unregulated at the federal level, but has been banned by the California Fish and Game Commission. Another example is Vermont's law on labeling of GMO products. Vermont's GE Food Labeling Act (Act 120) of 2014 requires foods produced using GE to be labeled as such. It also prohibits genetically engineered food from being advertised as "natural," "naturally made," "naturally grown," "all natural," or any other similar language that might mislead or confuse consumers [11]. This is the first law on GMO labeling to be implemented in the U.S. An example of fruit labeled as GMO is shown in Figure 15.4.

Some municipal governments in the U.S. have banned GMO crops. For example, in California, the counties of Marin and Mendocino have enacted ordinances forbidding the cultivation of GMOs. In Hawaii, Kauai County and Hawaii County similarly have banned the cultivation of most GMO crops.

15.6 GLOBAL POLICIES ON GMOS AND PRACTICES

With the globalization of GMOs have come policies that address international and national issues and concerns about GMOs. As subsequently described, the European Commission has developed and promulgated for the EU a set of directives and regulations on GMOs. This section will present a sample of global policies bearing on GMOs.

15.6.1 European Union GMO Policies

In contrast to the U.S., the EU has developed and promulgated a framework of directives and regulations that address GMOs. As a reminder from Chapter 5, an EU regulation is similar to a national law with the difference that it is applicable in all EU countries. Directives set out general rules to be transferred into national law by each country as they deem appropriate. As previously discussed, the U.S. framework relies on the use of existing laws and regulations for application to GMOs. In 2016 the EU announced a legal framework to ensure that the development of modern biotechnology, and more specifically of GMOs, takes place in safe conditions. The EU legal framework comprises three directives and two regulations, which are summarized herein [12]. Excerpts from each directive and regulation follow. Further details about each policy are available from the cited references.

Directive 2001/18/EC of the European Parliament and of the Council of March 12, 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC-Commission Declaration [13].

> **Objective:** In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when: a) carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community, b) placing on the market genetically modified organisms as or in products within the Community.

General obligations

1. Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs. GMOs may only be deliberately released or placed on the market in conformity with part B or part C, respectively.
2. Any person shall, before submitting a notification under part B or part C, carry out an environmental risk assessment. The information which may be necessary to carry out the environmental risk assessment is laid down in Annex III. Member States and the Commission shall ensure that GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment are taken into particular consideration when carrying out an environmental risk assessment, with a view

to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment. This phasing out shall take place by the December 31, 2004 in the case of GMOs placed on the market according to part C and by December 31, 2008 in the case of GMOs authorised under part B.

3. Member States and where appropriate the Commission shall ensure that potential adverse effects on human health and the environment, which may occur directly or indirectly through gene transfer from GMOs to other organisms, are accurately assessed on a case-by-case basis. This assessment shall be conducted in accordance with Annex II taking into account the environmental impact according to the nature of the organism introduced and the receiving environment.
4. Member States shall designate the competent authority or authorities responsible for complying with the requirements of this Directive. The competent authority shall examine notifications under part B and part C for compliance with the requirements of this Directive and whether the assessment provided for in paragraph 2 is appropriate.
5. Member States shall ensure that the competent authority organises inspections and other control measures as appropriate, to ensure compliance with this Directive. In the event of a release of GMO(s) or placing on the market as or in products for which no authorisation was given, the Member State concerned shall ensure that necessary measures are taken to terminate the release or placing on the market, to initiate remedial action if necessary, and to inform its public, the Commission and other Member States.
6. Member States shall take measures to ensure traceability, in line with the requirements laid down in Annex IV, at all stages of the placing on the market of GMOs authorised under part C.

Regulation (EC) No 1829/2003 of the European Parliament and of the Council of September 22, 2003 on genetically modified food and feed (Text with EEA relevance) [14].

> **Objective:** "The objective of this Regulation, in accordance with the general principles laid down in Regulation (EC) No 178/2002, is to: a) provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market; b) lay down Community procedures for the authorisation and supervision of genetically modified food and feed; c) lay down provisions for the labelling of genetically modified food and feed."

Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory [15].

> "Under that legal framework [i.e., Directive 2001/18/EC], GMOs for cultivation are to undergo an individual risk assessment before being authorised to be placed on the Union market in accordance with Annex II to Directive 2001/18/EC taking into account the direct, indirect, immediate and delayed effects, as well as the cumulative long-term effects, on human health and the environment. […] As from 3 April 2017 Member States in which GMOs are cultivated shall take appropriate measures in border areas of their territory with the aim of avoiding possible cross-border contamination into neighbouring Member States in which the cultivation of those GMOs is prohibited, unless such measures are unnecessary in the light of particular geographical conditions. Those measures shall be communicated to the Commission."

Regulation (EC) No 1830/2003 of the European Parliament and of the Council of September 22, 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [16].

> Article 1: **Objectives:** "This Regulation provides a framework for the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objectives of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products."

Directive 2009/41/EC on contained use of genetically modified micro-organisms. Regulation (EC) 1946/2003 on transboundary movements of GMOs [17].

> "Article 1: This Directive lays down common measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment. […]
>
> Article 4: 1. Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the contained use of GMMs. 2. To that end, the user shall carry out an assessment of the contained uses as regards the risks to human health and the environment that those contained uses may pose, using as a minimum the elements of assessment and the procedure set out in Annex III, Sections A and B. 3. The assessment referred to in paragraph 2 shall result in the final classification of the contained uses in four classes applying the procedure set out in Annex III, which will result in the assignment of containment levels in accordance with Article 5."

15.6.2 GMO Policies in China

In the People's Republic of China, restrictions on GMOs are primarily provided by the agricultural GMO regulations

enacted by the State Council in 2001 and relevant administrative rules [18]. The agricultural GMO regulations regulate not only crops, but also animals, microorganisms, and products derived from these sources. The testing, production, and marketing of GMOs in China are subject to government approval. Foreign companies that export GMOs to the PRC, including GMOs as raw materials, must apply to the Ministry of Agriculture (MOA) and obtain GMO Safety Certificates.

The country's legislation attempts to balance the promotion of agricultural GMOs with concern for consumers and environmental safety. As early as 2002, the PRC Agriculture Law incorporated safety controls over the research, testing, production, processing, marketing, and other applications of agricultural GMOs. When formulating the Regulations on Administration of Agricultural Genetically Modified Organisms Safety (GMO Regulations), currently China's primary legislation on GMOs, the State Council outlined the purposes of the Regulations in article 1, as [18].

- Strengthening the safety management of agricultural GMOs
- Safeguarding the health of human bodies and the safety of animals, plants, and microorganisms
- Protecting the ecological environment
- Promoting research into technologies of agricultural GMOs

China has not enacted a national law specifically regulating GMOs. Restrictions are primarily on agricultural GMOs, which are provided by the GMO Regulations enacted by the State Council in 2001 and the administrative rules implementing the GMO Regulations. The GMO Regulations are designed to regulate not only crops, but also animals, microorganisms, and their products. Agricultural GMO research, testing, production, processing, business operations, and import/export activities within the PRC's territory are subject to the GMO Regulations. GMO foodstuffs are subject to the Agricultural GMO Safety Regulations. There is no separate legislation specifically regulating GMO foodstuffs today.

According to the Ministry of Agriculture (MOA), as of April 2013, China had issued GMO Safety Certificates to seven domestically-developed, GM crops, including varieties of tomato (1997), cotton (1997), petunia (1999), sweet pepper and chili pepper (1999), papaya (2006), rice (2009), and corn (2009). Among them, the approved cotton has been broadly cultivated in China. As of 2010, China grew 3.3 million hectares of the approved cotton and a few hectares of the papaya, while the other GM crops had not been cultivated broadly, according to the MOA [18].

An International Service for the Acquisition of Agri-Biotech Applications brief, Global Status of Commercialized Biotech/GM Crops: 2012, indicates that as of 2012 China grew 4.0 million hectares of GM crops, including cotton, papaya, poplar, tomato, and sweet pepper, which constituted the largest biotech crop area among developing countries, and the sixth largest amount globally.

Licenses have been granted for the import into China of four foreign GM crops: cotton, soybean, corn, and rape. Among them, only cotton is permitted to be grown in China; the other crops can only be used as raw materials, according to the MOA. In 2011, imported GM soybeans constituted two-thirds of the soybeans consumed domestically.

In 2012 China grew 4.0 million hectares of GM crops, including cotton, papaya, poplar, tomato, and sweet pepper, which was the sixth largest amount globally.

The safety of GMOs is hotly debated in China through traditional media and the emerging online social media, where the public expresses deep concerns about the safety of GMO foodstuffs. Some nonprofit organizations have also alleged that GMOs generate food safety concerns and environmental dangers. Mainstream research institutes in China appear to share the government's view in promoting GMO research. Major research institutes contribute funds and laboratory facilities to GMO research. Among them, the Chinese Academy of Agricultural Sciences has established a Biotechnology Research Institute. The Institute not only supports GMO safety evaluations, but also carries out projects on GM plant research and production.

China is a party to the Convention on Biological Diversity, which became effective to China in 1993. China is also a party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, which entered in force in 2005 [18].

15.6.3 GMO Policies in Brazil

In 2012, Brazil was the second major global producer of GMO crops, with an area of 30 million hectares dedicated to the planting of GMOs, which was only behind the U.S. with an area of 69 million hectares. Brazil's policies on GMOs are therefore of global significance.

Brazil's Biosafety Law No. 11, 105 of March 24, 2005, enacted by the Brazilian Congress ended the controversy surrounding GMOs in Brazil. In addition to creating general rules on biotechnology research, Law No. 11, 105 regulates constitutional principles and establishes safety standards and mechanisms in Brazil for monitoring activities involving GMOs and their by-products. "The guidelines used for drafting this Law were the recognition of scientific advances in the areas of biosafety and biotechnology; the protection of life, human health, and the health of animals and plants; and the observance of the precautionary principle for the protection of the environment" [19].

Additionally, Law No. 11, 105 created a national technical commission (CTNBio), which became responsible for all regulation of the biotechnology sector. Since 2005, CTNBio has approved the commercial use of about 50 GMOs, of which 35 are plants, including beans, cotton, corn, and soy. Soy is the most cultivated GMO in Brazil. According to the president of CTNBio, the

Brazil was the second major global producer in 2012 of GMO crops, with an area of 30 million hectares dedicated to the planting of GMOs, which was only behind the U.S. with an area of 69 million hectares.

rules for the release of these organisms in Brazil are among the strictest in the world.

A GM product must go through five different stages before it can be sold in Brazil. First, a company must submit the project to CTNBio for approval. The Commission reviews the proposal and makes a site visit to determine whether the conditions exist for performing the work safely. If the proposal is approved, development and testing can begin, and must be performed in a restricted and controlled environment. If the work site is a plant, Brazil's MOA is in charge of supervising the experiment. Then, before the GM product's commercial release, CTNBio evaluates whether the data collected correspond to the Commission's biosecurity criteria. Prior to its marketing, however, the product is still subject to a political assessment conducted by a council of 11 ministers, who decide whether it is advantageous for Brazil to launch the new product commercially [19].

Perspective: It is interesting to compare GMO policies across the geographic areas described herein. For example, the U.S. stands alone without an umbrella GMO policy akin to that in the EU, China, and Brazil. As described, the U.S. policy is to consider products that contain GMOs, regulating the products, not GMO processes. The products are then considered through application of existing policies and laws, e.g., foods with GMO ingredients are considered under the Federal Food and Drug Act, as Amended. In contrast, the EU has developed and promulgated several directives and regulations concerning GMOs. A set of three directives and two regulations from the European Commission amount to a somewhat "cradle-to-grave" philosophy on GMOs and comprise the EU legal framework on GMOs. This framework comprises risk assessment of GMOs, traceability of GMO products, cross-border contamination of GMOs, labeling of GM food and feed, and transboundary movements of GMOs. Policies on GMOs in China and Brazil seem to occupy a middle position between the EU framework and the laissez-faire approach in the U.S.

15.7 LABELING OF PRODUCTS CONTAINING GMO INGREDIENTS

A major policy issue globally is whether and how to label GMOs and products containing GMOs. Pro-labeling advocates say the matter is simple—an issue of a consumer's right to know. But the biotechnology industry calls it more complicated. The FDA has long held that genetically modified foods are "substantially equivalent" to, and as safe as, naturally-derived foods. Therefore, they shouldn't require a label. However, more than 60 countries including members of the EU, Japan, and China, already label genetically engineered foods [11]. Consumer advocates in the U.S. have argued for GMO labeling to become mandatory in the U.S., as is the case in other countries.

15.7.1 U.S. Policies on Labeling of GMOs

On July 14, 2016, the U.S. Congress enacted the first federal legislation on labeling of genetically modified food, The Safe and Accurate Food Labeling Act of 2015 was signed into law by President Obama. The law directs the USDA to create a national labeling standard that allows food producers to choose how they want to disclose the presence of genetically modified ingredients. Under the legislation, manufacturers will be able to use text, symbols or a QR code that consumers must scan with a smartphone to relay the information. The bill also blocks states from issuing their own GM labeling laws [20].

Prior to enactment of the Labeling Act of 2015, some state governments undertook efforts to require GMO labeling. In addition to Vermont, which enacted a GMO labeling law in 2014, at least 18 states were considering laws that would make the labels mandatory, including Illinois and California, the country's biggest markets. Earlier in 2016, pro-labeling advocates marched from New York to Washington DC. In late 2015, about 500 groups, including some of the U.S.'s biggest consumer organizations, banded together as the Just Label It campaign. Further, the Washington-based Center for Food Safety filed a petition with FDA, calling for the agency to require labels [20a]. The examples of campaigns for labeling of GMO products are among several such events occurring in the U.S. This advocacy action by consumer groups can persuade companies to adopt a policy that government agencies themselves cannot effect. Quite simply, business entities are sensitive to customers' concerns and advocacy if sufficient pressure is evident.

Perspective: It is interesting that labeling of food with genetically modified ingredients became a matter of federal legislation, The Safe and Accurate Food Labeling Act of 2015. The politics of this action by the U.S. Congress are the same as other actions by Congress in yielding to pressure exerted by vested interests concerned about U.S. states' policymaking. In this example of GM labeling, the food and GE industries preferred not to have to deal with individual states, given that GM labeling regulations would likely differ across states. This federal labeling law is also noteworthy in regard to which federal agency was delegated the responsibility of developing food labels. The USDA, not the FDA, was designated. Apparently the Congress perceived labeling to be a matter of agricultural business, rather than as a matter of public health.

15.7.2 Industry's Voluntary Labeling of GMO Products

Partially in response to the Vermont law that requires labeling of products containing GMO ingredients, four of the largest food manufacturers in the U.S. have announced that they will join Campbell's in labeling genetically engineered foods sold in the U.S. to comply with Vermont's GMO labeling law [11].

General Mills, Kellogg, Con Agra, and Mars made their announcements after a bill to eliminate Vermont's GMO labeling law failed to advance in the U.S. Vermont's labeling law took effect on July 1, 2016, and all four companies say that they will label their products in accordance with Vermont's law. Campbell's announced in January 2016 that they will be labeling all their products sold in the U.S. and called for a national mandatory labeling standard.

A General Mills spokesperson commented, "We can't label our products for only one state without significantly driving up costs for our consumers and we simply will not do that. The result: consumers all over the U.S. will soon begin seeing words legislated by the state of Vermont on the labels of many of their favorite General Mills products" [11]. Comparable statements were provided by spokespersons from Mars and Kellogg. All four companies called for Congress to act to pass a uniform national standard for GMO labeling.

15.7.3 EU Policies on Labeling of GMOs

The EU has the most sweeping and strict GMO labeling policies of any regional group or individual nation. The EU policy is predicated on traceability and specified labeling. More specifically, as related by the European Commission, traceability enables tracking GMOs and GM food/feed products at all stages of the supply chain [21]. Traceability also makes labeling of all GMOs and GM food/feed products possible. It allows for close monitoring of potential effects on the environment and on health. Where necessary it can allow the withdrawal of products if an unexpected risk to human health or to the environment is detected.

The EU has the most sweeping and strict GMO labeling policies of any regional group or individual nation. The EU policy is predicated on traceability and specified labeling.

All operators involved, i.e., farmers or food and feed producers who introduce a product into the supply chain or purchases such a product, must be able to identify their supplier and the companies to which the products have been delivered. Operators must provide their customers with the following information, in writing: an indication that the product—or certain ingredients—contains, consists of, or is obtained from GMOs information on the unique identifier(s) for these GMOs.

In the case of products consisting of or containing mixtures of GMOs to be used only as food or feed or for processing, this information may be replaced by a declaration of use by the operator. It has to be accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture. Operators must also ensure that the information is passed on in writing to those who are next in the supply chain. For a period of 5 years after every transaction within the supply chain, every operator must keep a record of this information and be able to identify the operator from whom they bought the products and the one to whom he or she supplied them.

In the case of pre-packaged GM food/feed products, the list of ingredients must indicate "genetically modified" or "produced from genetically modified [name of the organism]." An example of the kind of label required in the EU is shown in Figure 15.5. In the case of products without packaging these words must still be clearly displayed in close proximity to the product (e.g., a note on the supermarket shelf). These labeling requirements do not apply to GM food/feed products in a proportion no higher than 0.9% of the food/feed ingredients considered individually and if this presence is adventitious or technically unavoidable [21].

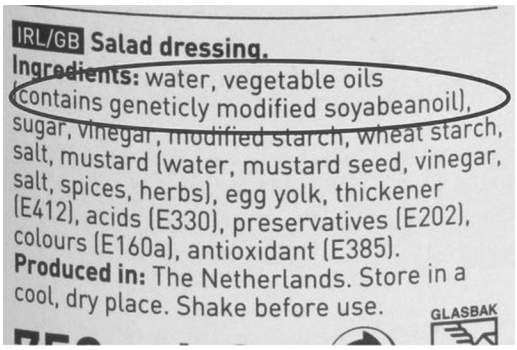

FIGURE 15.5 Label on EU food product with GMO identification. (From https://www.google.com/search?hl=en&site=imghp&tbm=isch&source=hp&biw=1024&bih=714&q=EU+food+product+label+showing+GMO+ingredient&oq=EU+food+product+label+showing+GMO+ingredient&gs_l=img.3...2901.2901.0.5861.3.3.0.0.0.0.37.37.1.1.0....0...1.2.64.img..2.0.0.0.mJppBPInW2Q#imgrc=hgK5A56e2ll6xM:.)

There exist "GM-free labels" pointing out that, in addition to what is laid down by the EU legislation on GMOs, specific measures have been taken on a voluntary basis to strictly exclude the presence or the use of GMOs in some food or feed products. Such voluntary labels are possible provided that they are not misleading for the consumer.

15.7.4 Other Nations' Policies on Labeling of GMOs

According to one GMO labeling advocacy organization, Just Label It! there are currently, 64 countries around the world that require labeling of genetically modified foods. As previously commented, unlike most other developed countries—such as 28 nations in the EU and the countries of Japan, Australia, Brazil, Russia and China—the U.S. has no federal laws requiring labeling of genetically modified foods [22]. The 64 nations that require GMO labels span the globe, but are regionally concentrated. For instance, most countries in Europe, Asia, and the northern countries of South America require labeling. In contrast, few Middle East and African countries require labeling. And of special note, no country in North America requires GMO labeling, an outcome possibly linked to trade exchanges with the U.S. A list of countries that require GMO labeling is available elsewhere [22].

For purposes of illustration, both China and Brazil have enacted national policies concerning GMO methods and products. These countries' policies on labeling of GMOs are excerpted as follows:

> China: "GMO products on the GMO list published by the state must be clearly labeled when sold within the PRC territory; unlabeled products may not be sold. The label should indicate the name of the GM materials and, if there are special restrictions on where it may be sold, the area in which it will be sold" [18].

Brazil: "Law No. 11, 105 determines that food and food ingredients for human consumption or animal feed containing or produced from GMOs or their by-products must provide information to this effect on their labels, in accordance with the regulation. Consumers must be informed when more than 1% of a product marketed as food for human or animal consumption contains or is produced from GMOs" [19].

15.8 PUBLIC'S PERCEPTIONS OF GMOS

A survey of a sample of the U.S. population conducted by the Pew Research Center included questions related to GM food [23]. The findings point to a mix of factors that are central to the public's beliefs about food safety. Women and blacks appear to be more leery of GM foods and pesticides on crops. And there are sizeable differences across education and knowledge groups in thinking about these foods. Additionally, the sampled public tends to be skeptical that scientists, on the whole, have a clear understanding of the health effects of GM crops.

A minority of adults (37%) say that eating GM foods is generally safe, while 57% say they believe it is unsafe. And most are skeptical about the scientific understanding of the effects of GMOs on health. About two-thirds (67%) of the sampled adults say scientists do not clearly understand the health effects of GM crops; 28% say scientists have a clear understanding of this.

> Fewer women (28%) than men (47%) believe eating GM foods is safe. Opinions also tend to vary by race and ethnicity with fewer blacks (24%) and Hispanics (32%) than whites (41%) saying that GM foods are safe to eat. Views about GMOs are roughly the same among both younger (ages 18 to 49 years) and older (50 and older) adults. Views about the safety of GM foods differ by education. Those who hold a college degree, especially those with a postgraduate degree, are more likely than those with less education to say GM foods are safe. Those with postgraduate degree say that GM foods are generally safe or unsafe by a margin of 57% to 38%. This is the only education group with a majority saying such foods are generally safe [23].

A review of published literature on the European public's attitudes toward GMOs revealed attitudes similar to those reported in the U.S. [24]. The findings indicated that although Europeans had a generally positive attitude about biotechnology, their attitude changed when consumers were asked about the specific application of biotechnology in GM foods. "In 2010, 23% of respondents from the EU's 27 states thought that GM food should be supported, while 61% disagreed with this view. […] A comparison of responses from different EU countries shows clear differences. Spain and Portugal, where Bt maize* is grown, are among the countries with the highest GM food approval rate, while countries with GM cultivation bans (like Austria, Germany, or France) had only a low approval. Most European consumers thus appear to be quite skeptical concerning GM food, when asked about this topic in isolation. However, in comparison with other perceived food risks, GM foods did not score very highly. When potential benefits of GM food of GM crops are pointed out, support seems to increase" [24]

15.9 ASSOCIATIONS BETWEEN GMOS AND HUMAN HEALTH

As with many new technologies introduced into commercial use (e.g., cell phones), concerns arise about potential adverse effects on human health. This dictum applies to the introduction into commerce of biotechnology products for use by the general public. Individuals and concerned groups have asserted that genetically engineered food might harm those who consume it. These concerns sometimes accompany media expression about the lack of labels on food containing GMO ingredients. Although the FDA has consistently proclaimed genetically modified food to be without harm to human health, concerns have remained. This has led to some research investigations of any associations between human health effects and contact with GMO methods and products. These and related concerns were addressed in a 2-year study conducted by the National Academy of Science, Engineering, and Medicine, the findings of which were published in 2016 [3]. The Academy's report *Genetically Engineered Crops: Experiences and Prospects* contain salient findings on issues of human and ecological health in relation to GMOs. Relevant excerpts from the report follow.

> […] while recognizing the inherent difficulty of detecting subtle or long-term effects on health or the environment, the study committee found no substantiated evidence of a difference in risks to human health between current commercially available genetically engineered (GE) crops and conventionally bred crops, nor did it find conclusive cause-and-effect evidence of environmental problems from the GE crops. However, evolved resistance to current GE characteristics in crops is a major agricultural problem. […]
>
> The committee examined almost 900 research and other publications on the development, use, and effects of genetically engineered characteristics in maize (corn), soybean, and cotton, which account for almost all commercial GE crops to date. […] In addition, the committee heard from 80 diverse speakers at three public meetings and 15 public webinars, and read more than 700 comments from members of the public to broaden its understanding of issues surrounding GE crops.
>
> The committee carefully searched all available research studies for persuasive evidence of adverse health effects directly attributable to consumption of foods derived from GE crops but found none. Studies with animals and research on the chemical composition of GE foods currently on the market reveal no differences that would implicate a higher risk to human

* Bt maize has been genetically altered to express one or more proteins from the bacterium *Bacillus thuringiensis*.

health and safety than from eating their non-GE counterparts. Though long-term epidemiological studies have not directly addressed GE food consumption, available epidemiological data do not show associations between any disease or chronic conditions and the consumption of GE foods.

There is some evidence that GE insect-resistant crops have had benefits to human health by reducing insecticide poisonings. In addition, several GE crops are in development that are designed to benefit human health, such as rice with increased beta-carotene content to help prevent blindness and death caused by vitamin A deficiencies in some developing nations [3].

15.10 ASSOCIATIONS BETWEEN GMOS AND ECOSYSTEM HEALTH

As related in Section 15.9, the U.S. National Academy of Science, Engineering, and Medicine conducted a 2-year study on issues of human and ecological health in relation to GMOs. The Academy's report *Genetically Engineered Crops: Experiences and Prospects* contains salient findings relevant to agriculture and ecosystem health. Relevant excerpts from the report follow. "The use of insect-resistant or herbicide-resistant crops did not reduce the overall diversity of plant and insect life on farms, and sometimes insect-resistant crops resulted in increased insect diversity […]. While gene flow—the transfer of genes from a GE crop to a wild relative species—has occurred, no examples have demonstrated an adverse environmental effect from this transfer. Overall, the committee found no conclusive evidence of cause-and-effect relationships between GE crops and environmental problems. However, the complex nature of assessing long-term environmental changes often made it difficult to reach definitive conclusions" [3].

The available evidence concerning effects on agriculture indicates "that GE soybean, cotton, and maize have generally had favorable economic outcomes for producers who have adopted these crops, but outcomes have varied depending on pest abundance, farming practices, and agricultural infrastructure. Although GE crops have provided economic benefits to many small-scale farmers in the early years of adoption, enduring and widespread gains will depend on such farmers receiving institutional support, such as access to credit, affordable inputs such as fertilizer, extension services, and access to profitable local and global markets for the crops.

Evidence shows that in locations where insect-resistant crops were planted but resistance-management strategies were not followed, damaging levels of resistance evolved in some target insects. If GE crops are to be used sustainably, regulations and incentives are needed so that more integrated and sustainable pest-management approaches become economically feasible" [3]. The committee also found that in many locations some weeds had evolved resistance to glyphosate, the herbicide to which most GE crops were engineered to be resistant. Resistance evolution in weeds could be delayed by the use of integrated weed-management approaches, says the report, which also recommends further research to determine better approaches for weed resistance management.

Insect-resistant GE crops have decreased crop loss due to plant pests. However, the committee examined data on overall rates of increase in yields of soybean, cotton, and maize in the U.S. for the decades preceding introduction of GE crops and after their introduction, and there was no evidence that GE crops had changed the rate of increase in yields. It is feasible that emerging genetic-engineering technologies will speed the rate of increase in yield, but this is not certain, so the committee recommended funding of diverse approaches for increasing and stabilizing crop yield" [3].

Another impact of GM crops is perhaps an indirect, but important, effect. Researchers have reported that widespread adoption of GM crops has reduced the use of insecticides, but increased the use of herbicides as weeds become more resistant, according to the largest study of GM crops and pesticide use to date. Researchers at the University of Virginia studied annual data from more than 5000 soybean and 5000 maize farmers in the U.S. from 1998 to 2011. Despite the decrease in insecticide use, the researchers noted that continued growth in herbicide use poses a significant environmental problem as large doses of the chemicals can harm biodiversity and increase water and air pollution [3a].

15.11 HAZARD INTERVENTIONS

As presented in this chapter, GMOs have become commonplace globally in methods used to add presumed desirable characteristics to existing species of plants, animals, and microbes. Because GMOs represent a new or altered species, precautions have been adopted as policies to protect against undesirable consequences of new species introduced into the environment. The precautionary policies include national and regional laws, regulations, and practices that are intended to prevent any unexpected hazards to human and ecosystem health. In particular, methods of risk assessment and surveillance of genetically engineered species and products, independent assessment of GMO methods and products prior to their release into commerce, and monitoring of applications of GMOs in the environment are traditional elements of hazard prevention. Additionally, labeling of products containing GMO ingredients or prepared using GMO methods will aid consumers in taking personal action to avoid any presumed health hazard.

15.12 SUMMARY

This chapter is about organisms created via a method of DNA manipulation that would not have existed in nature otherwise. GM is the introduction of new traits to an organism by making changes directly to its genetic makeup, e.g., DNA, through intervention at the molecular level. The development and commercialization of GMOs commenced in the late twentieth century, and became widespread for use in certain agricultural applications globally. As noted in a study conducted by the U.S. National Academy of Science, Engineering, and

Medicine [3], "since the 1980s, biologists have used genetic engineering to produce particular characteristics in plants such as longer shelf life for fruit, higher vitamin content, and resistance to diseases. However, the only genetically engineered characteristics that have been put into widespread commercial use are those that allow a crop to withstand the application of an herbicide or to be toxic to insect pests. In general, GMOs are often promoted as a means to increase crop yields, thereby improving crop revenues and supplying more food to a hungry world. Further, genetically engineered crops hold promise for a way to assuage of effects of climate change".

As noted in this chapter, GM corn, soy, and canola and cottonseed oil proliferate in our food system as ingredients in processed food and in animal feed, but there are very few GM crops—fruits and vegetables or GM grains—that are consumed as whole foods. The exceptions are some GM sweet corn grown in the U.S. and Canada, some GM squash varieties grown in the U.S., and GM papaya grown in the U.S. and China. However, critics of the use of GMOs have expressed concern that new varieties of organisms were being imposed on the world, with uncertain and undocumented outcomes.

To prevent any undesired health or environmental consequence of GMOs, national governments have developed and promulgated policies that are intended to intercept any consequence prior to release of a GMO or genetically engineered commercial product. As related herein, the EU framework on GMOs is the current most comprehensive set of policies on GMOs.

Some individuals and consumer advocacy groups have expressed health and environmental concerns about potential adverse effects of GMOs and genetically engineered products. Partially in response to these and other kinds of concerns, e.g., economic, a major study conducted by the U.S. National Academy of Science, Engineering, and Medicine found no evidence of any adverse health and environmental consequences of GMOs and related products.

Labeling of GMO products is the subject of vigorous debate in the U.S., since the U.S. has no federal laws or agency regulations that require such labeling. This is in contrast to most of the global community of nations, as described in this chapter. Some U.S. states are moving forward to legislate GMO labeling, and that effort may eventually result in federal legislation for purposes of national uniform labeling. As a matter of policy, large industries such as biotechnology are generally more comfortable dealing with one regulatory agency, rather than 50 or more state regulatory agencies.

15.13 POLICY QUESTIONS

1. As related in this chapter, the U.S. government has not been an active party to several of the international agreements and treaties that concern genetically modified organisms. Research the basis for the U.S. lack of engagement in international GMO agreements. Then prepare an essay of appropriate depth on whether the U.S. government should change or hold this current position on GMOs.
2. Good news! Your college class reunion has been announced and you are invited to attend. You are eager to meet your former "class buds" but notice the reunion is being catered by the university's genetics department. Only *bona fide* GMO foods will be served. Is this good news to you? If so, why? If not, why not? Would the presence of GMO food be a factor in your decision on whether to attend the class reunion?
3. What is your opinion of the Green Revolution that some have alleged saved a billion or more human lives in countries that lacked food security? Using Internet resources, prepare an essay of appropriate depth that outlines the alleged pros and cons of the Green Revolution. Similarly, prepare a one-page essay that discusses your opinion of the role of GMOs in combating world hunger.
4. As asserted in this chapter, a vigorous kerfuffle exists over labeling of products that contain GMO ingredients. After thoughtful consideration of the labeling issue, what is your position on whether any GMO ingredient in food should be labeled? Explain your decision. What method would you use to influence policymakers to adopt your position?
5. Your grandparents still reside on a medium-size farm. The farm has been in your family for six generations. The farm's principal cash crops are corn and melons. Your grandparents have taken pride in adamantly eschewing the use of GMO corn and melons, and their farm income has diminished. The neighboring farms have adopted GMO seeds and plants for their farms' crops and their farm income has nearly doubled. What arguments and data do you use to persuade your grandparents to switch to GMO crops? Or do you also eschew GMOs? Explain your decision.
6. As the parent of a young child, a neighbor has asked you to join a parents' group that has undertaken a social media campaign to eliminate any GMO ingredients in all food consumed by young children. As a responsible parent, how do you respond to your neighbor's request? Justify your answer with data specific for children's health.
7. You have been asked as a senior member of a municipal health department to represent the department at a local community meeting held for the purpose of discussing the increasing availability of GMO food in local retail markets. How will you prepare for this community meeting? What will be the gist of your comments at the meeting?
8. As presented in this chapter, the U.S. policy on GMOs is based on the application of existing environmental statutes, e.g., the Federal Food and Drug Act, as amended. A candidate for the Office of U.S. President supports a free market approach to the

development and use of GMO products. In support of the free market approach, the candidate advocates the revision of all GMO-applicable federal laws so as to eliminate any U.S. Government oversight of GMO products. As a voter, will you vote for or against this candidate? Why? Explain your decision.

9. The EU legal framework on GMOs comprises three directives and two regulations. Select any one of the three directives and describe in your opinion its primary, most significant, requirements viz. GMOs. Your reply must not exceed two pages, single spaced text.
10. The EU legal framework on GMOs comprises three directives and two regulations. Select either of the two regulations and describe in your opinion its primary, most significant, requirements viz. GMOs. Your reply must not exceed two pages of text.
11. Using Internet resources, locate three downloadable images of labels that appear on food that contains GMO ingredients. Discuss each label's effectiveness in informing you as a potential consumer of the labeled product. Would you have purchased the three labeled products without their GMO labels?
12. Both the U.S. and Canadian governments have approved the introduction into commerce of GMO salmon. Both governments have accepted the new salmon as a food product without adverse health effects to consumers. As a person who enjoys salmon filets for household meals, will you purchase the GMO salmon, assuming its market price is equal to that of ocean salmon? If so, what considerations will you take into account as justification for your choice of salmon? Does your answer change if the GMO salmon is half the market price of naturally caught salmon? Justify your answer.
13. Prepare an essay on the methods of GE currently used to modify animal species, e.g., salmon. As you have learned from this chapter's material, genetically engineered species contain genetic traits deemed useful for specific purposes, e.g., seeds that can resist fungus or specific pesticides. Some persons concerned about GE aver that humans could be genetically modified using these same methods, e.g., children with different anatomic features. Include in your essay your thoughts about GE of the species *Homo sapiens*.
14. Using Internet resources choose a developing country and research that country's policies on genetically modified organisms. Compare your selected country's GMO policies with those described for Brazil.
15. The precautionary principle was described in Chapter 2. Review its basis and practice and relate it to the EU's legal framework of three directives and two regulations. Provide details of your comparative analysis.
16. Assuming that genetic material is the staff of all life, discuss in a philosophical essay why humankind should not be imposing itself on other species through manipulation of their genetic material. Provide references to two or more published documents that support or disagree with your philosophy.
17. Accept an "alien species" to be defined as "a species introduced outside its normal distribution. Invasive alien species are alien species whose establishment and spread modify ecosystems, habitats, or other species." In your opinion, are genetically modified species alien species? If so, why? If not, why not? Be specific.
18. The management of a local farmers' market has elected to remove all labels from the GMO-labeled products sold at the market. You reside in a community that does not mandate GMO labels on products sold in commerce. The management justifies their policy by alleging that local farmers lose sales when GMO labels appear on their farm products. A grassroots group has begun a campaign to discourage patronage of the local farmers' market. Management of the market has threatened to litigate the grassroots group for slander and loss of business. You, as a senior member of the local health department, were assigned to arbitrate the differences between the market's management and the grassroots group. What do you do?
19. Determine if your university conducts GMO research. If so, ascertain the nature, purpose, and financial support of an ongoing GMO research project of your selection. In particular, what safeguards are in place to protect the researchers and community against the release of any GMOs? Select a different university if your school is not involved with GMO research.
20. Congratulations for completing this chapter. Hopefully, your astute assessment of the material in this chapter has left you with no genetic aftereffects. Please discuss the three most important lessons you learned. Was your personal environmental health behavior changed by the content of this chapter? If so, how? If not, why not?

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16 Biodiversity and Endangered Species

16.1 INTRODUCTION

Upon initial reflection, one might ponder why a book with a public health bent should include material on biodiversity and endangered species, even though throughout this work there has been an effort to intertwine human and ecosystem health. This nexus is important because our species, *Homo sapiens*, cannot exist without reliance on other life that the planet offers. This "other" includes life that spans the spectrum of taxonomy, from bacteria, to plants, to animals of various forms and functions. Our species early on became dependent on essential bacteria in our gut, feral animals for food and clothing, plants that could be consumed for nutrition, and domesticated creatures that could transport us. As we reflect on this symbiotic history of our species, we must acknowledge that little has changed in the way of our existence's needs for "other life" to support us. We exist due to the biodiversity in nature.

Over the ages of human history—and even before our species had a history—species came and went. Many went extinct, leaving only fossilized legacies of their existence. The story of dinosaurs is but one of myriad examples of species that have gone extinct. In modern times, the last passenger pigeon, Martha, died in captivity at the Cincinnati, Ohio, Zoo in 1914. A bird that had once existed in the billions was eliminated by uncontrolled commercial hunting of the bird for food and "sport." The American bison almost suffered the same fate as millions of bison were killed by migrating settlers moving westward across North America. In the twenty-first century, the Monarch butterfly's existence is threatened due to loss of its only food source, milkweed, as herbicides used in agriculture have diminished availability of milkweed. Illustrated in Figure 16.1 is a species, the Asian tiger, currently considered endangered.

Given the preceding comments, one might be tempted to say, "Too bad, but what's that got to do with me?" Well, there are several reasons to be concerned about elimination of a species. Species lost in existence are species lost as life potentially beneficial to humankind and the larger ecosystem. Perhaps the passenger pigeon evolved with a unique genetic structure that protected it against cancer. We will never know. And what if the plants whose existence is under assault from climate change are essential food sources for humans and other animals? Or what will be the impact of fish species overfished into extinction? Put simply, loss of any species brings consequences, many of which are dire to human and ecosystem well-being. For this reason, environmental policies to protect endangered species have been developed and are discussed in this chapter.

16.2 HISTORY

As characterized by the Center for Biodiversity, our planet is now in the midst of its sixth mass extinction of plants and animals—the sixth wave of extinctions in the past half-billion years. Our planet is currently experiencing the worst spate of species die-offs since the loss of the dinosaurs 65 million years ago. Although extinction is a natural phenomenon, it occurs at a natural "background" rate of about one to five species per year. Scientists estimate the current loss of species at 1000–10,000 times the background rate, with dozens going extinct every day. This scenario would lead to as many as 30%–50% of all species possibly heading toward extinction by the mid-century [1].

Unlike past mass extinctions, caused by events such as asteroid strikes, volcanic eruptions, and natural climate shifts, the current crisis is almost entirely caused by humans. In fact, 99% of currently threatened species are at risk from anthropogenic activities, primarily those driving habitat loss, introduction of exotic species, and global warming (Chapter 6). "Because the rate of change in our biosphere is increasing, and because every species' extinction potentially leads to the extinction of others bound to that species in a complex ecological web, numbers of extinctions are likely to accelerate in the coming decades as ecosystems unravel" [1].

The Center for Biodiversity forecasts that many thousands of species are at risk of disappearing forever in the coming decades. The Center has summarized their concerns according to those groups at greatest risk [1]:

> AMPHIBIANS—No group of animals has a higher rate of endangerment than amphibians. Scientists estimate that a third or more of all the roughly 6,300 known species of amphibians are at risk of extinction. The current amphibian extinction rate may range from 25,039 to 45,474 times the background extinction rate. Frogs, toads, and salamanders are disappearing because of habitat loss, water and air pollution, climate change, ultraviolet light exposure, introduced exotic species, and disease. Because of their sensitivity to environmental changes, vanishing amphibians should be viewed as a warning sign that something is amiss in the environment.
>
> BIRDS—[…] declining bird populations across most to all habitats confirm that profound changes are occurring on our planet in response to human activities. A 2009 report on the state of birds in the U.S. found that 251 (31%) of the 800 species in the U.S. are of conservation concern. Globally, BirdLife International estimates that 12% of the known 9, 865 bird species are now considered threatened, with 192 species, or 2%, facing an "extremely high risk" of extinction in the wild […] Habitat loss and degradation have caused most of the bird declines, but the impacts of invasive species, and capture by collectors play a big role too.
>
> FISH—Increasing demand for water, the damming of rivers throughout the world, the dumping and

FIGURE 16.1 Endangered Asian tiger with cubs in an Indian sanctuary. (From Ranthambhore National Park—Travel Plan India. https://travelplan1989.wordpress.com/ ranthambhore-national-park/.)

> accumulation of various pollutants, and invasive species make aquatic ecosystems some of the most threatened on the planet; thus, it's not surprising that there are many fish species that are endangered in both freshwater and marine habitats. […] Across the globe, 1,851 species of fish—21% of all fish species evaluated—were deemed at risk of extinction by the International Union for Conservation of Nature (IUCN) in 2010, including more than a third of sharks and rays.
>
> INVERTEBRATES—Invertebrates, from butterflies to mollusks to earthworms to corals, are vastly diverse […], estimated to account for about 97% of the total species of animals on Earth. Of the 1.3 million known invertebrate species, the IUCN has evaluated about 9,526 species, with about 30% of the species evaluated at risk of extinction. […]
>
> MAMMALS—Perhaps one of the most striking elements of the present extinction crisis is the fact that the majority of our closest relatives—the primates—are severely endangered. About 90% of primates—the group that contains monkeys, lemurs, lorids, galagos, tarsiers, and apes (as well as humans)—live in tropical forests, which are fast disappearing. The IUCN estimates that almost 50% of the world's primate species are at risk of extinction. Overall, the IUCN estimates that half the globe's 5,491 known mammals are declining in population and a fifth are clearly at risk of disappearing forever with no less than 1,131 mammals across the globe classified as endangered, threatened, or vulnerable. […]
>
> PLANTS—Through photosynthesis, plants provide the oxygen we breathe and the food we eat and are thus the foundation of most life on Earth. They're also the source of a majority of medicines in use today. Of the more than 300,000 known species of plants, the IUCN has evaluated only 12,914 species, finding that about 68% of evaluated plant species are threatened with extinction. […] Global warming is likely to substantially exacerbate this problem. […] With plants making up the backbone of ecosystems and the base of the food chain, that's very bad news for *all* species, which depend on plants for food, shelter, and survival.
>
> REPTILES—Globally, 21% of the total evaluated reptiles in the world are deemed endangered or vulnerable to extinction by the IUCN—594 species—while in the U.S., 32 reptile species are at risk, about 9% of the total. […] The main threats to reptiles are habitat destruction and the invasion of nonnative species, which prey on reptiles and compete with them for habitat and food.

These data on extinction projections are summarized in Table 16.1.

Perspective: These data, projections, and forecasts from the Center for Biodiversity paint a grim picture for the future

TABLE 16.1
Species Groups Deemed Endangered or Vulnerable

Group	State of Extinction
Amphibians	No group of animals has a higher rate of endangerment than amphibians. Scientists estimate that a third or more of all the roughly 6300 known species of amphibians are at risk of extinction.
Birds	A global estimate is that 12% of the known 9865 bird species are now considered threatened, with 192 species, or 2%, facing an "extremely high risk" of extinction in the wild.
Fish	Across the globe, 1851 species of fish—21% of all fish species evaluated—were deemed at risk of extinction, including more than a third of sharks and rays.
Invertebrates	Of the 9526 species evaluated, approximately 30% of the species evaluated are at risk of extinction.
Mammals	One-fifth are at risk of disappearing forever with no fewer than 1131 mammals across the globe classified as endangered, threatened, or vulnerable.
Plants	Of 12,914 species evaluated, approximately 68% of evaluated plant species are threatened with extinction.
Reptiles	Globally, 21% of the total evaluated reptiles in the world are deemed endangered or vulnerable to extinction.

Source: CBD (Center for Biological Diversity), The extinction crisis, http://www.biologicaldiversity.org/programs/biodiversity/elements_of_biodiversity/extinction_crisis/, 2015; Center for Biological Diversity, The extinction crisis, http://www.biologicaldiversity.org/programs/biodiversity/elements_of_biodiversity/extinction_crisis/, 2016.

of many species on planet Earth. Diminished biodiversity shrinks ecosystems and they in turn reduce humankind's well-being due to loss of such essentials as food, fiber, and predators. Predators are beneficial to humans by keeping in check many other species that can do harm to humans' existence. Anthropogenic activities are the root cause of endangerment of species endangered. Habitat loss is a prime factor in placing species at risk of extinction. Additionally, climate change has begun to emerge as another risk factor for species survival. While there are no simple, easy solutions to slowing or preventing the elimination of species at risk of disappearance, implementation of species-protective environmental policies are essential.

As characterized by the Center for Biodiversity, our planet is now in the midst of its sixth mass extinction of plants and animals in the past half-billion years. Our planet is currently experiencing the worst spate of species die-offs since the loss of the dinosaurs 65 million years ago [1].

16.3 THE IMPORTANCE OF BIODIVERSITY

The European Commission states, "Biological diversity, or biodiversity, is the scientific term for the variety of life on Earth. It refers not just to species but also to ecosystems and differences in genes within a single species. Everywhere on the planet, species live together and depend on one another. Every living thing, including man, is involved in these complex networks of interdependent relationships, which are called ecosystems.

Healthy ecosystems clean our water, purify our air, maintain our soil, regulate the climate, recycle nutrients and provide us with food. They provide raw materials and resources for medicines and other purposes. They are at the foundation of all civilisation and sustain our economies. It's that simple: we could not live without these 'ecosystem services.' They are what we call our natural capital.

Biodiversity is the key indicator of the health of an ecosystem. A wide variety of species will cope better with threats than a limited number of them in large populations. Even if certain species are affected by pollution, climate change or human activities, the ecosystem as a whole may adapt and survive. But the extinction of a species may have unforeseen impacts, sometimes snowballing into the destruction of entire ecosystems" [2].

As a matter of environmental policymaking, protection of endangered species is important for promoting biodiversity globally. Given this assertion, why is biodiversity so important and why conserve it? Amongst several sources, one source, Green-Schools Ireland, provides a well-organized survey of the importance of global biodiversity [3].

"Ecosystems and their species perform important biological services, for example, green plants remove carbon dioxide and release oxygen into the atmosphere, which helps keep the environment healthy and fit for human life. Although we still have much to learn about the often complex function of ecosystems, and about which species perform critical roles, we know that if an ecosystem is altered in any way, it might not be able to perform some of its important services. Economic arguments also provide compelling reasons for conserving species. Different species of plants, animals, fungi and micro-organisms provide us with food, medicines, fuel, building materials, fiber for clothing, and industrial products."

16.3.1 Biological Services Performed by Ecosystems

Ecosystems provide many services and give many societal benefits that include the following areas [3]:

Protecting areas from soil erosion, floods, and other harmful weather conditions: Woodlands and hedges provide useful windbreaks in farm areas, and the vegetation on mudflats and sand dunes can help protect coastal areas from erosion by the sea and wind.

Reducing the risk of local and global climate change: Ecosystems help maintain a healthy balance of gasses in the atmosphere. Trees and other plants store carbon and help prevent the buildup of carbon dioxide in the atmosphere, reducing the risk of global warming.

Recycling nutrients: Bacteria and fungi play a crucial role in recycling nutrients in ecosystems. Some plants play a crucial role in the fixation of nitrogen in the soil. Nitrogen fixation is the process of converting atmospheric nitrogen into ammonia.

Pollination and biological control: Some animals, especially birds, bats, and insects perform important functions as pollinators of food plants such as vegetables and fruit, and are also often the natural enemies of weeds, pests, and diseases that can harm crops.

Controlling pollutants: Plants like reeds act as natural filters, helping to remove waste from surface waters and many bacteria can help break down low-level pollutants.

Monitoring the health of the environment: Some species can indicate a change in the environment. For example, the breeding failure among birds of prey can point to a buildup of pesticides in the system. Lichens such as those found growing on school walls and on the trees may be sensitive indicators of levels of air pollution.

No group of animals has a higher rate of endangerment than amphibians. Scientists estimate that a third or more of all the roughly 6300 known species of amphibians are at risk of extinction. Frogs, toads, and salamanders are disappearing because of habitat loss, water and air pollution, climate change, ultraviolet light exposure, introduced exotic species, and disease [1].

16.3.2 Economic Values

Cultural and aesthetic values: Historically, some species have played an important role in the folklore and traditions of many cultures. Species may also have heritage value as

national symbols: for example, in Ireland, the three leafed clover (*Trifolium*) symbolizes the nation's identity and heritage. Biodiversity also has important recreational and aesthetic values. Biodiversity also has educational and inspirational value [3].

16.3.3 Intrinsic Values

For example, knowing that something exists is satisfying in itself, and the loss of a charismatic species, such as giant pandas and blue whales, represents a considerable loss of "existence value." However, it is impossible to quantify and, unfortunately, many species, such as slugs and slime molds, will never enjoy "existence value." "Many people also hold strong personal beliefs, feeling a great respect for the whole of nature and a responsibility to hand on to the next generation a world that is as rich in life as the world we live in today" [3].

16.4 U.S. AND GLOBAL POLICIES ON ENDANGERED SPECIES AND BIODIVERSITY

Beginning in the mid-twentieth century, awareness began to surface of the importance of protecting species facing marked reductions in their numbers. Conservations and NGO environmental groups commenced bringing pressure on policymakers to develop policies to protect endangered species. Gradually, this pressure yielded national legislation and global agreements on protection of endangered species and the importance of biodiversity. The U.S. Congress enacted legislation in 1972 and 1973. On a global scale, an assembly in 1973 of 80 nations commenced actions on a treaty to control international trade in endangered animals and fauna. These seminal actions are described herein. As will be described, although the number is considerable of animals and plants considered to be endangered or threatened of extinction, successes exist such as saving the American bald eagle, the U.S. national bird, from extinction (Figure 16.2).

FIGURE 16.2 American bald eagle in flight. (From USFWS (U.S. Fish and Wildlife Service), Listed species summary. Division of Conservation and Classification, Washington, DC, 2016.)

16.4.1 Marine Mammal Protection Act, 1972

The Marine Mammal Protection Act (MMPAct) was enacted by the U.S. Congress on October 1, 1972. This was the first Congressional act to call specifically for an ecosystem approach to natural resource management and conservation. From the Act, "The purpose of this legislation is to prohibit the harassing, catching and killing of marine mammals by U.S. citizens or within the jurisdiction of the United States, unless taken under the authority of a permit issued by an agency of the Executive Branch. The bill would also create an independent Commission to review the operation of the program and to recommend ways in which it might be improved" [4].

As overview, all marine mammals are protected under the MMPA. The MMPA prohibits, with certain exceptions, the "take" of marine mammals in U.S. waters and by U.S. citizens on the high seas, and the importation of marine mammals and marine mammal products into the U.S. Congress enacted the MMPAct based on the following findings and policies [4]:

- Some marine mammal species or stocks may be in danger of extinction or depletion as a result of human activities.
- These species or stocks must not be permitted to fall below their optimum sustainable population level ("depleted").
- Measures should be taken to replenish these species or stocks.
- There is inadequate knowledge of the ecology and population dynamics.
- Marine mammals have proven to be resources of great international significance.

The MMPAct was amended substantially in 1994 to provide

- Certain exceptions to the take prohibitions, including for small takes incidental to specified activities, when access by Alaska Natives to marine mammal subsistence resources can be preserved, and permits and authorizations for scientific research.
- A program to authorize and control the taking of marine mammals incidental to commercial fishing operations.
- Preparation of stock assessments for all.

As described subsequently, the NOAA Fisheries office of the National Oceanic and Atmospheric Administration has the lead responsibility for implementing and enforcing the MMPAct.

16.4.2 U.S. Endangered Species Act, 1973

The U.S. Congress passed the U.S. Endangered Species Act (ESAct) in 1966, thereby providing a means for listing native animal species as endangered and giving them limited protection. The Departments of Interior, Agriculture, and Defense were to seek to protect listed species, and, insofar

as consistent with their primary purposes, preserve the habitats of such species. The act also authorized the U.S. federal government to acquire land as habitat for endangered species. In 1969, Congress amended the act to provide additional protection to species in danger of "worldwide extinction" by prohibiting their importation and subsequent sale in the U.S. This act called for an international meeting to adopt a convention to conserve endangered species.

The U.S. Congress passed the Endangered Species Act in 1966, thereby providing a means for listing native animal species as endangered and giving them limited protection. The act also authorized the U.S. federal government to acquire land as habitat for endangered species.

In 1973, a conference in Washington, DC, led 80 nations to sign the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), which monitors, and in some cases, restricts international commerce in plant and animal species believed to be harmed by trade. Later that year, vanishing animals, plants, and their ecosystems got a further assist when President Richard Nixon signed into law the ESAct of 1973, which gave strong protections to native species and established a federal listing system of officially "Threatened" and "Endangered" species. Congress enacted significant amendments in 1978, 1982, and 1988, while keeping the overall framework of the 1973 act essentially unchanged. The act's primary provisions are as follows [5]:

- Defined "endangered" and "threatened"
- Made plants and all invertebrates eligible for protection
- Applied broad "take" prohibitions to all endangered animal species and allowed the prohibitions to apply to threatened animal species by special regulation
- Required federal agencies to use their authorities to conserve listed species and consult on "may affect" actions
- Prohibited federal agencies from authorizing, funding, or carrying out any action that would jeopardize a listed species or destroy or modify its "critical habitat"
- Made matching funds available to states with cooperative agreements
- Provided funding authority for land acquisition for foreign species
- Implemented CITES protection in the U.S.

As stated by the U.S. Fish and Wildlife Service (FWS), "The purpose of the ESAct is to protect and recover imperiled species and the ecosystems upon which they depend. The Interior Department's U.S. Fish and Wildlife Service (FWS) and the Commerce Department's National Marine Fisheries Service (NMFS) administer the ESAct. The FWS has primary responsibility for terrestrial and freshwater organisms, while the responsibilities of NMFS are mainly marine wildlife such as whales and anadromous fish such as salmon" [5].

Under the ESAct, species may be listed as either endangered or threatened. 'Endangered' means a species is in danger of extinction throughout all or a significant portion of its range. 'Threatened' means a species is likely to become endangered within the foreseeable future. All species of plants and animals, except pest insects, are eligible for listing as endangered or threatened. For the purposes of the ESAct, Congress defined species to include subspecies, varieties, and, for vertebrates, distinct population segments.

The ESAct requires species to be listed as endangered or threatened solely on the basis of their biological status and threats to their existence. "When evaluating a species for listing, the FWS considers five factors: 1) damage to, or destruction of, a species' habitat; 2) overutilization of the species for commercial, recreational, scientific, or educational purposes; 3) disease or Bart Gamett/USFWS predation; 4) inadequacy of existing protection; and 5) other natural or manmade factors that affect the continued existence of the species. When one or more of these factors imperils the survival of a species, the FWS takes action to protect it. The Fish and Wildlife Service is required to base its listing decisions on the best scientific information available" [5]. As of January 2013, the FWS has listed 2054 species worldwide as endangered or threatened, of which 1436 occur in the U.S.

The future of the ESAct became a matter of political debate in 2017 through hearings held in February 2017 by the Senate's Environment and Public Works Committee. Testimony presented to the committee asserted that the ESAct impedes land management plans, housing development, and cattle grazing, particularly in Western U.S. states [5a]. Other testimony argued that species protection should be the responsibility of individual states, not the federal government.

16.4.3 Convention on International Trade in Endangered Species, 1973

In the early 1960s, international discussion began to focus on the rate at which the world's wild animals and plants were being threatened by unregulated international trade. The CITES was drafted as the result of a resolution adopted in 1963 at a meeting of the International Union for the Conservation of Nature (IUCN) in Nairobi, Kenya. The text of the Convention was agreed upon at a meeting of representatives of 80 countries in Washington, DC, on March 3, 1973. CITES entered into force on July 1, 1975. For many years, CITES has been among the conservation agreements with the largest membership, with now 182 Parties.

CITES is an international agreement to which States (countries) adhere voluntarily. States that have agreed to be bound by the Convention ("joined" CITES) are known as Parties. Although CITES is legally binding on the Parties, it does not take the place of national laws. Rather, it provides a framework to be respected by each Party, which has to adopt its own domestic legislation to ensure that CITES is implemented at the national level.

As noted by CITES, "Widespread information nowadays about the endangered status of many prominent species, such

as the tiger and elephants, might make the need for such a convention seem obvious. But at the time when the ideas for CITES were first formed, in the 1960s, international discussion of the regulation of wildlife trade for conservation purposes was something relatively new. With hindsight, the need for CITES is clear. Annually, international wildlife trade is estimated to be worth billions of dollars and to include hundreds of millions of plant and animal specimens. The trade is diverse, ranging from live animals and plants to a vast array of wildlife products derived from them, including food products, exotic leather goods, wooden musical instruments, timber, tourist curios and medicines. Levels of exploitation of some animal and plant species are high and the trade in them, together with other factors, such as habitat loss, is capable of heavily depleting their populations and even bringing some species close to extinction. Many wildlife species in trade are not endangered, but the existence of an agreement to ensure the sustainability of the trade is important in order to safeguard these resources for the future" [6].

CITES works by subjecting international trade in specimens of selected species to certain controls. All import, export, re-export, and introduction from the spectrum of species covered by the Convention has to be authorized through a licensing system. Each Party to the Convention must designate one or more management authorities in charge of administering that licensing system and one or more scientific authorities to advise them on the effects of trade on the status of the species. Today, it accords varying degrees of protection to more than 35,000 species of animals and plants, whether they are traded as live specimens, fur coats, ivory tusks, or dried herbs.

16.4.4 EU Directives on Species and Biodiversity

The EU has adopted several laws for protection of nature and biodiversity. The two most prominent and sweeping laws are the Birds Directive of April 1979 and the Habitat Directive of 1992. The Birds Directive provides comprehensive protection to all wild bird species naturally occurring in the EU. The Habitats Directive was adopted in 1992 to help maintain biodiversity. It protects more than 1000 animals and plant species and more than 200 types of habitat. It also established the EU-wide Natura 2000 network of protected areas. In 2010 the EU adopted its Biodiversity Strategy to 2020, which commits the Member States to protect native biodiversity and ecosystem services against invasive alien species. Each of these actions by the EU are described herein.

The EU has adopted several laws for protection of nature and biodiversity. The two most prominent and sweeping laws are the Birds Directive of April 1979 and the Habitat Directive of 1992.

16.4.4.1 EU Birds Directive, 1979

As stated by the European Commission, "Europe is home to more than 500 wild bird species. But at least 32% of the EU's bird species are currently not in a good conservation status. The Birds Directive aims to protect all of the 500 wild bird species naturally occurring in the EU. Often migratory, wild bird species can only be protected by cooperating across borders. Urban sprawl and transport networks have fragmented and reduced their habitats, intensive agriculture, forestry, fisheries and the use of pesticides have diminished their food supplies, and hunting needed to be regulated in order not to damage populations. Concerned with their decline, Member States unanimously adopted the Directive 79/409/EEC in April 1979. It is the oldest piece of EU legislation on the environment and one of its cornerstones. Amended in 2009, it became Directive 2009/147/EC" [7].

Habitat loss and degradation are the most serious threats to the conservation of wild birds. The Directive therefore places great emphasis on the protection of habitats for endangered and migratory species. It establishes a network of Special Protection Areas (SPAs) including all the most suitable territories for these species. Since 1994, all SPAs are included in the Natura 2000 ecological network, set up under the Habitats Directive 92/43/EEC.

Under the provision of the Birds Directive, as amended, the 500 wild bird species naturally occurring in the EU are protected in various ways, as stipulated in the following annexes:

- "Annex 1: 194 species and subspecies are particularly threatened. Member States must designate SPAs for their survival and all migratory bird species.
- Annex 2: 82 bird species can be hunted. However, the hunting periods are limited and hunting is forbidden when birds are at their most vulnerable: during their return migration to nesting areas, reproduction, and the raising of their chicks.
- Annex 3: overall, activities that directly threaten birds, such as their deliberate killing, capture or trade, or the destruction of their nests, are banned. With certain restrictions, Member States can allow some of these activities for 26 species listed here.
- Annex 4: the directive provides for the sustainable management of hunting but Member States must outlaw all forms of nonselective and large scale killing of birds, especially the methods listed in this annex.
- Annex 5: the directive promotes research to underpin the protection, management and use of all species of birds covered by the Directive, which are listed in this annex" [7].

All Member States have to submit reports on the status and trend in bird populations as well as on derogations they may apply to the directive's obligations. In addition, the European Commission provides guidance on hunting practices, some of the key concepts of the Birds Directive and on the sustainable management of cormorant populations. The EU first sustainable hunting initiative was launched in 2001. The Commission also aims to eradicate the illegal killing, trapping, and trade of birds in the EU.

16.4.4.2 The Habitats Directive, 1992

The Habitats Directive ensures the conservation of a wide range of rare, threatened, or endemic animal and plant species. Some 200 rare and characteristic habitat types are also targeted for conservation in their own right. Adopted in 1992, the Council Directive 92/43/EEC of May 21, 1992, on the conservation of natural habitats and of wild fauna and flora aims to promote the maintenance of biodiversity, taking account of economic, social, cultural, and regional requirements [7a]. It forms the cornerstone of Europe's nature conservation policy with the Birds Directive and establishes the EU wide Natura 2000 ecological network of protected areas, safeguarded against potentially damaging developments.

The Birds and Habitats Directives have had to evolve to reflect successive enlargements of the EU. All in all, more than 1000 animal and plant species, as well as 200 habitat types, are listed in the directive's annexes and are protected in various ways:

- "Annex I concerns the natural habitat types of community interest whose conservation requires the designation of special areas of conservation.
- Annex II species (approximately 900): core areas of their habitat are designated as Sites of Community importance (SCIs) and included in the Natura 2000 network. These sites must be managed in accordance with the ecological needs of the species.
- Annex IV species (more than 400, including many annex II species): a strict protection regime must be applied across their entire natural range within the EU, both within and outside Natura 2000 sites.
- Annex V species (more than 90): Member States must ensure that their exploitation and taking in the wild is compatible with maintaining them in a favorable conservation status" [7a].

The European Commission has published guidance on species protection to help Member States implement correctly the directive's provisions. EU Species Action Plans are developed to restore the populations of certain species across their range within the EU. The European Commission also promotes the conservation of Europe's five species of large carnivores and supports the European Red Lists of Threatened Species, developed by the IUCN to provide an overview of the conservation status of approximately 6000 European species so that appropriate action can be taken to protect those threatened with extinction.

Of note, a study of the IUCN Red List of Threatened Species reported alleges the list has misclassified the threats to hundreds of animals, and as a result, conservation groups may be missing numerous species at risk of disappearing. The study's investigators state that the IUCN's criteria for assessing species are outdated and relies on old maps drawn by experts for its habitat data, and has not incorporated satellite and aerial imaging to better detect deforestation and encroaching human settlement [8]. The IUCN takes issue with the findings of the study.

16.4.4.3 The North American Bird Conservation Initiative, 1999

The EU Birds Directive of 1979 has no equal U.S. law, with bird species being protected under the Environmental Species Act of 1973. However, the North American Bird Conservation Initiative of 1999 addresses some of the issues of endangered birds in North America. Efforts to protect the birds of North American commenced during the global chaos of World War I when U.S. President Woodrow Wilson and Great Britain's King George V pledged an international commitment to protect the migratory birds of North America and put an end to market hunting of birds. Crafted in 1916, the Convention for the Protection of Migratory Birds promised collaborative conservation between the U.S. and Canada [8a]. Twenty years later, with his country in the aftermath of revolution, Mexican President Lázaro Cárdenas approved a treaty with the U.S. that protected migratory birds. Despite political unrest and competing economic priorities, the three nations joined together for birds to create some of the first international environmental agreements in North America.

In the late twentieth century, with duck populations in decline, the three nations of North America united again to build the North American Waterfowl Management Plan of 1986. With planning and wetlands conservation, ducks became more plentiful. The Plan remains in effect as an international trinational program [9]. An outgrowth of the Plan was the establishment of the North America Bird Conservation Initiative (NABCI). The launch of the Initiative began as an innovative resolution for the conservation of all birds in all habitats in North America. The resolution approved a strategy and action plan, which set forth preliminary goals, objectives and actions for the conservation of all birds of North America, and committed the three signatories (Canada, Mexico, and the U.S.) to creating National Steering Committees to guide the Initiative [8a]. In 2005, the three signatory countries signed the NABCI Declaration of Intent (DOI) to strengthen cooperation on bird conservation. The DOI is a means of increasing the profile and recognition of these partnerships and affirms the international importance of the NABCI.

The first of its kind to examine the vulnerability of bird populations in North America found that 37% of all 1154 species on the continent needed urgent conservation action [9].

One of the NABCI's efforts is to survey the state of bird populations across North America. A recent study completed under the auspices of NABCI was the first of its kind to examine the vulnerability of bird populations in Canada, Mexico, and the U.S. [9]. The study found that 37% of all 1154 species on the North American continent needed urgent conservation action. More than half the species for oceans and tropical forests are on a special NABCI watch list because of small and declining populations, limited ranges, and severe threats to their habitats. Many species in coastal, grassland, and arid habitats are declining steeply, in particular long-distance

migratory shore birds. The main causes are sea-level rise, coastal development, human activity, and oil spills, the report said.

The outlook for oceanic birds was the bleakest of any North American bird group, attributed to the presence of invasive predators such as rats and cats on nesting islands as well as overfishing, pollution, and climate change. The report suggested ways to address the threat to the continent's oceanic birds include removing predators, expanding protected marine areas, and reducing the amount of plastic products that end up in the ocean and can trap or choke birds.

In a separate study of North American bird populations, Partners in Flight, a coalition of North American public and private organizations with the common goal of protecting bird populations, found that North American bird populations have decreased by 1.5 billion birds [10]. The study was conducted via a survey of dozens of government, university and environmental agencies across North America. The report also listed 86 species of birds that are threatened by plummeting populations, habitat destruction, and climate change. For example, Evening grosbeaks have been down 92% since 1970. Snowy owls have lost 64% of their numbers, and The Canada warbler has lost 63% of its population. Nor are the declines stopping. Among those 86 species, 22 have already lost at least half of their population since 1970 and are projected to lose another 50% of their numbers within the next 40 years.

The study attributes diminished bird populations to factors such as: Agricultural disturbance of habitats of grassland birds and the introduction of pesticides into the landscape; logging fragmenting the intact forests birds use as refueling stations as they migrate; and domestic cats, which are thought to kill more than two billion birds a year. The report also notes that birds are crucial indicators of overall ecosystem health. Healthy forests and prairies need healthy bird populations.

16.4.4.4 Natura 2000

Natura 2000 is a network of sites within the EU that were selected to ensure the long-term survival of Europe's most valuable and threatened species and habitats.

Natura 2000 is a network of core breeding and resting sites for rare and threatened species, and some rare natural habitat types that are protected in their own right [11]. Natura 2000 is not a system of strict nature reserves from which all human activities are excluded. Rather, Natura 2000 is a network of sites within the EU that were selected to ensure the long-term survival of Europe's most valuable and threatened species and habitats. How a site is chosen depends on what it aims to protect. The Natura 2000 network stems from the Habitats Directive. Member States choose sites according to precise, scientific criteria, but the selection procedure varies depending on which of the two nature directives—Birds or Habitats—warrants the creation of a particular site. "Under the Habitats Directive, Member States designate Special Areas of Conservation (SACs) to ensure the favourable conservation status of each habitat type and species throughout their range in the EU. Under the Birds Directive, the network must include Special Protection Areas (SPAs) designated for 194 particularly threatened species and all migratory bird species.

Under the Birds Directive Member States designate Special Protection Areas (SPAs) according to scientific criteria such as '1% of the population of listed vulnerable species' or 'wetlands of international importance for migratory waterfowl.' While Member States may choose the most appropriate criteria, they must ensure that all the 'most suitable territories,' both in number and surface area, are designated. Site specific data are transmitted to the Commission using Standard Data Forms.

Based on the information provided by the Member States, the European Commission determines if the designated sites are sufficient to form a coherent network for the protection of these vulnerable and migratory species. These sites then become an integral part of the Natura 2000 network.

Under the Habitats Directive the choice of sites is based on scientific criteria specified in the directive, to ensure that the natural habitat types listed in the directive's Annex I and the habitats of the species listed in its Annex II are maintained or, where appropriate, restored to a favourable conservation status in their natural range. Member States first carry out comprehensive assessments of each of the habitat types and species present on their territory. They then submit lists of proposed Sites of Community Importance (pSCIs). Site specific data are transmitted to the Commission using Standard Data Forms and must include information such as the size and location of the site as well as the types of species and/or habitat found on this site and warranting its selection.

Based on the proposals provided by the Member States, scientific seminars are convened for each biogeographical region. With the support of the European Environment Agency, these expert biogeographical seminars aim to determine whether sufficient high-quality sites have been proposed by each Member State. Once the lists of Sites of Community Importance (SCIs) have been adopted, Member States must designate them as Special Areas of Conservation (SACs), as soon as possible and within six years at most. They should give priority to those sites that are most threatened and/or most important for conservation and take the necessary management or restoration measures to ensure the favourable conservation status of sites during this period.

The Commission updates the Union SCI Lists every year to ensure that any new sites proposed by Member States have a legal status" [11].

16.4.4.5 EU Biodiversity Strategy

The EU Biodiversity Strategy aims to halt the loss of biodiversity and ecosystem services in the EU and help stop global biodiversity loss by 2020. It reflects the commitments taken by the EU in 2010, within the international Convention on Biological Diversity. In 2011, the EU adopted a strategy setting out six targets and 20 actions to halt the loss of biodiversity and ecosystem services in the EU by 2020. The six targets are as follows and the 20 companion actions are available elsewhere [2]:

- *Target 1—Protect species and habitats*: By 2020, the assessments of species and habitats protected by EU nature law show better conservation or a secure status for 100% more habitats and 50% more species.
- *Target 2—Maintain and restore ecosystems*: By 2020, ecosystems and their services are maintained and enhanced by establishing green infrastructure and restoring at least 15% of degraded ecosystems.
- *Target 3—Achieve more sustainable agriculture and forestry*: By 2020, the conservation of species and habitats depending on or affected by agriculture and forestry, and the provision of their ecosystem services show measurable improvements.
- *Target 4—Make fishing more sustainable and seas healthier*: By 2015, fishing is sustainable. By 2020, fish stocks are healthy and European seas healthier. Fishing has no significant adverse impacts on species and ecosystems.
- *Target 5—Combat invasive alien species*: By 2020, invasive alien species are identified, priority species controlled or eradicated, and pathways managed to prevent new invasive species from disrupting European biodiversity.
- *Target 6—Help stop the loss of global biodiversity*: By 2020, the EU has stepped up its contribution to avert global biodiversity loss.

Perspective: The EU has taken several affirmative actions to protect biodiversity and species diminution. The EU directives on birds and habitats are central to the EU strategy of species and biodiversity protection. Of note are the two more recent EU policies on biodiversity and habitat protection. Natura 2000 is a network of sites within the EU that were selected to ensure the long-term survival of Europe's most valuable and threatened species and habitats. This network of protected sites is the largest such protectorate in the world. Similarly, the EU biodiversity strategy, with targets set for 2020, is a globally unique policy.

16.4.5 Australia's Environment Protection and Biodiversity Conservation Act, 1999

Australia is globally unique as an island, country, and continent. As a relatively young island continent, Australia can claim a wide spectrum of many unique animals and plants. It is home to between 600,000 and 700,000 species, many of which are endangered or threatened. The Environment Protection and Biodiversity Conservation Act 1999 (the EPBC Act) is the Australian Government's central piece of environmental legislation [12]. It provides a legal framework to protect and manage nationally and internationally important flora, fauna, ecological communities, and heritage places—defined in the EPBC Act as matters of national environmental significance.

Australia's Environmental Protection and Biodiversity Conservation Act enables the Australian Government to join with the country's states and territories to provide a national scheme of environment and heritage protection and biodiversity conservation [12].

The EPBC Act is the Australian Government's key piece of environmental legislation, which commenced July 16, 2000. The EPBC Act enables the Australian Government to join with the country's states and territories to provide a national scheme of environment and heritage protection and biodiversity conservation. The EPBC Act focuses Australian Government interests on the protection of matters of national environmental significance, with the states and territories having responsibility for matters of state and local significance. "The objectives of the EPBC Act are to:

- Provide for the protection of the environment, especially matters of national environmental significance
- Conserve Australian biodiversity
- Provide a streamlined national environmental assessment and approvals process
- Enhance the protection and management of important natural and cultural places
- Control the international movement of plants and animals (wildlife), wildlife specimens and products made or derived from wildlife
- Promote ecologically sustainable development through the conservation and ecologically sustainable use of natural resources
- Recognise the role of Indigenous people in the conservation and ecologically sustainable use of Australia's biodiversity
- Promote the use of Indigenous peoples' knowledge of biodiversity with the involvement of, and in cooperation with, the owners of the knowledge" [12].

Amendments to the EPBC Act became law on June 22, 2013, making water resources a matter of national environmental significance, in relation to coal seam gas and large coal mining development. The EPBC Act, as amended, provides for the listing of nationally threatened native species and ecological communities, native migratory species, and marine species. The EPBC Act protects Australia's native species and ecological communities by providing for:

- Identification and listing of species and ecological communities as threatened
- Development of conservation advice and recovery plans for listed species and ecological communities
- Development of a register of critical habitat
- Recognition of key threatening processes
- Where appropriate, reducing the impacts of these processes through threat abatement plans [12].

16.4.6 Convention on Biological Diversity

An increasing concern for loss of global biodiversity led UNEP to convene the Ad Hoc Working Group of Experts on

Biological Diversity in November 1988 to explore the need for an. international convention on biological diversity. The work of subsequent ad hoc groups culminated on May 22, 1992, with the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity. The Convention was opened for signature on June 5, 1992, at the United Nations Conference on Environment and Development (the Rio "Earth Summit"). It remained open for signature until June 4, 1993, by which time it had received 168 signatures. The Convention entered into force on December 29, 1993, which was 90 days after the 30th ratification [13]. In June 1993, U.S. President Clinton signed the CBD on behalf of the U.S. However, the U.S. Senate has never ratified the Convention as an international treaty, resulting in the U.S. becoming a non-party to the Convention.

The Convention on Biological Diversity was inspired by the world community's growing commitment to sustainable development. It represents a dramatic step forward in the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the use of genetic resources.

At the tenth meeting of the Conference of the Parties, held from October 18 to 29, 2010, in Nagoya, Aichi Prefecture, Japan, and the Parties adopted a revised and updated Strategic Plan for Biodiversity, including the Aichi Biodiversity Targets, for the 2011–2020 period. Some illustrative goals in the Strategic Plan include the following: (1) At least halve and, where feasible, bring close to zero the rate of loss of natural habitats, including forests; (2) establish a conservation target of 17% of terrestrial and inland water areas and 10% of marine and coastal areas; (3) restore at least 15% of degraded areas through conservation and restoration activities; and (4) make special efforts to reduce the pressures faced by coral reefs [14].

16.5 CURRENT U.S. ENDANGERED SPECIES PRACTICES AND ISSUES

The U.S. Fish and Wildlife Services (US FWS) and the NOAA Fisheries are the two primary U.S. agencies responsible for protection of endangered species under the ESAct, as amended, and the MMPAct, respectively. Other federal agencies also have satellite responsibilities under the ESAct, as will be subsequently described. How these two primary agencies perform their responsibilities are important to understand. Moreover, as with other U.S. environmental statutes, the agencies' actions on specific matters of endangered species and loss of biodiversity in ecosystems is sometimes a matter of litigation or legislative challenge, as described subsequently.

16.5.1 U.S. Fish and Wildlife Service

The US FWS an agency within the U.S. Department of Interior, is one of two federal partners responsible for administering the ESAct. The agency's two major goals are to (1) protect endangered and threatened species, and then pursue their recovery; and (2) conserve candidate species and species at risk so that listing under the ESAct is not necessary. Under the ESAct, the FWS's endangered species responsibilities include the following [14a]:

- Listing, reclassifying, and delisting under the ESAct
- Providing information and biological opinions (through the Project Reviews process), to federal agencies on their activities that may affect listed species
- Enforcing species protection under the Act
- Overseeing recovery activities for listed species
- Providing for the protection of important habitat
- Providing assistance to States and others to assist with their endangered species conservation efforts

Under the ESAct, species may be listed as either endangered or threatened. "Endangered" means a species is in danger of extinction throughout all or a significant portion of its range. "Threatened" means a species is likely to become endangered within the foreseeable future. All species of plants and animals, except pest insects, are eligible for listing as endangered or threatened. For the purposes of the ESAct, Congress defined species to include subspecies, varieties, and, for vertebrates, distinct population segments.

When deciding whether a species should be added to the Endangered Species List, the following criteria are evaluated:

- "Has a large percentage of the species vital habitat been degraded or destroyed?
- Has the species been overconsumed by commercial, recreational, scientific, or educational uses?
- Is the species threatened by disease or predation?
- Do current regulations or legislations inadequately protect the species?
- Are there other man-made factors that threaten the long-term survival of the species?" [14b].

If scientific research reveals that the answer to one or more of the above questions is yes, then the species can be listed under the ESAct. The listing is conducted through announcements in the *Federal Register* and other means of engaging the public, inviting review and comment. Correspondingly, species can be removed from the list of endangered or threatened species if data analysis dictates. Shown in Table 16.2 are the numbers of animals (1227) and plants (367) in the U.S. that are listed by the US FWS as endangered or threatened. As indicated in the table, amphibians are at special risk of endangerment. Also shown in the table are foreign species, found only in areas outside the U.S. and U.S. waters.

To delist or down list species, the USFWS follow a process similar to what is used in considering whether to list species. The agency assesses populations and recovery achievements in eliminating or reducing threats, and seeks advice via peer-review. In assessing threats, the USFWS review five factors: (1) Is there a present or threatened destruction, modification,

TABLE 16.2
Numbers of Endangered or Threatened Animals and Plants

	The United States		World	
	Endangered	**Threatened**	**Endangered**	**Threatened**
Animals	497	201	698	586
Plants	732	166	898	1
Subtotals	1227	367	1596	587
Totals	1594		2183	

Source: CBD (Center for Biological Diversity), The extinction crisis, http://www.biologicaldiversity.org/programs/biodiversity/elements_of_biodiversity/extinction_crisis/, 2015.

or curtailment of the species' habitat or range? (2) Is the species subject to over-utilization for commercial, recreational, scientific, or educational purposes? (3) Is disease or predation a factor? (4) Are there adequate existing regulatory mechanisms in place, taking into account the initiatives by States and other organizations, to protect the species or habitat? and (5) Are other natural or manmade factors affecting its continued existence? [15].

* * *

Administration of the ESAct has engendered some praise from environmental and similar advocacy groups as well as criticism from business interests. Wildlife NGOs have commented in support of the removal of some species from the endangered or threatened list. Business organizations have alleged that the law impedes economic development. The Defenders of Wildlife conducted a study of extent of intervention by the US FWS in administered its ESAct responsibilities [16]. The study analyzed more than 88,000 proposed projects assessed by the US FWS between January 2008 and April 2015 and found that the agency concluded that only two (0.002%) of them warranted further action. In contrast, an analysis from 1991 found 350 such judgments out of 73,560 previous consultations.

The study's investigators noted that under §7 of the ESAct, all federal agencies must hold a consultation with the wildlife service or the National Marine Fisheries Service to ensure that any project the agencies fund, authorize, or carry out is unlikely to "jeopardize" an endangered species or "destroy or adversely modify" critical habitat. The study noted that unlike during previous decades, no project had been stopped or extensively altered as a result of FWS concluding jeopardy or destruction/adverse modification of critical habitat.

Discontent by business groups over the ESAct has resulted in legislative attempts in the U.S. Congress to change the current law. Some of the bills presented in 2016 attempted to protect specific economic interests. For instance, the Federal Land Freedom Act of 2015 would transfer oil and gas development from federal to state control and thereby make it exempt from the provisions of the ESAct. Another bill, the Endangered Species Management Self-Determination Act, would require congressional approval for a new species listing and automatic removal of protections for listed species after 5 years—about 20 fewer years than the average time needed for a species to recover. Many of these recent bills call for reforms that would transfer greater authority to states and reduce opportunities for public and environmental groups to sue the government for failure to act on a listing request [18].

The Obama administration reshaped the ESAct in a series of executive reforms [19]. Of special note, the administration shifted course on how the law is applied, utilizing incentives over regulations to coax industry and private landowners to save vanishing habitats. One major change is the administration's increased use of special rules that allow people to incidentally kill or harm listed species if they commit to certain conservation practices. The Obama administration has issued more of these so-called 4(d) rules than under any president other than the Gerald Ford administration. Such policies have drawn plaudits from land users and scrutiny from conservation groups. One of the administration's biggest mark on ESAct is its 2011 settlement with green groups that required final listing decisions on roughly 250 candidate species, which has resulted in scores of species being added to the list of threatened and endangered wildlife.

In 2014 the US FWS and the National Marine Fisheries Service released a suite of proposed changes in how they designate and protect critical habitat, the lands that are deemed essential to a listed species' conservation and recovery. It included a policy to exclude from critical habitat those private lands where landowners have committed to voluntary conservation measures. The policy intends to stimulate conservation actions that otherwise would not occur, while reducing the amount of land that must be designated as critical habitat. Landowners typically oppose such designations, fearing that the restrictive label will reduce property value [19].

The two agencies' critical habitat package also contained a controversial proposal to redefine what constitutes "destruction or adverse modification" of critical habitat, a key test for whether federally funded or permitted projects may be approved. The agencies have also finalized a rule dictating when and how they calculate the costs of setting aside critical habitat for endangered and threatened wildlife. In a noncontroversial move, the rule requires that the agencies to provide an analysis of the costs of designating habitat at the same time

that such designations are proposed, rather than months or years afterward.

In 2014 the Obama administration finalized a controversial policy that dictates when a species is granted federal protection and, if so, where. The rule change elaborated on how to determine if a species is in danger of extinction "throughout all or a significant portion of its range," a key, albeit oft-debated, phrase in the ESAct. The services concluded that "a portion of the range of a species is 'significant' if the species is not currently endangered or threatened throughout all of its range, but the portion's contribution to the viability of the species is so important that, without the members in that portion, the species would be in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range" [19].

The policy of seeking more voluntary agreements on critical habitat protection rather than sole reliance on regulatory action under the ESAct and similar U.S. state statutes has led to a philosophical kerfuffle within some conservation groups. Some environmentalists argue that for conservation to succeed, [...] "it must work on a larger scale, focusing not on preserving single species in small islands of wilderness but on large landscapes and entire ecosystems, and the benefits that nature provides to humans. Conservation efforts, according to this view, will be more effective if they accept humans as a part of nature and come to terms with the fact that they have irrevocably altered the landscape. And instead of seeing landowners and leaseholders, who control the vast majority of the land where endangered species live, as enemies, many conservationists believe it makes more sense to enlist them as partners, convincing them that conservation is in their interests" [20]. This new view, sometimes referred to as "eco-pragmatism," is already accepted by some conservation organizations and as such, shaping endangered species policies within some public agencies and NGOs.

16.5.2 National Marine Fisheries Service

The second of two federal agencies with responsibilities for protecting endangered species is NOAA Fisheries, also known as the National Marine Fisheries Service (NMFS). This agency is an office of NOAA within the Department of Commerce [21]. NOAA's Office of Protected Resources is responsible to conserve, protect, and recover species under the ESAct and the MMPAct.

NOAA Fisheries works with the US FWS to manage ESAct-listed species. Generally, NOAA Fisheries manages marine species, while the USFWS manages land and freshwater species. The endangered and threatened species under NOAA Fisheries jurisdiction comprise: marine mammals, sea turtles and other marine reptiles, fish (marine and anadromous), and marine invertebrates and plants. Marine mammals are mammals that are well adapted for life in the marine environment. Two major groups of marine mammals are: Cetaceans (dolphins, porpoises, whales) and Pinnipeds (seals, sea lions, walruses [under jurisdiction of the FWS]).

Approximately 125 marine mammals worldwide are protected under the MMPA. Most are under Fisheries' jurisdiction, but eight species are under the jurisdiction of the USFWS: walrus, polar bear, sea otter, marine otter, West African manatee, Amazonian manatee, West Indian manatee, and dugong. All marine mammals are protected under the MMPAct; some marine mammals may be designated as "depleted" under the MMPA. Endangered and threatened marine mammals are also protected under the ESAct. Stocks of marine mammals may also be considered "strategic" under the MMPA [21].

16.5.3 EPA's Responsibilities under the Endangered Species Act

The ESAct requires that all federal agencies ensure that any action they authorize, fund, or perform won't jeopardize the existence of listed species or "destroy or adversely modify" any designated critical habitat for that species. The EPA has an important responsibility under the ESAct. In particular, the agency must ensure that the use of pesticides is not likely to jeopardize listed species or destroy or adversely modify their critical habitat when we register pesticides.

The goal of the EPA's Endangered Species Protection Program (ESPP) is to conduct the EPA's responsibilities under FIFRA (Chapter 11) in compliance with the ESAct. Under FIFRA, the EPA is responsible for reviewing information and data to determine whether a pesticide product can be registered for a particular use. As part of that determination, the EPA determines if listed species or their designated critical habitat may be affected by use of the product. All pesticide products that EPA determines "may affect" a listed species or its designated critical habitat may be subject to EPA's ESPP.

The EPA established the ESPP in 1988 to meet its obligations under the ESAct. The original ESPP was not an enforceable program but relied on cooperation between the Services (i.e., FWS, NOAA Fisheries), EPA, states, tribes and pesticide users. At that time, the program provided geographically specific pesticide use limitations in the form of voluntary county bulletins in areas of concern based on Biological Opinions issued from the Services.

The EPA published on November 2, 2005, its final approach to field implementation of the ESPP. As stated in the final notice, when the EPA determines that use limitations are necessary to protect listed species, the agency will propose to make such limitations enforceable under FIFRA. When the EPA determines that use limitations are necessary to ensure that legal use of a pesticide will not harm listed species or their critical habitat, the agency may seek to change the terms of the pesticide registration to establish either generic or geographically specific pesticide use limitations.

16.6 SPECIES AT RISK OF ENDANGERMENT

Investigations of the loss of Earth's species all conclude that significant loss of species has occurred in the past and is continuing at a pace not previously experienced. In one report, a compilation of wildlife trends suggests that populations of some feral animals have fallen by half in the past 40 years, according to a report from the World Wildlife Fund (WWF) [22]. The WWF 2014 *Living Planet Report* gave an index that

tracks the numbers of animals in selected populations of vertebrates—mammals, birds, reptiles, amphibians, and fish—across the globe. This "Living Planet Index" declined by 52% between 1970 and 2010, "a much bigger decrease than has been reported previously," according to the report. The 52% figure refers to a general trend of vertebrate species populations shrinking, on average, to about half the size that they were 40 years ago, according to the WWF report, which attributes the declines primarily to habitat loss and degradation, hunting and fishing, and climate change. Though the new index received intense global media attention, establishing a broad trend for all animals is difficult—and controversial—because of the limited data on global wildlife populations [22].

The World Wide Fund for Nature reports the loss of almost half the world's marine mammals, birds, reptiles, and fish in a single generation [23].

A compilation of wildlife trends suggests that populations of some feral animals have fallen by half in the past 40 years, according to the World Wildlife Fund (WWF) [22].

In another report, a World Wide Fund for Nature report says humanity's mismanagement of the ocean has led to the loss of almost half the world's marine mammals, birds, reptiles, and fish in a single generation [23]. The emergency edition of *Living Blue Planet Report* revealed a 49% decline in marine vertebrate populations between 1970 and 2012. For some fish, this figure was almost 75%. For example, scombridae, the family that includes tunas, mackerels, and bonitos, suffered a 74% decline between 1970 and 2010. Overfishing, destruction of marine habitats, and climate change were factors associated with the declines of marine life. The report highlighted the impact of commercial fish stocks and the role the private sector must play in slowing rates of overfishing, suggesting that species essential to commercial fishing and global food supply were suffering the greatest declines [23].

Several investigations have been conducted in order to assess species at risk of threat or endangerment. A sample of the most significant investigations is provided in Table 16.3. A review of the table provides a picture of potential global loss of numerous species, including both animals and plants. Amphibians, birds, reptiles, marine life, and plants appear particularly at risk of endangerment.

TABLE 16.3
Selected Forecasts of Species Endangerment

Species	Forecast	Cause	Reference
Amphibians, global	41% of all amphibians on the planet now face extinction.	Spread of agriculture; rising temperature	[39]
Birds, Europe	Bird populations across Europe have decreased by more than 420 million in the past 30 years.	Agricultural intensification	[40]
Birds, Indonesia	Thirteen species of Indonesian birds, including the country's symbolic Javan hawk-eagle, are at serious risk of extinction.	Pet trade in birds	[41]
Birds, migratory, global	Migratory birds are declining at a fast rate—in some cases faster than resident species.	Lack of coordinated global conservation effort	[42]
Birds, North America	37% of all 1154 species on the continent needed urgent conservation action	Sea-level rise, coastal development, human activity, and oil spills	[43]
Butterfly, UK	Six species of UK butterflies were lost from several areas of the country as soon as the mid-century.	Climate change caused by carbon emissions from power stations and vehicles	[44]
Cod, New England	The Atlantic cod is on the brink of disappearing.	Ocean warming in the Gulf of Maine	[45]
Crocodile, global	As many as half of the world's 27 species of crocodilian face extinction.	Land use changes, pollution, culling, and feral animal invasions	[46]
Elephant, Mali	Mali's elephants, one of just two remaining desert herds in the world, face extinction.	Poaching	[47]
Frogs, global	Approximately 200 frog species have already gone extinct, and hundreds more may be on their way out.	A variety of factors could be at play, including habitat destruction and the devastating effects of a deadly fungus	[48]
Ocean life, global	There exists Unprecedented damage to the oceans and the animals living in them	Overharvesting, large-scale habitat loss	[49]
Plants, global	One in five plant species faces risk of extinction, according to the first report to assess global plant life.	Deforestation, agricultural and urban expansion	[50]
Reptiles, global	Nearly one in five of the world's estimated 10,000 species of reptiles are threatened with extinction.	The spread of farming and deforestation in tropical regions represents two of the greatest threats	[51]
Trees, Amazon	More than half the tree species in the Amazon could become extinct.	Mining, climate-related drought and fires, overharvesting	[52]

16.7 SUCCESSFUL RESCUES OF ENDANGERED SPECIES

Enforcement of the ESAct and the MMPAct, together with other actions by NGOs, zoos, some U.S. state agencies, and international authorities have resulted in several U.S. animals being saved from extinction. This includes the American alligator, whooping crane, bald eagle (Figure 16.2), peregrine falcon, grizzly bear, American gray wolf, Eastern red wolf, and the California condor [24]. Others saved include the brown pelican, American bison, Virginia flying squirrel, Steller sea lion, Aleutian Canada goose, Island night lizard, Lake Erie water snake, and gray wolf [25]. A global list includes the white rhino, great whales, Siberian tiger, Przewalski's horse, Brazil's golden monkey, China's giant panda, and the Chinese Tu Long alligator [ibid.], and the American eel [25a]. While this list is certainly incomplete, it does demonstrate that some efforts to save some animals from extinction have succeeded. Illustrated in Table 16.4 are examples of successful efforts to increase the numbers of selected species whose populations had decreased. These examples of birds, tigers, manatees, otters, butterflies, and fish represent the successful products of human interventions. Shown in Figure 16.3 is an Agattu Island, Steller Sea Lion bull, an animal whose numbers have rebounded from near extinction due to conservations efforts of the FWS.

A review by the U.S. Department of Interior reported that more species protected by the ESAct have recovered during President Barack Obama's administration than under all other presidents combined. During Obama's presidency, 19 species have now recovered and been delisted; this compares to seven such removals under George W. Bush, six during Bill Clinton's administration, and five under Ronald Reagan [26].

16.8 ASSOCIATIONS BETWEEN ENDANGERED SPECIES AND HUMAN HEALTH

Put simply, reduced biodiversity means millions of people face a future where food supplies are more vulnerable to pests and disease, and where fresh water is in irregular or short supply.

FIGURE 16.3 Agattu Island, Steller Sea Lion bull. (From Anne E. Morkill, U.S. Fish and Wildlife Service, Fremont, CA, 2006.)

Humans harvest an estimated 50,000–70,000 plant species for traditional and modern medicine worldwide. About 100 million metric tonnes of aquatic life, including fish, mollusks, and crustaceans are taken from the wild every year. Meat from wild animals forms a critical contribution to food sources and livelihoods in many countries, especially those with high levels of poverty and food insecurity [27]. These consequences to human health and well-being will be made even direr due to the effects of climate change and increased global human population.

16.9 ASSOCIATIONS BETWEEN ENDANGERED SPECIES AND GLOBAL ECOSYSTEM HEALTH

A study group at the University of Michigan concluded: "Studies over the last two decades have demonstrated that more biologically diverse ecosystems are more productive. As a result, there has been growing concern that the very high rates of modern extinctions—due to habitat loss, overharvesting and other human-caused environmental changes—could reduce nature's ability to provide goods and

TABLE 16.4
Examples of Species Recovering from Reduced Numbers

Species	Outcome	References
Galápagos tortoise	Biologists hope to revive George's species and reintroduce the extinct tortoises to the island on which they evolved.	[31]
Groundfish	Environmentalists and fishermen worked together to revive a local fishery.	[32]
Herring	Herring are spawning in a tributary to New York's Hudson River for the first time in 85 years after a dam was removed.	[33]
Maltese falcon	There may be as many as three pairs of breeding peregrine falcons on the Maltese archipelago for the first time since the 1980s.	[34]
Manatees	Manatees increased from a low of about 1000 in 1973 to about 6200 in the last annual count.	[35]
Monarch butterfly	Monarch butterfly populations were up 255% in a reserve Mexico created for their protection.	[35]
River otters	Transplanted river otters are thriving in the state more than 60 years after they disappeared.	[36]
Tigers	For the first time in a century, the global wild tiger population has increased to 3890 tigers.	[37,38]

services like food, clean water and a stable climate. […] Loss of biodiversity appears to impact ecosystems as much as climate change, pollution and other major forms of environmental stress, according to the study from an international research team" [28].

The study was the first comprehensive effort to directly compare the impacts of biological diversity loss to the anticipated effects of a host of other human-caused environmental changes. The results highlighted the need for stronger local, national and international efforts to protect biodiversity and the benefits it provides.

Also, the IUCN notes that threats to biodiversity are numerous and anthropogenic activity is responsible for most of them.

- "Habitat loss and degradation affects 86% of all threatened birds, 86% of the threatened mammals assessed and 88% of the threatened amphibians.
- Introductions of Invasive Alien Species that establish and spread outside their normal distribution. Some of the most threatening invasive species include cats and rats, green crabs, zebra mussels, the African tulip tree and the brown tree snake. Introductions of alien species can happen deliberately or unintentionally, for example, by organisms "hitch-hiking" in containers, ships, cars or soil.
- Over-exploitation of natural resources. Resource extraction, hunting, and fishing for food, pets, and medicine.
- Pollution and diseases. For example, excessive fertilizer use leads to excessive levels of nutrients in soil and water.
- Human-induced climate change. For example, climate change is altering migratory species patterns, and increasing coral bleaching" [29].

Perspective: The associations between loss of biodiversity as related herein and the impact on human and ecosystem health are consequential. This loss portends threats to food security, ecological sustainability, economic development, and health. The consequences of loss of biodiversity are compounded by climate change and population growth. The various policies developed to protect species and to promote biodiversity are important, but anthropogenic pressures brought by population growth place a challenge to policymakers for continued protection of biodiversity policies.

16.10 HAZARD INTERVENTIONS

This chapter has stressed the importance to humankind of biodiversity. The animals and plants with which we share our planet bring enormous benefits to human existence. For instance, the provision of food is the most fundamental benefit that humans get from other life forms, and humans have always depended on animals and plants for meat, fruit, vegetables, nuts, and other natural products. Wild species have served as sources of drugs for thousands of years. Moreover, human societies have traditionally used plant and animal products for numerous commercial purposes such as cotton and wool for use in making clothing and forest products for building materials. And historically, some species have played an important role in the folklore and traditions of many cultures. Yet, given the essential symbiotic relationship between humans and other life forms on our planet, many species are endangered, as summarized in Table 16.1. This necessitates interventions to lessen the hazard to human well-being and ecological health posed by loss of species and biodiversity:

- On a global scale, support through sociopolitical means those policies that are based on consensus science, presented in transparent reports, and implemented through diplomatic dialog and resolution.
- On a national scale, support through sociopolitical means those policies and policymakers that advocate for the development and promulgation of policies for protection of species and acknowledgment of the importance of biodiversity.
- On a personal scale, use objective, transparent sources of species biodiversity information as the basis for personal decisions and policies. This could include choosing consumer products manufactured by sources that comply with regulations on protecting endangered species.
- Industrial entities should understand their role in complying with global restrictions on the trade of endangered or threatened species as well as their products.
- Encourage schools and other education institutions to include curriculum material on biodiversity and species endangerment.
- Support through volunteer services and/or financial assistance those zoos that work to protect endangered species and support seed banks that preserve seeds of threatened plants.

The establishment of species sanctuaries is one method of intervention against species endangerment, assuming that the sanctuaries are effectively monitored and enforced. Some examples of protective sanctuaries are listed in Table 16.5. While most of the examples are domestic, e.g., Chile, the establishment of international sanctuaries promises an opportunity for larger areas of species protection. Of particular note, in August 2016 President Barack Obama created the largest protected area anywhere on Earth—a half-million-square-mile arc of remote Pacific waters known for both exceptional marine life and importance to native Hawaiian culture. The Papahānaumokuākea Marine National Monument, established in 2006 by President George W. Bush, already covered 140,000 square miles of ocean around the uninhabited northwestern islands of Hawaii [54].

TABLE 16.5
Examples of Sanctuaries Established for Species Protection

Sanctuary	Location	Protected	Reference
Papahānaumokuākea Marine National Monument	Hawaii	Marine life, native Hawaiian culture	[54]
Marine conservation zones doubled	England	Marine life	[53]
New marine sanctuaries in Lake Michigan	Wisconsin	Marine life	[55]
Chile set 200,000 mi^2 sanctuary in the Pacific Ocean	Chile	Marine life	[55]
620,000 km2 ocean sanctuary declared	New Zealand	Marine life	[56]
Oslo creates a route filled with flowers and "green roofs"	Norway	Bees, pollinators	[57]
Largest dam removal in U.S. history,	Washington State	River and terrestrial life	[58]
Oyamel fir trees planted at higher altitudes	Mexico	Monarch butterfly	[59]

16.11 SUMMARY

The importance of biodiversity and the protection of species with which humans share the resources of planet Earth constitute the gist of this chapter. The policies that have emerged globally to protect endangered species and to protect biodiversity were described. Two U.S. laws, the ESAct and the MMPAct, were presented and the US FWS and the NOAA Fisheries, the two U.S. federal agencies responsible for implementing the two laws were described. Of particular note are the policies of the EU, stated as EU directives and regulations, which are specific to protection of bird species, habitat, and international trade. But notwithstanding the array of domestic and international policies on protection of biodiversity and species, human activities continue to place both biodiversity and specific species in harm's way, principally due to human population growth, climate change, and economic development.

16.12 POLICY QUESTIONS

1. Both the FWS and NOAA's NMFS have authorities under the ESAct, have authorities under the ESAct, as amended. Discuss the distinction between the two agencies' responsibilities under the act and opine why Congress chose to divide protection of endangered species between two federal agencies.
2. Using Internet resources access the list of endangered species prepared by the FWS and select five species from the list. For each species discuss the environmental, social, and economic consequences of each species' extinction.
3. Using Internet resources access the list of endangered species prepared by the NOAA Fisheries and select five species from the list. For each species discuss the environmental, social, and economic consequences of each species' extinction.
4. Described in this chapter are the responsibilities of the EPA under provisions of the ESAct. Excluding the FWS, the NOAA Fisheries, and EPA, select a different U.S. agency and prepare a two-page description of that agency's responsibilities under the Act.
5. The American bald eagle is the national bird of the U.S. For many years it was listed as endangered of extinction, but was removed from the list as the eagle's numbers increased. Is the bald eagle's recovery a source of pride to you? If so, why? If not, why not? Be specific in your choice of reply.
6. As noted in this chapter, amphibians are at particular risk of endangerment due to such factors as habitat loss, climate change, disease, and adverse environments. Choose any particular amphibian and discuss the implications of its disappearance as a member of the planet's life forms. Be specific and be sure to give details of any measures being taken to protect the amphibian you chose.
7. Recent news just arrived! The genetic engineering department at a local university just announced the discovery of a method that would eliminate ALL mosquitoes globally. The researchers' invention cannot discriminate between species of mosquitoes. Is this discovery good news? List in detail the pros and cons of eliminating the species of mosquitoes. State how this species' elimination would affect you personally.
8. This chapter has presented the importance of biodiversity to human well-being. Discuss what diminished biodiversity might mean to your personal daily life. What changes might you have to make in your daily routines?
9. Some scientists have asserted that loss of biodiversity will be accelerated by the effects of climate change. Research and prepare an essay of appropriate depth that characterizes this assertion and present your personal opinion about the assertion.
10. As described in this chapter, CITES is an international treaty specific to preventing trade in endangered species and related products. Using Internet and other resources, describe actions taken by CITES in regard to the trade of elephant ivory and related products. Complement your reply by accessing and discussing information about Kenya's national protection of elephant herds.

11. Assume that you have a chum who works for the local health department. What do you predict would be your chum's reply to your question about how her/his work involves biodiversity? Describe in some detail how you would reply to your chum's answer.
12. As discussed in this chapter, some efforts have been made to weaken some of the provisions of the ESAct. Some proponents of the subject change assert that the law simply needs updating, since its origin dates to 1973. However, conservation and environmental groups state their concerns that the law's intent is clear and the passage of time is not a justification for weakening the law. What is your opinion about periodically reviewing laws, e.g., the MMPAct, which have been in force for four decades or more? List the pros and cons of elected policymakers' conducting this kind of retrospective review.
13. A prominent policy of the EU's commitment to protecting biodiversity is its Natura 2000 system of protected habitats. Choose any one of the EU Member States and then identify one Natura 2000 area in the chosen country. Describe the selected Natura 2000 area in sufficient detail to make clear its contribution to biodiversity.
14. Discussed in Chapter 11 (Hazardous Chemical Substances) were some of the consequences of pesticides used in agriculture and for other applications of pest control. Discussed therein was the debate on the use of pesticides and the consequences to pollinating species, e.g., bees. Review the role of the EPA in determining if a pesticide's use might endanger a species' existence. What authority is EPA using to make its determination?
15. Australia is home to many unique species. Choose one species unique to Australia and research whether your selection is endangered or otherwise threatened. Describe any actions taken by the Australian Government to protect the selected species. If your selected species is not currently listed as endangered or threatened, describe what socioeconomic factors might contribute to the species' endangerment.
16. China is home to one of humankind's favorite animals, the giant panda. Using Internet resources, determine if this species is endangered or threatened. Describe what policies the Government of China has developed to protect the giant panda.
17. The last living passenger pigeon, Martha, died in captivity at the Cincinnati, Ohio, Zoo in 1914. She was the last living member of her species. Write one-page homage to the life of Martha. Be specific and evidence a bit of apologetic lament.
18. Using Internet resources research the list of endangered species and identify any endangered or threatened species that reside in your state. Describe each species and identify what measures are being taken to protect them. If your state has no endangered or threatened species choose an adjacent state and conduct the same research and description. Discuss what you personally can contribute to protection of endangered species in your state or elsewhere.
19. Discuss in an essay of appropriate depth what you consider to be the ecoethics (Chapter 2) of protection of nonhuman species.
20. Congratulations! You have successfully—without precipitous endangerment we assume—completed another chapter. Discuss the three most important lessons you learned from your study of this chapter's material. Was your personal environmental health behavior or policymaking changed by the content of this chapter? If so, how? If not, why not?

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17 The Built Environment

17.1 INTRODUCTION

Communities are where people live together in close proximity. For urban communities, this means quite a large number of people, while for more rural communities, the number can be quite small. Regardless of size, there are many environmental health consequences of people residing closely together. Additionally, the many modifications we make to the environment—whether buildings or the structures that allow us to move between them—can add additional hazards and greater risk to human and ecosystem health. The broad area of concern over the modified environment in a community is often called *the built environment*. This encompasses the physical elements and structures where people spend their days [1]. This not only includes buildings and green spaces, but also sidewalks, traffic, watersheds, powerlines, and internal environments between members of the community [2]. As illustrated in Figure 17.1, there are several determinants of health and well-being in human habitation, including the built environment, which is the subject of this chapter.

The study of the built environment transcends academic disciplines, with fields like architecture, engineering, and sociology, all learning from each other. Disciplines like public health and urban planning can both trace their roots to the similar concerns regarding the built environment in the nineteenth century: the conditions for many living in urban centers, and their rapidly decreasing quality of life [3]. As the twentieth century progressed and those initial concerns (communicable diseases, sanitation, overcrowding, and injury prevention) no longer commanded popular attention, the two fields began to drift apart. Public health shifted toward preventing childhood diseases and public health delivery systems, while urban planning focused more on housing and development. However, as will be discussed later in this chapter, a central irony of public health and urban planning is that the decisions made at the time to manage poor sanitation and overcrowding had unintended consequences that contributed to many modern issues facing community health [3].

Today's urban planners and public health professionals are once again working together, along with many other disciplines, to address built environment issues of physical activity, health promotion, and sustainability. As described by Frank and Engelke [1], this requires a multidisciplinary perspective. For example, policies that make street networks denser could help increase physical activity and decrease overall vehicle emissions. However, the resulting, centrally-located populations may be exposed to traffic congestion and the toxicants that come with that exposure, which can create additional health problems.

The context of these issues will be explored in this chapter, first by detailing how the urban planning approach to the built environment has evolved, and how it is currently being managed. This will be done by first introducing key terms and concepts that are used in the built environment. Next, the history of built environments in the U.S. will be described as a survey of how these issues developed through internal and external forces. Key U.S. policies will be introduced and these will be compared to related policies, pursuits, and problems being experienced in China, India, and across Europe. While the U.S. has certain unique attributes to the development of its built environment, this chapter will show how trends and policies have spread globally.

17.2 TERMS AND CONCEPTS

Prior to discussing policies and actions that attend the built environment, it is important to define key terms and concepts that are used throughout this chapter.

17.2.1 Land-Use Policy Tools

Central to how the built environment is designed and how it is now being used to improve human and ecological health are several policy tools—almost all of which are available exclusively to local and regional government organizations. The policy tools include the following:

- Comprehensive plans: These are official documents that create protocols for making changes to land use and transportation. They prepare capital improvement programs and for determining the rate, timing, and location of future growth.
- Zoning codes: These codes are the fundamental tool in urban planning. Codes regulate how land can be used. Zoning can also control most of the physical attributes of any proposed structure—what it looks like, how tall it can be, where it can sit on the land, and what can be around it.
- Building codes: These have been used for centuries. They determine the material and methods used in constructing the building—its bulk, scale, and style. They also can dictate what type of material can be used (or not used), and how it is to be used.
- Subdivision regulations: This tool, along with zoning and building codes, carry out the comprehensive plan of a community. These manage how large parcels of land can be divided into units for development. In contrast to zoning, subdivision regulations dictate the quality of the development. They contribute to how streets and systems (e.g., sewage and water) are laid out in the context of the surrounding community. Subdivision regulations tend to be more

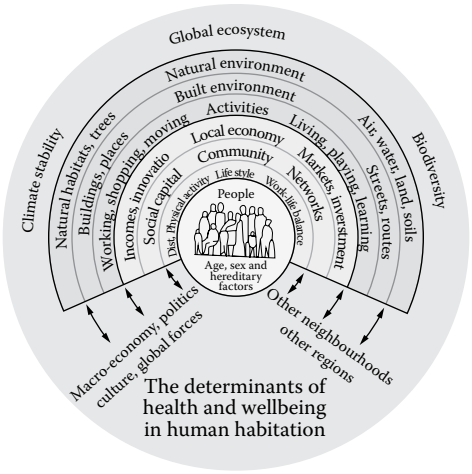

FIGURE 17.1 Model of the determinants of health and well-being in human habitation. (From Bath & North East Somerset Council, http://www.bathnes.gov.uk/.)

permanent than zoning codes. Development patterns are set by this policy tool and can have long-lasting impacts on taxes, overcrowding of schools, and environmental issues such as overextended sewage and water resources.

17.2.2 Land-Use Policy Actors

The planning of how land is to be used is necessarily difficult and often complex. Experience over time has shown that the reliance on various policy actors can be vital for successful land use planning. The most prominent of these kinds of policy actors include the following:

City Planning Commissions: In many circumstances, this organization has the greatest influence over a community's built environment. These commissions are traditionally seen as apolitical, citizen-led organizations that impact how their recommendations are heeded by the political city government. Following the model for planning set in 1929, these groups are responsible for creating ordinances through (1) commissioning studies, (2) creating and adopting master plans, (3) advising on zoning and subdivision regulations, (4) advising on capital improvements, and (5) responding to queries from elected officials.

Regional Planning Commissions: As communities developed, and as services provided by the government (e.g., transportation) and resources available to a region (e.g., water) crossed city lines, regional planning commissions emerged to manage an area's development

Metropolitan Planning Organizations (MPOs): MPOs are responsible for planning and programing transportation funds in a metro area. The Federal-Aid Highway Act of 1962 mandated—in exchange for federal highway funds—that cities create these groups, and the act charged them to take on "continuing, comprehensive, and cooperative" planning [4]. Specifically, they have five core functions: (1) frame regional decision-making in the metro area, (2) determine and evaluate alternative transportation options, (3) prepare and maintain the region's long-range transportation plan, or metropolitan transportation plan (MTP), (4) develop 4-year transportation improvement plans (TIPs), and (5) engage the public in the development of TIPs [5]. MPOs consist of local elected officials and state agency representatives.

MPOs historically were seen as a rubber stamp for state agencies, but with the passage of the Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991 and the Transportation Equity Act for the 21st Century (TEA-21) of 1998, MPOs were given greater authority and a broader scope (e.g., considering other modes of transportation beyond automobiles, and environmental concerns). This new power gave members of the MPT greater authority to affect land use and environmental health issues in a metro region. Beyond this federal charge, some states have added additional responsibilities to MPOs or given them a more specific charge. For example, Virginia mandates land use and transportation planning, and California mandates additional considerations to climate change [5].

Region Council of Governments (COGs): In contrast to the federally mandated MPOs, COGs were traditionally formed through a grassroots-level mobilization. There are more than 500 COGs in the U.S., and their specific charges can cover air quality protection, waste management, water quality planning, and transportation modeling. COGs and MPOs serve together as a regional medium for built environment decision-making. States differ in how they organize COGs and MPOs. While most are separate entities, some regions join them into one organization. For example, central Ohio merges the COG and MPO under what is called Ohio's Mid-Ohio Regional Planning Commission. Additionally, some COGs are established by state statutes while some operate as nonprofits. Historically, they are seen as a body lacking clear statutory direction and have no direct accountability to the citizens of the region. Additionally, COGs tend to represent the interests of suburbs over urban centers, as their vote apportionment is typically based on member jurisdiction and not population [6].

17.3 HISTORY OF U.S. PLANNING PRACTICES

Planning practices have existed for thousands of years. The customs and precedents established early still influence how cities are laid out today. Gridded streets were widely used

in ancient Roman times and were carried over to the U.S. with the first colonial communities and cities (e.g., Boston, Philadelphia, and Savannah). The grid principle spread to the U.S. frontier, as grid systems fit nicely with land surveys; they were also widely adopted by the U.S. through The Land Ordinance Act of 1785, which mandated land be parceled via a rectilinear land survey [7].

Similarly, nuisance laws were widely established for several centuries before the Industrial Age. Early planning documents demonstrate the premise that certain noxious facilities be placed on the edges of towns. In the Middle Ages, it was common for shops like leather tanning to be forced away from city centers [7]. This concept was further codified into English common law through public nuisance laws. It was then carried over to the British colonies. For example, a 1692 regulation in the Massachusetts colony designated that slaughterhouses be confined to specific areas. U.S. cities continued these traditions, offering the first uses of zoning for these particular situations [7].

17.3.1 Industrialization and the Birth of a Movement

During the nineteenth century, industrialization in the U.S. led to rapid immigration and migration to urban centers. Due to a combination of overcrowding and unchecked environmental contamination from city industries, people in this period were exposed to a wide range of environmental health issues [3]. Communicable disease spread and death rates in tenements were extremely high, with sanitation being almost impossible to maintain. This contributed to the public pressures that birthed both the progressive public health movement and urban planning.

Many cities responded to these threats and outbreaks by creating health boards to improve sanitation in cities. As cities instituted city-wide sewer systems for the first time, it became apparent that a more comprehensive approach was needed to ensure proper grading of roadbeds and housing drainage. These initial actions of sanitation reform merged concepts of the historical nuisance laws with late nineteenth century police powers. There was also a growing, broader interest in more robust attempts at planning emanating from these public health reforms. The influential *Shattuck Report of the Sanitary Commission of the State of Massachusetts* of 1850 offered, among its many other public health recommendations, specific recommendations regarding how towns and villages could be laid out to reduce disease transmission [8]. Cities like Memphis, Tennessee, went further by pushing for "systematized" and "comprehensive" plans that would seek to improve health and sanitation within city boundaries [8].

Meanwhile, the unhygienic conditions of the late nineteenth century helped spur two competing visions of communities. For some, the ills that were associated with cities—such as poor sanitation, overcrowding, and substandard housing—made urban living intrinsically unhealthful. Those in this camp believed the only way to substantially address these issues was to remove the population (or just those affluent enough to leave) from the unhealthful sectors of industry. Through ideas like the Garden Suburb and Garden City movement, reformers argued for the bucolic health benefits of country living. Specifically, they emphasized modest housing, small-scale agriculture, and local industry [9]. These movements helped affirm the principles that drove much of suburban development in the twentieth century of: (1) low population density, (2) separation of industry from housing, and (3) physical separation of structures with green space [1].

Competing with the Garden City movement was the City Beautiful movement, which had a significant influence on urban planning. Stemming from a popular exhibition featured at the 1893 World's Columbian Exposition in Chicago, this movement popularized the aesthetics of cities and promoted social consciousness into urban life. Supporters believed that well-designed cities could improve health and inspire a sense of civic pride that would cure many modern ailments [9]. Specifically, it led to interest in: (1) planned civic centers, (2) formally-arranged complexes, such as concert halls, and (3) open space systems and circulation systems [10]. In the years after the exhibition, there were several successful attempts to institute these ideals, under the goal of "designing" cities to promote health and bringing nature back into cities [3]. Daniel Burnham, one of the principal architects of the Chicago Exposition, was commissioned to develop a plan for the entire Chicago region. The Burnham Plan for Chicago was published in 1909 and was viewed as the first metropolitan plan [11].

The years during and after the City Beautiful movement led to a flurry of public movements in cities in the U.S. The policies produced in many of these cities later served as the foundation for urban planning. Hartford, Connecticut, was the first to establish an official planning commission in 1907. A year later, Wisconsin enacted legislation authorizing certain cities to create planning commissions. In 1913 Massachusetts required all cities with population exceeding 10,000 people to have planning commissions [12].

In New York City, led by the work of Lawrence Veiller, who produced a survey of poor housing conditions in the city, the right to regulate and enforce housing conditions was given to the public health departments, which allowed the group to clear slums. In 1916, a comprehensive zoning ordinance was also passed that regulated land use, height/bulk of buildings, and density of population. The New York City model zoning ordinance was quickly passed by many municipalities across the U.S. These early developments eventually evolved into more formal codifications of state authority to dictate the organization of communities. However, this and similar movements in the following years saw a rise in civic pride, where city residents considered it a sign of civic maturity that they had utilized planning [13].

At the same time, an equally influential development was occurring with the rise in automobiles. As cars became popular, city streets—which had always been dangerous—became the epicenter of a public health crisis. Cities initially reacted against the small minority of the population that were car owners by restricting access and heavily limiting

speed in cities. In 1923, the political power shifted. During that year, the city of Cincinnati responded to a citizen petition to decrease all vehicle speed limits in the city to 25 mph. This energized vehicle owners and manufacturers to mobilize pressure against the proposal, and were able to help defeat its passage. This mobilization led to the emergence of a powerful political organization group that pushed to make city streets more vehicle friendly (and as a consequence less friendly to pedestrians) [14].

17.3.2 U.S. Federal Government's Growth into Planning

In 1922. the U.S. Department of Commerce distributed a model law for local zoning programs called "A Standard State Zoning Enabling Act." It was promptly adopted by a majority of U.S. states, and still serves as the institutional framework for modern local zoning purposes [15]. Responding to opponents who were pushing back at the rights of the government to dictate what was being done on private property, the U.S. Supreme Court affirmed the constitutional right of local governments to dictate planning ordinances. Under the 1926 ruling in the Village of Euclid, Ohio v. Amber Realty, Co., the ruling gave formal constitutional approval of zoning, emanating from the common law principles of public nuisance [16]. Finally, in 1929, the federal government expanded its recommendations for planning by creating model traffic laws that enacted strict pedestrian controls, such as the first rules against jaywalking. These types of federal interventions set the precedent, as all three branches of federal government took steps to: (1) emphasize local control over the built environment, yet (2) influence how the nature of those decisions and principles were being emphasized [17].

As the Great Depression began in 1929, the federal government slowly grew more involved in dictating built environment policy priorities through: (1) low-income housing in city centers, (2) highway construction through cities, and (3) subsidizing development in suburban neighborhoods. Each of these developments saw a decreasing voice of public health in decision-making. Factors that led to the birth of public health and urban planning—sanitation and infectious disease outbreaks—were no longer dominating the public dialogue because both fields had moved on to new, more pressing issues [8]. Public health officials shifted toward public infrastructure, food sanitation, prenatal care, and childhood vaccinations. Meanwhile, urban planning shifted gears toward such policies as "urban renewal" and mass suburbanization, which would have long-term effects on the built environment. As later detailed by researchers in the early twenty-first century, this separation allowed public policy to be made without knowledge of public health consequences.

The first low-rent housing program was created with the passage of the Public Housing Act of 1937 and signified a shift in the social responsibility of homelessness and poor housing. Even more so, with the creation of housing projects in city centers across the U.S., it affirmed two principles that shaped policy decision-making in urban planning: (1) While the federal government shouldered most of the financing of these buildings, almost all decision-making power was left to local housing authorities and (2) The replacement of private slums with public-owned buildings gave the government greater ownership of city property, allowing elected officials greater leverage to shape the composition of neighborhoods. The public housing movements had a wide-ranging impact on several aspects of the built environment. In an effort to add housing stock it created the Federal Housing Authority (FHA) in 1934. This agency helped to improve financing of home purchases and in the long run created incentives that favored suburban housing development over existing urban neighborhoods [8].

A second movement that both increased federal control over local planning and also had major public health consequences was the development of highways. During the Great Depression, several industry groups created the National Highway Users Conference to influence the U.S. public's role in creating roads, and in turn, pressure on how those policies would be drafted. They were successful, as Congress released a planning document in 1939 that: (1) echoed industry's sentiments, and (2) mapped out the idea of an interstate system [18]. By 1955, the U.S. Department of Commerce's "yellow book maps" furthered that idea by publishing a series of maps detailing the routes the interstate system would traverse through city centers. Notably, no public health or city planning professionals were a part of how these plans were designed [18]. As a result, the routes were not designed to promote mobility or maintain community structure, but rather to promote mobility through the city—which unsurprisingly led highways to cut through the core of every major city. The maps laid the foundation for the birth of the interstate system, which was implemented through the Federal Aid Highway Act of 1956. In exchange for 90% of the cost of the highways being paid by the federal government, U.S. states had to consent to the routes dictated by the yellow book [19]. Some cities (San Francisco, Cleveland, and New York City) were able to move highway plans through particularly well-off, politically organized communities, yet every city eventually had neighborhoods isolated due to road construction [14].

Finally, the third aspect that dramatically shifted the built environment was the emergence of the U.S. federal government's providing easy FHA mortgage money for some new suburban developments. The Housing Act of 1949 was enacted as part of President Truman's domestic agenda, the Fair Deal. It expanded federal power in issuing mortgage insurance and providing federal financing for "urban renewal" projects, which demolished low-income neighborhoods in urban centers. This legislation had two major legacies. It drastically expanded the exodus of White Americans to the suburbs, and displaced many African-American communities, where housing was replaced with either more expensive housing or nonresidential public works [20]. Additionally, the legislation continued the pattern of federal housing policy, where cities are given federal funds to acquire and clear slums and make the land available for residential reuse. With the availability of incentives and the World War II postwar population boom,

there was a run on suburban development. This led to poorly planned development of subdivisions with poor access to sewage, utilities, and public transportation. In cities, the creation of highways and the effects of the Housing Act of 1949 decimated huge swaths of many neighborhoods and redesigned most cities in order to prioritize highways systems and use of automobiles.

The Housing Act of 1954 continued the trends of earlier U.S. federal policies. It established a mandatory requirement for comprehensive planning as a prerequisite to funding for urban renewal. It also put the federal government in the business of providing financial aid for planning. Any city wanting to undertake urban renewal was required to develop a "workable program for community improvement" (WPCI), including a comprehensive master plan. Under § 701 of the Housing Act of 1954 the federal government mandated all state, areawide, and local public agencies to use comprehensive planning to solve problems in urban areas [21]. Recognizing the need for planning and that the financial stress would be difficult, it granted funding for master plan studies through approved state agencies. There was 50/50 cost share for communities with less than 25,000 populations, and it dropped to a 25% local cost share with a larger population. Subsequent models in the 1960s used similar carrot/stick funding mechanisms to encourage local action to focus on the urban built environment (HUD, Model Cities, New Towns, etc.)

17.3.3 New Federalism and the Reemergence of Public Health

With the election of Richard Nixon as U.S. President, the federal government's approach to local planning shifted with the Nixon administration's New Federalism Initiative. This strategy sought to redefine how power was shared between levels of government by ceding more control to local authorities and creating fewer stipulations for federal money. Specifically, one of the more recognized components of this policy was the movement away from categorical funding (those with specific functions) to block grants and revenue sharing. The Housing and Community Development Act of 1974 consolidated various categorical grants into a single block grant. It merged separate programs like the Model Cities program into single "Community Development Act" funds. Communities were awarded federal money based on a formula designed to attempt to assure fair and equitable distribution. However, its structure also led to further eroding of urban centers. The program required no local financial contribution and no stipulation to focus on the most distressed neighborhoods. Additionally, reflective of the shift in national politics, the programs expanded access of recipient communities. No longer were cities the only eligible communities. Suburbs and rural areas—sometimes with high relative incomes—received federal dollars, which further shrank the pool for which city centers could rebuild [7].

By the late twentieth century, the separation of public health from planning had never been more pronounced. As described by Perdue [8], the 1995 edition of *Urban Land Use Planning*, a standard text for planners, contained no mention of "health and safety." In 2000, however, the Centers of Disease Control and Prevention (CDC) reasserted the public health impacts of the built environment by calling for increased focus on the way that sprawl (the expansions of developments away from city centers) impacts health [8]. To illustrate how out of the ordinary this pronouncement was, the Southern California Building Industry Association reacted harshly to the report, calling it "a ludicrous sham" and argued that CDC should stick to "fighting physical disease, not defending political ones." A representative from the National Association of Home Builders accused CDC of being overly focused on regulating lifestyle, arguing further that surveys show that people like sprawl. Nevertheless, this event represented a turning point in how public health pressures grew in urban planning [22].

This was further advanced through the Brookings Institute's (2007) Blueprint for American Prosperity initiative, which connected economic growth with the built environment that: (1) promoted healthful lifestyle and (2) was sustainable [23]. With the election of U.S. President Obama, this convergence was further cemented with the creation of the Sustainable Communities Initiative. This HUD/DOT/EPA MOA partnership consisted of two grant programs. The Sustainable Communities Regional Planning Grants supported local planning efforts to integrate planning with land use, economics, and workforce transportation. And the Community Challenge Planning Grants aimed to achieve communities that were both affordable and sustainable. Overall, they were driven by a call to "Work together to ensure that these housing and transportation goals are met while simultaneously protecting the environment, promoting equitable development, and helping to address challenges of climate change" [23].

Perspective: With the election of Donald Trump as U.S. President in 2016, the policy direction of the U.S. government shifted. The 2018 Presidential Budget calls for a 13.2% decrease in the HUD budget. The cuts would target many low-income housing assistance efforts, and rental assistance programs. Related to the built environment, the Trump administration has proposed eliminating the Community Development Block Grant Program, which provided assistance to local governments to fund community development initiatives. The budget would reduce the Department of Energy's budget by 5.6%. The Weatherization Assistance Program would be eliminated, which helps retrofitting efforts on a household level. While the budget blueprint will likely be amended by the Congress, it signals a shift in federal policy.

17.4 SOCIAL ENVIRONMENT

It is increasingly recognized that certain communities with positive social indicators tend to also have certain built environment features that appear to facilitate those social interactions. The social environment is best described as the structure and characteristics of relationships among people in a community. Components include social networks, social capital, and social support systems that provide interpersonal interaction [24].

Much of the City Beautiful movement and other similar movements during the Progressive Era of 1890–1920 was that the "look" of a community could stimulate more social capital. In her 1961 groundbreaking book, *The Death and Life of Great American Cities*, the urban planner Jane Jacobs reflected on how some neighborhoods were able to encourage community and safety through how it prioritized people's interactions with each other. Many of her suggestions became a centerpiece in the New Urbanism movement. And her view of how design elements and the social environment could reduce crime has become commonly accepted [25].

However, as planning moved away from these urbanism principles, and toward suburbanization, many of these principles (public/private demarcation, public focus on the streets, dense public transportation) were not prioritized in suburban development. Several decades later, in the equally seminal 2001 book *Bowling Alone*, the sociologist Robert Putnam investigated why several metrics of social life and community participation had declined in the late twentieth century. Putnam argued that the design of sprawling communities, where people lived and worked in different locations, and spent much of their free time in cars, were a likely candidate for the loss in social capital. Specifically, he stated that "each 10 additional minutes of daily commute time cuts involvement in community affairs by 10%" [26].

Putnam's hypothesis has been further supported by researchers in the early twenty-first century. Frank and Engelke [1] found that how communities are laid out can strongly influence the psychosocial health of its residents. This occurs by affecting how they see themselves within the community, their connection to others, their safety, and relationship with nature [27]. Other studies showed that higher collective efficacy—and higher political participations, social trust, and social engagement—was associated with residing in a community with mixed-use zoning (combination of businesses and residences), and high walkability scores [28].

This social environment is further hypothesized to affect health through a variety of pathways [24]. Norms believed to be associated in dense areas can promote healthful activities related to smoking, diet, exercise, and sexual behavior. Additionally, the relationships found in these communities are also believed to help connect at-risk individuals to the necessary services that can keep them healthy [29].

17.5 POLICY OVERVIEW

As with many other political/policy issues, prime authority rests with local municipalities and communities. However, the federal government's influences built environment policy by both soft and hard influences. Soft influences involve federal publications, National Academies Press reports, and studies through National Institutes of Health (NIH) and CDC, which affect the national discourse of positive and negative aspects of community design. Harder influences, for example, came from highway fund stipulations, which have traditionally been a popular mechanism to mandate particular policy ideas through the power of the purse.

As described by Perdue, there are five main policy tools that exist to modify the built environment [30]:

- Zoning ordinances that designate an area for special use and related development requirements
- Building and housing codes that set standards for structures
- Tax policy that can encourage or discourage activities
- Government expenditures that directly provide resources for projects and programs related to the built environment
- Environmental regulations that set quality or emission standards

Two policy tools have emerged as powerful levers in emphasizing environmental and public health in built environment decision-making. One tool is the Health Impact Assessment (HIA). The other tool is the environmental impact assessment (EIA), which is mandated by the NEPAct of 1969 (Chapter 4). EIAs detail a process in which environmental effects are forecast based on the proposed project, policy, or public action. If those effects are determined to be severe enough, the EIA helps stakeholders find appropriate measures to mitigate these affects [31].

While EIAs are required to include considerations of human health effects, EIAs have rarely been used for those purposes. As a result, a specific policy tool was developed to focus solely on health impacts. HIAs are a tool used to evaluate the potential health effects of a project before it is built or a policy before it is implemented. It can provide recommendations to increase positive and minimize adverse health outcomes. A HIA follows a series of well-defined steps:

- Screening—Determines whether an HIA would be useful for the proposal under consideration.
- Scoping—Established a plan for conducting the HIA.
- Assessments—Describes the baseline conditions of the group likely affected by the proposal and how the proposal may affect their baseline conditions.
- Recommendation—Based on the assessment, the HIA develops practical implications to improve the health.
- Reporting—Engages stakeholders in discussing the results.
- Monitoring and Evaluating—Evaluates the HIA process and the impact they have.

While HIAs are largely done voluntarily, as of 2010 a total of 119 HIAs have been completed in the U.S. They have been completed by governmental and nongovernmental sectors. While a majority deal with a built environment, many deal with energy and education issues as well [32,33].

17.6 CURRENT PRACTICES AND ISSUES

Several key practices can affect how built environment policies are developed. Some these practices are as follows:

Sprawl: As stated by Frumkin in 2002, the growing sprawl of communities away from city centers has wide-ranging

public health and environmental health consequences. Cities have continued to grow and expand over ever larger geographic distances, with undeveloped (forests, wetlands) or underdeveloped (farm land) land being converted to residential use. This places additional strain on utilities, with increased demands on resources. Due to lower population density in these suburban communities, public transportation is not always financially or logistically feasible, leading to greater reliance on automobiles. The style that these communities represent (low density, low land-use mix, strict separation of work and home) can also lead to poor economic, health, and social outcomes [34].

Air quality: While outdoor air is heavily regulated, as noted in Chapter 8, the influence of sprawl on transportation has been shown to have large effects on air pollution [3]. On the other hand, indoor air in the built environment is seldom regulated in the U.S. Due to issues of privacy and logistical complications, fewer guidelines exist in what constitutes clean indoor air. Radon—still mostly a regional problem—is a colorless odorless radioactive gas that can lead to increased risk of lung cancer. Radon is most frequently addressed by reducing exposure in a building by sealing leaks in basements and constructing improved building foundations. EPA sets exposure standards above which radon levels can be considered a health hazard. However, no policy mechanisms exist to intervene or regulate. Volatile Organic Compounds and household chemicals can lead to numerous adverse health outcomes and in particular are connected with a built environment disorder called *Sick Building Syndrome*. These chemicals are addressed through policy by educating consumers and setting standards that address a building's ventilation and operations.

Housing and health issues: Several environmental health issues have emerged in the twentieth century where populations are exposed through their interactions with the built environment. For most hazards, building codes regulate (or prohibit) their presence in new housing stock. For older housing stock, separate policies have been addressed to mandate removal in publically-owned properties and to provide funding for removal of hazards in private property. For instance, asbestos was seen as inexpensive, easily mined, easily manufactured, and, most importantly, a nonflammable form of insulation. However, with the discovery of a wide range of serious health risks, policies were enacted to remediate older housing stock, to regulate how it was removed, and regulate how workers were informed of its presence in buildings. Few governmental regulations exist for mold removal, but building codes often dictate that its presence is a violation of standards. Finally, with lead, its presence in paint required a similar approach to remediate, educate, and monitor. EPA and OSHA set lead exposure standards. Enforcement includes the adoption of strict laws that establish landlords' liability for ensuring that children are protected and the careful establishment of procedures that promote safe removal.

Brownfields: These are sites that were the former location of abandoned industrial or commercial activities, and as a result of either real or perceived environmental risk, their future land use is limited (Chapter 12). Through the CERCLAct the federal government takes the responsibility to remediate brownfields, which are defined as "real property, the expansion, redevelopment, or reuse of which may be complicated by the presence or potential presence of a hazardous substance, pollutant, or contaminant" [35]. Typically, remediation is complicated by liability and costs. Determining liability for the cleanup can be complicated already, but fearing legal action, the current property owners may hide the true nature, location, and scope of the contamination. Also due to the assessment and remediation process, the investment (whether planned or potential) may be scared away. The Small Business Liability Relief and Brownfields Revitalization Act of 2002 authorized funding for site assessment and remediation and clarified liability and environmental insurance issues, which in turn helped to transfer liability, and stimulate investment [36,37].

Transportation priorities: For much of the history of urban planning in the U.S., the automobile was the most important determinant in how street networks were constructed. Federal transportation spending underwent a significant reorganization in 1991 with the Intermodal Surface Transportation Efficiency Act (ISTEA) [24]. It introduced new flexibility, public involvement, and accountability into the transportation planning process. One key change was to ensure that transportation projects would not lead to air pollution emissions that exceeded limits set in state air quality improvement plans. Since then, a growing built environment issue has been the battle over how alternative modes of transportation are encouraged.

Hazards of being a pedestrian in an automobile-focused environment are well-documented. As described by Pucher and Dijkstra [38], efforts to improve walkability often focus on six types of approaches: (1) better facilities for walking and cycling, (2) traffic calming lanes (lower speed limits) in residential neighborhoods, (3) urban design oriented to people not cars, (4) Restriction on motor vehicle use, (5) traffic education, and (6) traffic regulations and enforcement. Policies for bikers have evolved to both: (1) decrease bike-related accidents and injuries, and (2) promote biking as an alternative mode of transportation. Bike lanes have emerged as one of the more popular products to deal with both goals, but whether they only affect people of higher socioeconomic status remains unknown [39].

Current issues of transportation in the U.S. are balancing several emerging principles in urban design. Mobility has historically been the main concern of planners, as their role was to connect various points in a regional area with the assumption that they would be made in an automobile. However, accessibility has emerged as an equally important principle. With this principle, the goal is not to drive, but to access goods and services. As a result, it leads to reducing the distance between two points (rather than just allowing cars to get there as quickly as possible). Transit-oriented development seeks to integrate land use and transportation by developing higher density housing, retail, and other uses within walking distance of a station.

Related to the issue of transportation is the problem of street design. This is also dictated by two principles. Streets can encourage proximity (where many destinations are concentrated in a small area) through mixing uses and increasing density. They can also encourage connectivity (where there are many linkages of transportation points that are direct). This is illustrated by a community with several street intersections (e.g., it has a grid network of streets). In this first case, the commuter can get between two points more directly. However, a community with few street intersections (e.g., it has many cul-de-sacs), would be unlikely for a commuter to get anywhere directly [1].

Sustainability: Finally, the issue of sustainability has grown to be one of the more central issues in twenty-first century built environment policy. Sustainable development emerged in the early 1970s as a realization that current projections of population, resource use, pollution, and economic growth were in a period of "overshoot," where needs were much greater than the planet could support for much longer. Early efforts aimed at finding how to reduce these demands in the long term. In 1987 the UN's World Commission on Environment and Development would define sustainable development as the "development that meets the needs of the present without compromising the ability of future generations to meet their own needs" [40].

Sustainability is also involved in a separate pursuit that was advanced by Ian McHarg, who postulated that humanity was part of a local ecosystem, not outside of it. Therefore, how humanity built and designed its cities could be improved if they acknowledge the interrelationship of people and their natural environment. The U.S. National Science Foundation initiated the long-term ecological research program in 1980 to better understand the processes in the environment and how they change in different regions and across time [41].

Sustainability policies still exist as a patchwork of initiatives. The Partnership for Sustainable Communities is a collaboration among EPA, HUD, and the Department of Transportation that seeks to help families attain improved access to accessible and affordable transportation options. Along with that, the Smart Growth Network is a network of private, public, and nongovernmental organizations that seeks to improve development practices in the U.S.

17.7 POLICIES

Due to the independent nature of local planning decisions, a laboratory effect takes place, as each city works to develop its own unique strategy to combat the issues of the built environment. Some of these policies grow regionally, nationally, and even internationally due to a bottom-up, or a top-down process. Policies move bottom-up as cities seek to replicate policies that appear to have worked in other locations. This leads to ideas quickly spreading around the globe. Top-down policies occur as organizations (international, national, or state or province) develop a new idea and offer incentives (whether financial, or administrative support) for local planning governments to implement.

17.7.1 Health in All Policies

A major policy that evolved top-down is the Health in All Policies (HiAP). This is an approach that integrates health considerations across policy sectors. While it is a recent movement, it has its roots back in the WHO Declaration of Alma-Ata in 1978. It is based on the premise that health is influenced by a variety of determinants, and therefore, health should be integral to the development of a variety of policies. HiAPs differ from HIAs by expanding the HIA approach to use multiple strategies to systematize and integrate across agencies. In other words, HIA is one tool that can be used as a part of a larger array of tactics to address health through HiAP [42,43]. It took shape in 2006 throughout the EU to strengthen human protection in the creation of policies. It was first used in the U.S. through a partnership with HUD and EPA through the Partnership for Sustainable Communities, which prioritized six livability recommendations and targeted improvements in affordable housing, green buildings, transit, water management, and brownfield space. More recently, HiAP has been included in the Patient Protection and Affordable Care Act, which mandated the creation of the National Prevention Council, which plans and carries out programs that promote health and prevent disease [44]. In 2017, the Trump administration commenced efforts to repeal the Affordable Care Act; hence, whether the National Prevention Council continues to exist is uncertain.

17.7.2 Complete Streets

Complete Streets is another top-down policy approach that takes a similar holistic approach to improving transportation policy and city design. It establishes a standard of safe (and accessible) facilities for bikers and pedestrians for all transportation projects. This can be done by improving conditions and opportunities for walking and bicycling, integrating either into transportation systems, and providing safe facilities for all modes. The policy has its roots in the 1970s but the term "complete streets" came about in the early twenty-first century through Smart Growth America [45]. The National Complete Streets Coalition was founded in 2005 and had a diverse array of backers such as the American Association of Retired Persons (AARP), American Planning Association, and the National Association of Realtors. In 2010 the U.S. DOT issued a policy statement supporting the use of Complete Streets policy, and by 2016 several hundred jurisdictions, and dozens of U.S. states have enacted Complete Streets policies that mandate transportation plans to incorporate Complete Streets principles. An ideal Complete Streets policy:

- Includes a vision for how and why the community wants to complete its streets.
- Specifies that "all users" includes pedestrians, bicyclists, and transit passengers of all ages and abilities, as well as trucks, buses, and automobiles.
- Applies to both new and retrofit projects, including design, planning, maintenance, and operations, for the entire right of way.

- Makes any exceptions specific and sets a clear procedure that requires high-level approval of exceptions.
- Encourages street connectivity and aims to create a comprehensive, integrated, connected network for all modes.
- Is adoptable by all agencies to cover all roads.
- Directs the use of the latest and best design criteria and guidelines while recognizing the need for flexibility in balancing user needs.
- Directs that Complete Streets solutions will complement the context of the community.
- Establishes performance standards with measurable outcomes.
- Includes specific next steps for implementation of the policy.

An even broader attempt at addressing public and environmental health impacts of the built environment is WHO's Healthy Cities Initiative. It seeks to promote health in cities by measuring health in policies and making local agencies understand the health impacts of local planning. It is a notable policy, as it shows more global partnership in promoting the connection between health and city planning. Notably it follows the traditional role of the federal government in applying soft pressure by providing free research, analysis, and support to make switching to more health-friendly policies easier [24].

17.7.3 Leadership in Energy and Environmental Design

The U.S. Green Building Council's (USBC) Leadership in Energy and Environmental Design (LEED) developed rating systems that establish different standards in how buildings are constructed at each stage. Buildings that meet high standards are given a high rating and credit as a green building. The Natural Resources Defense Council initiated the development of LEED in 1994 and deals with its own set of guidelines: sustainable sites, water efficiency, energy and atmosphere, materials and resources, indoor environmental quality, and innovation and design process. The LEED program also operates a LEED Neighborhood focus, which considers the broader picture of sustainability: street connectivity, access to public transportation, and storm water impact mitigation [46].

17.7.4 Other Built Environment Policies

Beyond these larger programs, there are several smaller, developing policies that seek to address sustainability issues in the built environment. These include the following:

- Urban Greening—Focuses on planting or replanting trees along streets. This aims to make the street network more walkable. It also addresses sustainability by mixing species, thus making the network of trees more resistant to disease [47].
- ReGen Villages—This policy is working to create a circle of homes in a closed-loop system that produces its own solar and biogas power, grows organic vegetables, farms fish and chickens, harvests water, and recycles waste into fertilizer [48].
- Zero net emission (ZNE) requirements—The carbon footprint of commercial, residential, and municipal buildings would not consume more energy for heating, hot water, lights, and appliances than they produce.

Several policies seek to promote more density in city centers. Urban Growth Boundaries set a regional boundary that mandates high density zoning on the urban side of the boundary and low density zoning on the rural size. This has been incorporated in Portland, Oregon, and Lexington, Kentucky, and has been argued to reign in urban sprawl. Greenbelt policies go about this in another way. Through NGOs or governments, lands on the peripheries of the urban center are purchased in order to keep it from being developed. This also nudges developers to build more dense properties in city centers, but can be very expensive. San Jose, California, has used this policy to buy several hundred thousand acres.

Another policy direction is to directly amend existing zoning/build code rules. Generally, zoning code reforms change codes so that they permit and encourage development that is more consistent with new ideas that promote sustainability and physical activity. Other strategies include density bonuses, which is an incentive that allows developers to build more units, taller buildings, or more floor space than otherwise would be allowed in exchange for their putting a specified number or percentage of units into their development that are considered affordable. This has been argued to help with affordability and density. Upzoning is a similar policy that directly changes zoning in an area from pure residential to increase commercial use. This allows for greater density, but has been argued to increase congestion.

Several policies also exist to modify traffic [49]. Along with the Complete Streets policy pursuit, the Traffic Choices Study is a federally-funded pilot program that tested various ways to reduce traffic congestion in cities and improve walkability. Road network tolling is often seen as a way to reduce congestion while raising revenue. Traffic calming policies try to deliberately slow down vehicles' speed, so that the distance to cross streets is reduced and the sight lines for pedestrians are improved. This can be done by using corner "bulb-outs," making the sidewalk wider at the intersection so that the distance to cross the street is reduced, and raised pavements that can result in drivers instinctively reducing their speed. Other policies include congestion charging (which imposes a toll on cars on entering into the city), and pedestrian zones (which eliminate automobile traffic in city centers to promote walkability). Finally, the road diet policy involves converting roads by reducing the number of lanes to allow for use of bike lanes, pedestrian refuge islands, transit stops, or parking. Some U.S. cities have adopted policies to reverse the effects that urban freeways have had on their city centers. For example,

Rochester, New York, through a two-decade long effort with the help of a grant from the U.S. DOT, removed a 2/3-mile long stretch of highway called the Inner Loop. Cities that have removed freeways—sometimes by an act of nature—saw decreases in traffic congestions. In some of these cases, traffic congestion dropped as much as 50%. This has motivated a program through the DOT called the Every Place Counts Design Challenge, which aims to study situations where infrastructure divides communities.

17.8 GLOBAL PERSPECTIVE

Many of the built environment problems and potential solutions have been experienced in countries globally. Relatively speaking, the U.S. was late in the game, as Europe had been developing building ordinances and regulations of urban life as early as the seventeenth century, which were standardized by the nineteenth century. Zoning was formally established in Germany in 1870. This was partly driven by the fact that municipal governments often owned at least half of city land, which gave regulators greater power to shape cities.

17.8.1 Europe's Built Environment

Countries in the EU have taken the lead on many fronts related to the built environment. Reducing the energy demand of the building life cycle has been a focus, as seen in the 2010 EU Energy Performance of Buildings Directive (EPBD) [50]. The directive sets energy requirements for new buildings in the EU, as well for major renovation, replacement, or retrofitting of buildings. The directive establishes a certificate program (similar to the U.S. LEED program) that is required to be included in all advertisements in rental and building sales. Financial measures are being produced. All of this aims to reach the goal of all new buildings in the EU being zero-energy by the end of 2020 (with public buildings having a target end date of 2018).

Another EU policy is the 2012 Energy Efficiency Directive (EED) [51], which requires EU countries to make energy efficient renovations to at least 3% of buildings owned and occupied by the government. It also mandates that EU governments can only purchase buildings that are certified as highly energy efficient. As per the policy, EU members are required to develop long-term national building renovation strategies to be included in their plan (called a "National Energy Efficiency Action Plan").

The EU has several other initiatives aimed at addressing built environment issues. To help provide an exchange between member countries of best practices and evidence-based results from different policies, the EU established the Concerted Action EPBD. BUILD UP Skills retrains displaced industry workers to help institute energy efficient building renovations. The BUILD UP also establishes a portal (similar to the EPBD) that allows countries to share their lessons and best practices toward training [52].

In a manner similar to U.S. federalism, EU member countries have approached the built environment through a wide variety of approaches. Sweden has perhaps approached built environment reform most aggressively. The country has an energy saving system (for small-to-medium size businesses), as well as investment aids for the transportation and industry sectors. Sweden also operates a robust local program for capacity-building. Specially, the policies help to finance the reform and better operation of regional and local administrative boards to help improve local built environment decisions-making and building code policies. Similarly, a program called "The Constructive Dialogue" is being pilot tested in five Swedish cities to improve local community planning. Taking elements from the HIA, it applies a holistic view to planning issues, to help find the most sustainable options for construction and renovation proposals [53].

17.8.2 China's Built Environment

Regardless of the roots of built environment policy, urbanization—and its negative externalities—will be a major global issue for the next century. By 2025, 5.5 billion of the world's 8.5 billion people will be residing in urban places. Of this number, one billion will be residing in China and 750 million in India [24]. As a result, how these two countries approach the built environment will help dictate much of the world's population and ecosystem.

China has experienced radical changes in urbanization policy, political ideology, and stage of economic development. Following the Chinese Revolution of 1949, China first followed a Soviet template for city development, which incorporated central control over local development. Every city is made by a planning authority under a defined planning management system and according to defined standards. Unlike the U.S., where cities operate as laboratories of projects, Chinese cities share a singular vision. The vision for much of the country's growth was established in 1978 at the Central Urban Work Conference. At that time, Chinese officials determined how to best fund the development of cities, resulting in a car-centric, concrete sprawl for the next several decades. From 1978 to 2016 the number of Chinese cities grew from 193 to 653, but little effort was made to modernize urban planning efforts until recently [54].

Since then, the population has boomed and has become overwhelmingly urban. More than half of the country's population reside in cities. The government has made it known that it would like to move 100 million more rural residents to cities by 2020 [54]. However, the urbanization of China has led to similar public and environmental health issues that the U.S. saw in the early twentieth century. Air pollution reports are a common problem and obesity rates have skyrocketed over the last generation. There is also an issue of inequality in the urbanization movement. Since many of the urban influx comes from the migration of rural workers, a two-tiered population structure of rural and urban citizens ensues. Walkability and built environment characteristics have been found to be connected with obesity in Chinese cities.

Recently, there have been two instances of innovation in Chinese city planning. Shenzhen was the first Chinese city to pilot reforms. Notably, it contains 320 "urban villages," which allows flexibility for incoming migrants. In Jiaxing, near Shanghai, there have been attempts at incorporating urbanism tenants, of multipurpose complexes, walkways, and green fields on roofs. However, China is also experiencing a similar bout of suburban sprawl. Between 2000 and 2010, the suburban population grew by at least 50% more than the central districts. By 2010, a majority of the population in Shanghai lived in a suburban area.

A Chinese middle class has developed in these suburban areas and many are becoming increasingly politically active. In recent years, these stakeholders have begun putting pressure to stop the building of chemical plants, or making high-speed rail safer. At the same time, there has been a growing policy movement to return some urban residents to villages. In 2016, central government officials met for the first time since 1978 to modify city planning, resulting in pledges to tackle air pollution, traffic gridlock, and sustainability. Much of this action came through pressure from this newly empowered middle class population group [54].

China is also pledging to modernize through improved sustainability efforts. Through a 2016 summit with President Obama, China officials committed to promoting low-carbon buildings and transportation. They established a goal of increasing the stock of green buildings, with the proportion reaching 50% by 2020. Additionally, they set a goal of increasing the share of public transportation of total commute reaching 30% the same years [55].

17.8.3 India's Built Environment

Similar in many ways to China, India is facing unique built environment issues. With 1.1 billion people residing in the country, it is estimated that more than 900 million more people will be living in India's urban centers by 2050 [56]. Country officials have noted that a dramatic revamp of planning and development practices are essential, making the cities' infrastructure a focus of public policy. A recent report claims the nation will need to spend $1.2 trillion over the next two decades in order to create functioning cities. While most of the money arrives through federal and state grants, there is little publically released data about how cities or urban local bodies (ULBs) are spending money [57].

Many of India's cities lack the high-rise characteristic of other global urban centers. Several factors have influenced the look of Indian cities. First, this is partly driven by the work of Charles Correa, an influential architect, who chaired the National Commission of Urbanization in 1988 [58]. He endorsed the principle of low-rise housing as useful to India due to its low-cost nature; as a result, much of the development in the ensuing years followed his guidelines. Additionally, many Indian officials in the early 90s wanted to limit density in order to discourage migrants from moving into cities. Finally, an issue related to the push against density is energy demand. Many developers went against high core-area density due to their low confidence in the city's ability to plan for services and infrastructure. Because of all of these reasons combined, many building codes in India have extremely low floor-area ratios (FARs).

Many cities in India have a FAR of 1.25, while Manhattan, New York's FARs can be as great as 24. A low FAR is believed to help cut down on consumption. A 2003 study found that Bangalore's low FAR reduced household consumption by 6%; however, it also pushed energy usage into greater travel lengths [58]. There is growing pressure to increase density, as New Delhi is debating permitting more skyscrapers. However, cities like Bangalore recently approved new small, contained towns surrounding the city. This, along with the need for land and water, puts strain on the services needed to reach the hundreds of millions of people in the city.

The traffic demand relates to a broader built environment issue in India related to traffic fatalities. Traffic laws have been an issue, as many roads are extremely unsafe for pedestrians. Cities like Mumbai are estimated to host around 15 million walking trips; however, Indian cities have some of the lowest walkability scores, often scoring 1/3 the score as cities in England. Because of the dramatic increase in cars, this is becoming a problem. Mumbai saw a 45% increase in registered vehicles from 2003 to 2008, with traffic fatalities increased 10% across the country. One study estimated that 78% of road fatalities in Mumbai involve pedestrians [59]. Projects and citizen groups have advanced policies to create more pedestrian infrastructure in industrial areas. There also is an effort—similar to the Complete Streets project—to influence the government to think holistically when addressing issues by considering the effects on pedestrians. This has pushed Indian activists to advocate that cities move away from a single-use design to one of mixed use.

17.8.4 Seminal Issue of Selected Global Built Policies

Broadly, policies focused on the built environment (whether from China, the EU, India, or the U.S.) are mostly focused on the issue of reforming energy efficiency. As countries develop national strategies to address climate change, it is becoming clear that inefficiencies in the built environment offer an effective (and politically popular) way to reduce energy demand and improve built environment health. Three policy measures mostly constitute how countries have addressed energy efficiency:

- Financing schemes to incentivize private property owners to upgrade to more efficient systems.
- Acceleration of efficient products (e.g., air conditioners, laundry equipment).
- Smart billing that incentivizes private property owners to direct energy savings (or generated electricity from solar panels) back into the grid.

17.9 ASSOCIATIONS BETWEEN THE BUILT ENVIRONMENT AND HUMAN HEALTH

The built environment can affect human health both directly and indirectly. Directly, the built environment can unwittingly expose populations to physical, radiological, and chemical agents in air, water, or building materials. For example, vehicle emissions are a major contributor to air pollution and have been linked to a range of respiratory and cardiovascular diseases and premature deaths annually, as discussed in Chapter 8.

Chemical exposure can also occur through proximity to industrial pollution. The Environmental Justice movement (Chapter 18) emerged in the 1980s in response to the unequal distribution of industrial emissions in communities of color, and has brought attention to the number of facilities with high emissions which disproportionately reside in majority non-White neighborhoods. Additional, proximity to high-traffic or industrial areas also expose populations to noise pollution. This has been linked to chronic issues such as hypertension, high blood pressure and heart disease, hearing impairment, and stress.

The built environment has also been associated with three major environmental exposures that have caused widespread health issues. Lead is a deadly neurotoxin that was distributed through the built environment through paint, gasoline, and water pipes. Millions in the U.S. and abroad have likely been lead poisoned due to these policies. It is still affecting the human population today in cities with older housing stock, which are more likely to have lead in paint; and water service lines, which can increase the risk of lead exposure, as was the situation in Flint, Michigan, when nonpotable municipal water supplies resulted in exposure of residents to lead (Chapter 9). Built environment policies can decrease these types of exposure by developing and enforcing stricter building codes, or by setting standards for how rental units are inspected.

Relatedly, asbestos is an incredibly toxic product that due to built environment policies was put in close proximity to human populations for decades. Unlike lead and asbestos, radon occurs naturally. However, built environment policies—how houses are built, and the choices of ventilation and insulation—can increase the risk of lung cancer due to exposure to radon. Ventilation and building codes also greatly influence the quality of the indoor air. Air exchange rates and standards of types of materials used in buildings can quickly raise the amount of volatile organic compounds in the air, as well as other aeropathogens and aeroallergens.

The built environment can also directly affect public health through injuries, as many community factors affect injury morbidity and mortality. Community violence rates have historically been higher in high-density communities (though some argue some of those differences are due to differences in lead exposure). However, built environment decisions, ranging from residential unit design to visibility and access to opportunities, have also been linked to changes in violence rates.

Most injuries and unintentional accidents result from motor vehicle crashes. This is heavily influenced by policies including the presence and quality of roads, enforcement of driving regulations, and misuse of alcohol [24]. Pedestrians and cyclists in the U.S. have a higher risk of being struck by cars than a similar person in Europe [38]. Other injury rates in communities may be affected by the built environment. Building conditions (e.g., how it is lighted, how it is designed, the materials it contains, and the presence of smoke detectors), and the outdoor condition (e.g., the layout of roads and sidewalks) both are related to a population's risk of injuries [8].

Secondly, the built environment can also affect human health indirectly. It is well established that the built environment can influence human behavior, and a growing amount of research shows that certain built environment designs of where we live and work can influence our physical activity. It is known that a sedentary lifestyle combined with high-calorie, high-fat diets contribute to higher rates of obesity. Connections between design choices and active lifestyles have also been correlated with obesity rates. Research has found an association between a "sprawl index," physical activity, and obesity. This "sprawl index" was also associated with other chronic medical conditions [60,61]. It was also found that people residing in communities with more interconnected street networks were more likely to have adequate physical activity per day than those with barriers related to physical activity, which in turn influences the energy balance of individuals [62]. Principles associated with new urbanism (density, street connectivity, and mixed use) were found to be associated with increased physical mobility [16].

The built environment also indirectly affects health behavior through individual transportation choices and the environmental exposure that occurs from these design patterns. This can be seen in whether driving or walking is preferable, and through the proximity of traffic congestion and food outlets. These traffic choices can affect public health by increasing pedestrian and cyclist safety. As people drive less, the risk of collision (whether as a cyclist or pedestrian) decreases. These health effects can also be decreased through modifications of the built environment to increasing walkability and better signage and bike lanes for cyclists.

At a regional level the built environment also influences health by the decisions in where—and how quickly—communities grow. These decisions directly influence travel behavior, which can dictate how much time people in a community spend in a car versus in their neighborhood. It also determines the amount of sedentary time spent in cars. These decisions also, in turn, affect the direct environmental exposures to which populations are exposed. Sprawl into undeveloped regions can put populations closer to vector-borne diseases. It can also strain the local environmental health systems such as sewer or septic systems or water systems.

17.10 ASSOCIATIONS BETWEEN THE BUILT ENVIRONMENT AND ECOSYSTEM HEALTH

At its most basic function, a community is established by modifying the surrounding environment. As communities grew, so too did the fitting of the area to the needs of the population, its industry, and its energy demands. In the decades following World War II, the rise of the environmental movement can be linked to the visible degradation of the environment, for example, smog and acid rain. In response to these pressures (increasingly industrialization and growing concern of environmental contamination) the sustainability movement emerged fostering built environment policies ensured the long-term health of the ecosystem.

Much of the sustainability movement is rooted in the principle that city developments have short- and long-term effects on the surrounding environment. Every feature of the built environment requires resources from the natural environment, so the movement seeks to be efficient in how resources are used, and how to make those resources last longer.

The built environment also influences the ecosystem in how many areas become developed. As a result, the continuing sprawl of urban and suburban development into formerly undeveloped land has considerable impact on an ecosystem. Directly, sprawl spreads environmental health systems (sewage and drinking water) thin, and can affect water supply and quality [1]. Indirectly, this development can influence other communities, especially when the sprawl develops upstream of the water sources of larger communities. Low density development increases the regional dependence on motor vehicles and requires new infrastructure to be delivered to these remote locations. Sprawl also increases the prevalence of less permeable surfaces. Rain collects on these surfaces, picks up pollutants and waste in the community, and can drain into the nearest surface water. This not only affects the nearby ecosystem, but can feed downstream into larger communities that rely on that local water source [1,63].

17.11 HAZARD INTERVENTIONS

A multitude of hazards exist in the built environment, and communities have adapted many ways to mitigate those threats. Unfortunately, due to the complexity of human interactions, many of those solutions have created brand new problems. Regardless, the history of the built environment is a history of hazard interventions. Town fires were a major issue in early communities, and some of the first steps to modify the built environment was to standardize how houses should be built. For example, houses in Germany during the Middle Ages were required to build chimneys out of stone and roofs out of tile due to the past disasters related to fire. The first sewer systems, which were built in response to cholera and other communicable disease outbreaks, were a more collective step to manage community health threats. After science uncovered the immense risk posed by the exposure to lead or asbestos, policies were enacted to stop their use in new developments and finance their removal from old housing stock. Additionally, after disasters exposed the weaknesses of buildings in the San Francisco earthquake, or the vulnerability of communities in New Orleans subsequent to Hurricane Katrina, policies were proposed and some implemented to modify the built environment to reduce future public risks.

While policy mechanisms exist to quickly address built environment hazards, there are a number of factors that make interventions unique. Due to the local control over planning and zoning, many cities can act quickly. However, due to that same local autonomy, it is hard to get cities in the U.S. to act uniformly. Likewise, modifications to how local planning boards incorporated health, such as through HIAs or HiAP, came slowly through the soft influence of the federal government (e.g., providing research, support, and expertise).

A critical barrier to quick hazard intervention is the costs associated with built environment developments. As discussed with the rush of suburban development, once property is developed according to the rules in place at that time, it can be very difficult to retrofit to new rules later. Even after a disaster, it remains hard to uproot the community that calls a certain area home. After Hurricane Katrina and flooding struck New Orleans, there was a push to eliminate subdivisions and neighborhoods that were deemed to be too risky. However, through local pressure these policies proposals were rejected. This further emphasizes the need for deliberate planning strategies that (1) incorporate all stakeholders—including those of lower socioeconomic status, and (2) consider all potential impacts of the proposed development, especially associated with the environmental and public health.

17.12 SUMMARY

As presented in this chapter, the broad area of concern over the modified environment in a community is often called the built environment. This encompasses the physical elements and structures where people spend their days and includes buildings, green spaces, sidewalks, vehicle and pedestrian traffic, watersheds, powerlines, and internal environment between members of a community. These built structures and their conditions of use can have beneficial as well as detrimental impacts on a community's well-being and its individuals. Central to how the built environment is designed and how it is now being used to improve human and ecological health are several policy tools: comprehensive plans, zoning codes, building codes, and subdivision regulations, which are available exclusively to local and regional government organizations. The U.S. federal government's gradual entry into planning of built environments became significant when public health representation was absent from planning forums. A seminal consideration in policies relevant to the built environment is how to make building more energy efficient for purposes of lessening impacts on climate change. Another important consideration is how to build transportation systems that are less disruptive to social structures and more protective of environmental quality.

17.13 POLICY QUESTIONS

1. Describe the room in which you are sitting and list the potential problems that could contribute to environmental and public health issues.
2. As countries continue to develop around the globe, how might the built environment problems they face be similar to the problems faced by the rapidly industrialized U.S.? How might they be different?
3. What are the features of a healthy community? What are the tools available to make your community healthier?
4. What are the barriers to implement programs aimed at addressing a built environment? Why do those barriers exist?
5. How do the principles of mobility and accessibility change how built environments are created?
6. Urban sprawl was discussed as a problem for the built environment. Using Internet and other sources, research how your state of residence is assisting in controlling urban sprawl. Should federal or state governments have a presence in what is a local policy issue?
7. Using the material in Chapter 6, together with other resources, prepare an essay of appropriate depth that examines the projected impacts of climate change on the global built environment. Be specific and cite data in support of your thesis.
8. The U.S. Department of Housing and Urban Development (HUD) is the principal federal agency involved with urban built environments. Research to what extent the community where you reside is receiving built environment assistance from HUD. If your community is not receiving assistance, select a city that does.
9. Sweden was cited as a country that has implemented holistic built environment policies. Prepare an essay that lists the most significant policies that you believe should be implemented in your country of residence.
10. Does your community of residence support biking lanes on the major thoroughfares? If so, detail the policies that permit bikers sharing local traffic resources. If not, opine whether such policies should be adopted in your community.
11. Assume that your county commissioners have announced their potential consideration of a property developer's proposal to remove 10 acres of old forest and thereon to build a complex of apartment and condo building. Further assume that you chair a local environmental quality advocacy group. Using the PACM model discussed in Chapter 2, discuss the actions your group would take.
12. The LEED program also operates a LEED Neighborhood focus. Research whether your community of residence is working with a LEED project and provide details on the project. If your community is not involved with LEED, select a community that is involved.
13. Prepare a comparative analysis that contrasts China's and India's building policies. Does either set of policies provide better environmental protection than the other?
14. Make contact with your local planning commission to ascertain its composition and evaluate to what extent the group has public health representation. If the commission has no public health member, examine the reasons why.
15. Describe the social climate in the community in which you reside, using the material in this chapter that indicates a positive social climate has beneficial effects. Write an essay describing how you perceive the benefits of your social climate's affect you.
16. Develop an abbreviated Complete Streets policy for your community of residence. Discuss in brief the elements of your policy and the surmised benefits to your community.
17. Describe in your opinion the two most important changes that could be made to your community of residence in order to improve its benefits to residents. Provide rationales for each of your proposed changes.
18. Some cities in Europe have banned motor vehicle traffic from entering city center areas. Select two such cities and summarize the outcomes of this kind of policy. Additionally, opine on whether your city of residence should adopt a similar policy.
19. Ascertain if your university or other school of higher learning offers a program in urban planning. If so, summarize the purpose and resources associated with the program. If your school does not offer such a program, select a university that does.
20. Well done! You have completed another chapter. We trust this chapter has built further knowledge about environmental health policymaking. Discuss the three most important lessons you learned from your study of this chapter's material. Was your personal environmental health behavior or policymaking changed by the content of this chapter? If so, how? If not, why?

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Section IV

Influences on Environmental Health Policymaking

18 Policy Impacts of Environmental Justice

One man's justice is another's injustice.

Ralph Waldo Emerson
(*Essays: First Series*)

Injustice anywhere is a threat to justice everywhere.

Rev. Dr. Martin Luther King, Jr.
(*Letter from Birmingham City Jail*)

18.1 INTRODUCTION

A major environmental health concern arose in the 1970s, as will be subsequently discussed in this chapter. The concern is called *environmental justice*, although other terms have been used. The Environmental Protection Agency (EPA)'s current definition of environmental justice is "[t]he fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies" [1]. As the definition implies, fair treatment lies at the heart of environmental justice. But fair treatment in what and whose context? The answer to this essential question requires awareness of the history of environmental justice, which will be discussed later in this chapter. However, it can be stated at this point that fair treatment involves the prevention of inequitable distribution of environmental hazards across the segments that comprise a society. Moreover, environmental justice must be considered as a matter of environmental ethics and morality, as discussed in Chapter 2. As illustrated in Figure 18.1 the environmental justice movement in the U.S. has its roots in Warren County, North Carolina, as will be subsequently described.

As a prelude to comments on the environment's impact on people of color and on communities challenged by economic and social conditions, the generally inferior health status (compared with Caucasians) of people of color, particularly those of African-American descent, should be borne in mind [2]. According to the *CDC Health Disparities and Inequalities Report—United States, 2013* [1a], four findings illustrate the depth of health disparities in the U.S. population:

- Cardiovascular disease is the leading cause of death in the U.S. Non-Hispanic black adults are at least 50% more likely to die of heart disease or stroke prematurely (i.e., before age 75 years) than their non-Hispanic white counterparts.
- The prevalence of adult diabetes is higher among Hispanics, non-Hispanic blacks, and those of other or mixed races than among Asians and non-Hispanic whites. Prevalence is also higher among adults without college degrees and those with lower household incomes.
- The infant mortality rate for non-Hispanic blacks is more than double the rate for non-Hispanic whites. Rates also vary geographically, with higher rates in the South and Midwest than in other parts of the country.
- Men are far more likely to commit suicide than women, regardless of age or race/ethnicity, with overall rates nearly four times those of women. For both men and women, suicide rates are highest among American Indians/Alaska Natives and non-Hispanic whites.

The causal factors that define these kinds of health disparities are multiple and often complex, including such factors as genetics, lifestyle choices, education, economics, housing, access to health care, and the environmental conditions. This chapter will discuss the emergence of what is most commonly called environmental justice, although other terms have been used to describe the alleged imposition of environmental hazards on communities of color. As discussed in this chapter, the history of environmental justice is intertwined with issues of waste management; that is, allegations that hazardous waste, in particular, was deliberately targeted for storage and/or processing in communities of color and/or low income. These allegations stimulated a series of demographic investigations of persons residing near hazardous waste sites. Findings from these studies are described, with a synthesis of their findings. The policy implications of environmental justice are presented and conclude the chapter.

18.2 THE MATTER OF DEFINITION

Several terms have been used to characterize the social condition of unequal distribution of environmental hazards, especially when experienced by people of color or groups with low income. One term is called *environmental equity.* Other terms that have been used by community groups and some environmental organizations are *environmental racism* and *environmental inequity* [3]. The term *environmental justice* is the term now favored by many grassroots groups, government agencies, and elected officials. Fairness is the core concern of both environmental equity and environmental justice. As a consequence of individuals' differences, a healthy democracy that treats people fairly may not always be able to treat

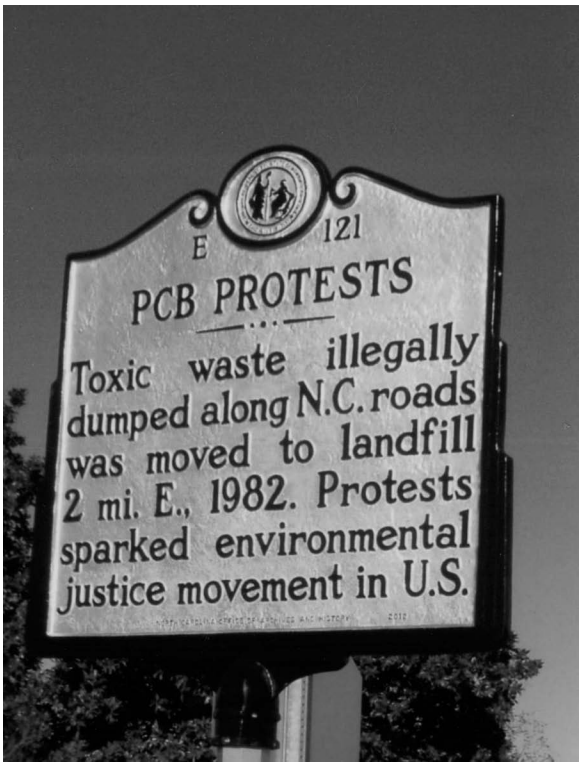

FIGURE 18.1 Warren County, North Carolina, environmental justice marker. (From North Carolina Highway Historical Marker Program, PCBs protest, ID: E-121, North Carolina Department of Cultural Resources, Raleigh, NC. http://www.ncmarkers.com/Markers.aspx?MarkerId=E-121, 2016. With copyright permission.)

them equally. Although equity and justice are both rooted in a concern for fair treatment, equity seems more directly synonymous with fairness than justice. Justice has a more litigious image than equity, and litigation does not always result in fair outcomes. Moreover, equity seems to connote a more prospective approach—actions that will guard against inequities in how environmental hazards are shared. Justice seems more retrospective—actions that give emphasis to redressing past actions that imposed disproportionate shares of environmental hazards.

In 1992 the EPA gave a different argument in favor of the term environmental equity in their report on reducing risk for all communities [4]: "EPA chose the term environmental equity because it most readily lends itself to scientific risk analysis. The distribution of environmental risks is often measurable and can be quantified. The agency can act on inequities based on scientific data. Evaluating the existence of injustices and racism is more difficult because they take into account socioeconomic factors in addition to the distribution of environmental benefits that are beyond the scope of this report. Furthermore, environmental equity, in contrast to environmental racism, includes the disproportionate risk burden placed on any population group, as defined by gender, age, income, as well as race." In sum, the EPA's preference in 1992 for the term environmental equity was based on their belief that measurability (i.e., of equity) was important.

Similar to the EPA, in 1992 the state of Washington preferred the term environmental equity "[b]ased upon the connotation that the word 'equity' better relates to something measured, as opposed to 'justice'" [5]. They defined environmental equity as, "[t]he proportionate and equitable distribution of environmental benefits and risks among diverse economic and cultural communities. It ensures that policies, activities, and the responses of government entities do not differentially impact diverse social and economic groups. Environmental equity promotes a safe and healthy environment for all people."

However, the Protocol Committee that organized the National Environmental Justice Conference of 1994, held in Washington, DC asserted, "Environmental justice encompasses more than equal protection under environmental laws (environmental equity). It upholds those cultural norms and values, rules, regulations, and policies or decisions to support sustainable communities, where people can interact with confidence that their environment is safe, nurturing, and productive. Environmental justice is served when people can realize their highest potential, without experiencing sexism, racism and class bias. Environmental justice is supported by clean air, water and soil; sufficient, diverse and nutritious food; decent paying and safe jobs; quality schools and recreation; decent housing and adequate health care. Environmental justice is supported by democratic decision-making and personal empowerment; and communities free of violence, drugs, and poverty and where both cultural and biological diversity are respected" [6]. This definition of environmental justice is more expansive and idealistic than that used to define environmental equity. Moreover, the Protocol Committee's concept of environmental justice does not seem as amenable to measurement as do the definitions of environmental equity.

The National Environmental Justice Conference had considerable impact on the EPA, leading it to move away from the term environmental equity in favor of environmental justice. In 1995, as a consequence of a Presidential Executive Order on environmental justice that was signed by President Clinton during the conference, the EPA developed working definitions for "environmental justice" and "fair treatment" [7]:

- Environmental justice means the fair treatment and meaningful involvement of all people, regardless of race, ethnicity, culture, income, or education level with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.
- Fair treatment means that no population, due to political or economic disempowerment, is forced to shoulder the negative human health and environmental impacts of pollution or other environmental hazards.

The Presidential/Congressional Commission on Risk Assessment and Risk Management (CRARM) defined environmental justice as "Concern about the disproportionate occurrence of pollution and potential pollution-related health effects affecting low-income, cultural, and ethnic populations

and lesser cleanup efforts in their communities" [8]. This definition seems directed to the Comprehensive Environmental Response Compensation and Liability Act's (CERCLAct's) purposes, given the mention of cleanup efforts, and therefore would be more limited in application.

The EPA's definition of environmental justice is "Environmental Justice is the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies" [1]. This definition was chosen for use in this chapter.

18.3 HISTORY

Pinpointing any one event that triggered what became the environmental justice movement in the U.S. is difficult. As seen in much of the U.S. civil rights movement and social justice crusade, societal change occurs as the result of many events acting over time. A societal movement occurs if sufficient supportive public opinion develops and enough supporters are drawn to the cause. The movement then mobilizes its energy to prevail upon institutions—often governmental bodies—that can effectuate change. Federal voting rights legislation and ordinances that protect against sexual discrimination are examples of such changes.

18.3.1 Warren County, North Carolina, Protest, 1982

Several key events have shaped the environmental justice movement. But if any one event can be termed "the" event, it occurred in Warren County, North Carolina, in 1982 [10]. As background, in the summer of 1978, Ward Transformer Company paid a trucking company to drive along rural North Carolina roads at night to discharge liquid contaminated with PCBs onto the shoulders of roads. The deception, a violation of the Toxic Substances Control Act, contaminated soil along 240 miles of roads in 14 North Carolina counties. In December 1978 the state of North Carolina, responsible for the cleanup, purchased farmland from a Warren County farmer who was in financial distress. There, in the community of Afton, the state proposed to construct a landfill in which to bury the toxic waste. The state thought that it had found what seemed to be an expeditious solution to the problem—inexpensive land in a sparsely populated community [10a].

However, local opposition arose when the state announced its proposal to locate a hazardous waste facility in this county, which had a large African-American population. The landfill was targeted to receive PCB-contaminated waste [11] at a site near the community of Afton, which was 84% African-American [9]. When protests resulted that were very similar to those of the U.S. civil rights movement of the 1960s, and more than 500 persons were arrested by police, the protests and arrests caught the attention of national news media. Despite the protests and media attention, delivery began of hazardous waste to the landfill.

The final attempt to stop the landfill occurred in July 1982. The local chapter of the National Association for the Advancement of Colored People sought a preliminary injunction in federal court to prohibit placement of PCBs in the Warren County landfill. The court denied the request, stating that race was not an issue in siting the landfill because race was never mentioned as a motivating factor throughout all federal and state hearings and private party suits [12]. Although community opposition, national media attention, and legal proceedings did not halt construction and use of the landfill, the civil rights demonstrations and their aftermath mobilized attention on a new issue, which some called environmental racism [13].

The events in North Carolina led Walter Fauntroy (D-DC), District of Columbia Delegate to Congress, and Congressman James Florio (D-NJ) to ask the General Accounting Office (GAO)* in 1982 to assess the racial implications of facilities in the southern states that received hazardous waste. The GAO found African-Americans were the predominate population living near three of the four largest facilities in the south [15]. That gave weight to the belief that landfills were deliberately being targeted for location in minority communities.

Issues that came from the Warren County, North Carolina, PCB landfill siting set into motion a series of events that have shaped the current environmental justice movement. Twelve key events that shaped the movement are summarized in Table 18.1. Described in subsequent sections of this chapter is the nature and importance of the events listed, but for historical perspective, one report and four events merit elaboration here.

18.3.2 Bullard's 1990 Book and Thesis

The events in Warren County, North Carolina, gave impetus to research that Robert D. Bullard, a sociologist, published in 1990 as *Dumping in Dixie: Race, Class, and Environmental Quality* and in 1994 in *Unequal Protection: Environmental Justice and Communities of Color* [9,17]. The former book, which quickly became a cardinal, seminal work within the civil rights movement, focused on five African-American communities struggling with environmental problems: Houston, Texas; Dallas, Texas; Institute, West Virginia; Alsen, Louisiana; and Emelle, Alabama. Bullard described in detail the concerns of local residents and the potential health risk ascribed by them to the presence of hazardous waste landfills or operating chemical plants.

Bullard's 1990 book contains methods of dispute resolution and grassroots strategies that can be used to counter environmental inequities. This work places him at the center of scholars who developed the intellectual framework that constitutes environmental justice [9,11,13,16,17] and has contributed much to improving social and environmental policies intended to prevent environmentally discriminatory actions. Bullard's published work is essential reading for persons seeking basic information about environmental justice.

* The GAO Human Capital Reform Act of 2004 changed the agency's name to Government Accountability Office, effective July 7, 2004 [14].

TABLE 18.1
Key Events That Shaped the U.S. Environmental Justice Movement

Event/Year	Impact of Event	Event/Year	Impact of Event
1. Warren County, NC, civil rights opposition to a proposed PCBs landfill/1982	Brought national attention via news media and made environmental concerns a matter of civil rights	7. First National People of Color Environmental Leadership Summit/1991	First national conference of environmental justice activists; developed first set of Principles of Environmental Justice
2. GAO study of four hazardous waste sites in southeastern U.S./1983	Elevated to congressional attention the potential inequity of placing hazardous waste facilities in areas that have large minority populations	8. National Conference on Environmental Justice/1994	Second federal conference on environmental justice; developed strategies for environmental justice pursuits; led to Presidential Executive Order
3. Release of Commission on Social Justice study of minorities and waste facilities/1987	Report gave credence to concerns that minorities were over represented in areas around waste sites; became seminal document within U.S. civil rights and social justice movements	9. Issuance of Presidential Executive Order on environmental justice/1994	Provided resources, authority, and imprimatur of U.S. federal government
4. University of Michigan Natural Resources Conference and formation of the Michigan Coalition/1990	Michigan Coalition had a major impact on EPA's recognition of environmental equity as a concern	10. Second National People of Color Environmental Leadership Summit/2002	Reaffirmed Principles of Environmental Justice from Summit 1
5. Publication of the book *Dumping in Dixie*/1990	First academically-based report of patterns of environmental inequities according to race	11. Establishment of EPA's National Environmental Justice Committee/1993	NEJAC provides a forum for discussions about integrating environmental justice with other EPA priorities and initiatives.
6. ATSDR's National Conference on Minorities and Environmental Pollution/1990	First federal government conference to focus on research findings and gaps in knowledge about health effects of environmental hazards on minorities	12. Establishment of NAACP Environment and Climate Justice Program/2010	Provides resources and legal actions from a key civil rights organization

18.3.3 Five Key Conferences/Meetings

Several conferences have had great impact on the evolution of environmental justice by helping identify disparities according to race, income, or culture. Each influenced subsequent actions that advanced environmental justice policies, particularly those of federal government agencies.

18.3.3.1 University of Michigan's Natural Resources Conference, 1990

The debate over environmental justice had advanced sufficiently by 1990 to warrant a conference on race and environmental hazards. In January of that year, the University of Michigan's School of Natural Resources convened scholar-activists in a national conference to address the distribution and management of environmental risk [18,19]. Nine of twelve scholars who presented papers were minorities, marking the first environmental justice conference where the majority of presenters of scholarly papers were people of color [19]. The Michigan conference resulted in a compilation of papers that advanced the debate about race and environmental justice.

However, the most important outcome of the Michigan conference was the creation of what became known as the Michigan Coalition, a subgroup of conferees who composed an agenda for environmental justice and conducted a series of meetings with senior federal government officials to present their agenda. According to EPA Administrator William Reilly, "It was the arguments of this group that prompted me to create the Environmental Equity Workgroup" [9]. In turn, the EPA Equity Workgroup evaluated environmental risk and race data and produced the report "Environmental Equity: Reducing Risk for All Communities." This EPA report, which is described in this chapter, was the federal government's first official expression on environmental justice and became a primary resource for environmental justice advocates who lobbied for government support and action.

18.3.3.2 ATSDR Environmental Justice Conference, 1990

In 1990, the Agency for Toxic Substances and Disease Registry (ATSDR) organized the first U.S. federal government conference on environmental justice and environmental contamination [20]. The conference was held in Atlanta, Georgia. The 400 participants were primarily researchers and investigators from government agencies and universities. The conference concentrated on adverse health effects of hazardous substances in minority populations, educational needs of low-income communities, and improvements needed in risk assessment to account for potential disproportionate impact of hazardous

substances on minorities. The meeting resulted in agreement that minorities were at increased health risk from various environmental hazards, that risk assessments should integrate concern for minorities and susceptible populations (e.g., children), and that additional research and data collection were warranted.

18.3.3.3 First National People of Color Environmental Leadership Summit, 1991

Two national meetings have been organized and conducted by a coalition of environmental justice advocates. The coalition included grassroots and community groups, labor organizations, civil rights organizations, tribal representatives, cultural representatives, and feminists, among others. The First National People of Color Environmental Leadership Summit occurred in 1991, held in Washington, DC [21]. In later years, this meeting became known as Summit I. Approximately 1000 persons attended. Summit I was a historic meeting in several regards. It was the first national environmental justice meeting organized by, and focused on, activists concerned with the personal and social issues of environmental hazards imposed upon people of color. Summit I set into motion a national network of groups committed to environmental justice goals and practices.

Delegates to Summit I produced a set of 17 Principles of Environmental Justice (Table 18.2), which was a sweeping declaration of socioeconomic and political statements. The 17 principles contain elements of sustainable development, Native American rights, pollution prevention, workers' health and safety, victims' compensation, informed consent, cultural involvement in decision making, and anti-war sentiment, among others. The set of principles represent an idealistic statement of how communities and people of color expect

TABLE 18.2
Principles of Environmental Justice from the First National People of Color Environmental Leadership Summit

We, the People of Color, are gathered together at this First National People of Color Environmental Leadership Summit, to begin to build a national movement of all peoples of color to fight the destruction of our lands and communities, do hereby reestablish our spiritual interdependence to the sacredness of our Mother Earth; we respect and celebrate each of our cultures, languages and beliefs about the natural world and our roles in healing ourselves; to insure environmental justice; to promote economic alternatives which would contribute to the development of environmentally safe livelihoods; and to secure our political, economic and cultural liberation that has been denied for over 500 years of colonization and oppression, resulting in the poisoning of our communities and land and the genocide of our peoples, do affirm and adopt these Principles of Environmental Justice.

1. Environmental justice affirms the sacredness of Mother Earth, ecological unity and the interdependence of all species, and the right to be free from ecological destruction.
2. Environmental justice demands that public policy be based on mutual respect and justice for all peoples, free from any form of discrimination or bias.
3. Environmental justice mandates the right to ethical, balanced and responsible uses of land and renewable resources in the interest of a sustainable planet for humans and other living things.
4. Environmental justice calls for universal protection from extraction, production and disposal of toxic/hazardous wastes and poisons that threaten the fundamental right to clean air, land, water and food.
5. Environmental justice affirms the fundamental right to political, economic, cultural and environmental self-determination to all peoples.
6. Environmental justice demands the cessation of the production of all toxins, hazardous wastes, and radioactive substances, and that all past and current producers be held strictly accountable to the people for detoxification and the containment at the point of production.
7. Environmental justice demands the right to participate as equal partners at every level of decision-making including needs assessment, planning, implementation, enforcement and evaluation.
8. Environmental justice affirms the right of all workers to a safe and healthy work environment, without being forced to choose between an unsafe livelihood and unemployment It also affirms the right of those who work at home to be free from environmental hazards.
9. Environmental justice protects the rights of victims of environmental justice to receive full compensation and reparations for damages as well as quality health care.
10. Environmental justice considers governmental acts of environmental injustice a violation of international law, the Universal Declaration on Human Rights, and the United Nations Convention on Genocide.
11. Environmental justice recognizes the special legal relationship of Native Americans to the U.S. government through treaties, agreements, compacts, and covenants affirming their sovereignty and self-determination.
12. Environmental justice affirms the need for an urban and rural ecology to clean up and rebuild our cities and rural areas in balance with nature, honoring the cultural integrity of all our communities, and providing fair access for all to the full range of resources.
13. Environmental justice calls for the strict enforcement of principles of informed consent, and a halt to the testing of experimental reproductive and medical procedures and vaccinations on people of color.
14. Environmental justice opposes the destructive operations of multi-national corporations.
15. Environmental justice opposes military occupations, repression and exploitation of lands, peoples and cultures.
16. Environmental justice calls for the education of present and future generations which emphasizes social and environmental issues, based on our experiences and an application of our diverse cultural perspectives.
17. Environmental justice requires that we, as individuals, make personal and consumer choices to consume as little of Mother Earth's resources and to produce as little waste as possible, and make the conscious decision to challenge and reprioritize our lifestyles to insure the health of the natural world for present and future generations.

Source: Anonymous, First national people of color environmental leadership summit, http://www.apcd.org/permit/t5tutorial/t5ej/tsld005.htm, 1991.

to be respected and involved in environmental decisions that can affect them. To what extent these 17 principles have been adopted as policy by environmental and public health policymakers remains unclear in most instances.

18.3.3.4 National Environmental Justice Conference, 1994

The ATSDR meeting of 1990 led to a much larger federal-sponsored conference in 1994 in Washington, DC that brought together 1100 environmental justice advocates, state/territorial, tribal, and federal government representatives, university researchers, and others. The meeting was preceded by issuance of a set of 10 review papers that helped shape dialogue during the conference [21]. The conduct of the meeting ranged from confrontation to conciliation. From the meeting came agreement on a set of five recommendations designed to impact government actions on environmental justice [6]:

I. Conduct meaningful health research in support of people of color and low-income communities. Preventing disease in all communities and providing universal access to health care are major goals of health care reform. Effective preventive measures cannot be equitably implemented in the absence of a targeted process that addresses the environmental health research needs of high risk workers and communities, especially communities of color.
II. Promote disease prevention and pollution prevention strategies. Although treating disease and cleaning up environmental hazards are essential, long-term solutions must rely upon truly preventive approaches.
III. Promote interagency coordination to ensure environmental justice. Although at-risk communities and workers are most threatened by occupational and environmental hazards, government agencies (federal, regional, state, local and tribal) are also important stakeholders. Unfortunately, environmental problems are not organized along departmental lines. Solutions require many agencies to work together effectively and efficiently.
IV. Provide effective outreach, education and communications. Findings of community-based research projects should be produced and shared with community members and workers in ways that are sensitive and respectful to race, ethnicity, gender, and language, culture, and in ways that promote public health action.
V. Design legislative and legal remedies. [No narrative accompanied this recommendation.]

These five elements were accompanied by specific strategies and activities recommended for pursuit by government and private sector entities. The five elements have had substantive impact on the federal government's environmental justice strategies, as described later in this chapter. During the conference, President Bill Clinton issued an executive order on environmental justice, which is described in a following section. The long-term effect of the executive order remains to be determined, but clearly the national environmental justice conference held in 1994 played a large role in the issuance of the executive order.

The events in Table 18.1 were seeds that planted environmental justice in the orchard of civil rights. A series of studies followed that tried to better define minority groups and persons of low income who are at health risk because of exposure to environmental hazards. Most of these studies concentrated on the demographics of populations living near uncontrolled hazardous waste sites or facilities permitted to treat, store, and disposal facilities (TSDFs).

18.3.3.5 Second National People of Color Environmental Leadership Summit, 2002

A decade after the First National People of Color Environmental Leadership Summit was held in 1991, the second summit occurred in October 2002 [22]. Summit II, held for 4 days in Washington, DC, commencing on October 28, brought together more than 1200 delegates who represented community and grassroots organizations, civil rights groups, organized labor, and academic institutions, among others. Delegates recommended that environmental justice must be a top priority in the twenty-first century. Delegates also reaffirmed the Principles of Environmental Justice (Table 18.2), which had been developed at Summit I. Summit II enlarged the networking of environmental justice organizations and gave special attention to the training of future environmental justice leaders, particularly young persons.

In addition to these five key conferences, seven reports of environmental injustice studies were also important for shaping opinions and actions on environmental justice. They are described in Section 18.3.4.

18.3.4 Seven Seminal Studies

Concerning environmental justice, are hazardous waste TSDFs and uncontrolled hazardous waste sites (i.e., CERCLAct sites) found more often in minority communities than elsewhere? Moreover, as to environmental justice, do data support the assertion that minority populations and persons of low income have been targeted for placement of TSDFs in their communities? Seven investigations attempted to bring light onto these and related questions.

18.3.4.1 GAO Study, 1983

In December 1982, following the Warren County, North Carolina, event, District of Columbia Delegate to Congress Walter Fauntroy (D-DC) and Congressman James Florio (D-NJ) requested GAO to "[d]etermine the correlation between the location of hazardous waste landfills and the racial and economic status of the surrounding communities" [12]. According to GAO, agreement with the study's requesters led to examining sites only in the eight southeastern states. The agreement also included examining only off-site landfills, those not contiguous to industrial facilities.

The GAO identified four operating landfills in the southeast that were receiving hazardous waste: Chemical Waste Management (CWM), Sumter County, Alabama; Industrial Chemical Company (ICC), Chester County, Alabama; SCA Services, Sumter County, South Carolina; and the Warren County PCB Landfill, North Carolina. For each site, Bureau of Census racial and economic data of 1980 were obtained for census areas in which the landfills were located and the census areas that had borders within about 4 miles of the landfill.

GAO found Blacks* were the majority population in census areas at three of the four sites: CWM, ICC, and Warren County PCB Landfill. At all four sites, Black populations in census areas containing landfills had mean incomes lower than the mean income for all races combined in the same census area. The data showed that percentages of Blacks in census tracts containing landfills generally mirrored the minority population of the counties in which the landfills were located. For all four sites, the mean family income for Blacks living within the landfills' census area was lower than the mean income for all races in the landfills' census areas. These data suggested to GAO that Blacks living near the four landfills had lower incomes than other persons in the areas. However, little in the GAO report sheds light on what factors led to each site's location. Nonetheless, GAO's findings added weight to the belief in 1982 that areas with high percentage of minorities were being targeted for location of hazardous waste sites.

18.3.4.2 United Church of Christ Report, 1987

Influenced by findings in the GAO report, the United Church of Christ's Commission for Social Justice (CSJ) conducted two studies to determine racial and socioeconomic characteristics of persons in the U.S. living (1) in residential areas surrounding commercial TSDFs and (2) near uncontrolled toxic waste sites [23].

The first CSJ study sought to determine whether the variables of race and socioeconomic status played significant roles in the location of commercial TSDFs. The methodological approach compared geographic characteristics presumed to be relevant to the siting of commercial hazardous waste facilities. The study analyzed five sets of national data: (1) minority percentage of the population, (2) mean household income, (3) mean value of owner-occupied homes, (4) number of uncontrolled toxic waste sites per 1000 persons, and (5) pounds of hazardous waste generated per person. Racial classifications were taken from the 1980 U.S. Census, and data on TSDFs were obtained from EPA databases.

Results of discriminant function analysis showed that minority percentage of the population was statistically significant in relation to the presence of TSDFs. The percentage of community residents that belonged to particular racial and ethnic groups was a stronger predictor of the level of commercial hazardous waste activity than was household income, the value of homes, the number of uncontrolled toxic waste sites, or the estimated amount of hazardous wastes generated by industry. A key finding was that in ZIP code areas† having one commercial TSDF operating in 1986, the percentage minority population, on average, was twice that of areas that did not contain TSDFs.

The second CSJ study was descriptive in nature. Its primary purposes were (1) measure the number of racial and ethnic persons who lived in residential areas where uncontrolled toxic waste sites were located and (2) make comparisons between the extent to which uncontrolled waste sites were located among different racial populations. Investigators used U.S. Census data for 1980 and data in EPA's national list of uncontrolled hazardous waste sites, which is called the Comprehensive Environmental Response, Compensation, and Liability Information System (CERCLIS; Chapter 12). At the time of the study, CERCLIS contained information on 18,164 uncontrolled toxic waste sites. Residential 5-digit ZIP code areas were used to define "communities."

The CSJ's descriptive study found the presence of uncontrolled waste sites to be "highly pervasive." More than half the U.S. population lived in residential ZIP code areas with one or more uncontrolled toxic waste sites. Moreover, three of every five African-American and Hispanics lived in communities with uncontrolled toxic waste sites, which amounted to more than 15 million African-Americans and 8 million Hispanics. The investigators estimated that 2 million Asian/Pacific Islanders and 700,000 Native Americans also lived in such communities.

18.3.4.3 Mohai and Bryant Study, 1992

Mohai and Bryant examined the regional demographics of persons living near 16 commercial TSDFs in three counties (Macomb, Oakland, Wayne) in the Detroit, Michigan, area [24]. Data on race and income were obtained from face-to-face interviews of persons in a sample of households selected with equal probability. An additional oversample was drawn of households within 1.5 miles of existing ($n=14$) and proposed TSDFs ($n=2$). Information about race and household income was obtained for 793 respondents; for analysis, all nonwhites were combined into one category "minority." Analyses were conducted of respondents living within 1 mile of a facility; from 1 to 1.5 miles of a facility; and persons living more than 1.5 miles from a facility. Results showed that percentage minority population and percentage below poverty level varied with distance from TSDF facilities. Within 1 mile, 48% were minority and 29% were below the poverty level; for 1–1.5 radial distances the corresponding numbers were 39% and 18%; and for more than 1.5 miles, 18% and 10%. Chi-square tests indicated all these percentage differences were statistically significant.

A second objective of the Mohai and Bryant study was to examine relationships between race and income on the

* The current, preferred terminology is African-Americans. Mention of Blacks is a consequence of terminology used by the investigators whose work is described herein.

† ZIP code areas are administrative units established by the U.S. Postal Service for the distribution of mail and do not generally respect political or census statistical area boundaries [26]. ZIP code areas for 1980 contained, on average, about twice as many persons (6500) as did census tracts (3900) [25].

distribution of commercial hazardous waste facilities. Multiple linear regression was used to test the strength of associations. Investigators tested whether race (coded as 1 = white and 0 = minority) and household income (measured in dollars) had independent relationships with the distance of residents from a TSDF. The investigators found that the relationship between race and location of TSDFs in the three-county area was independent of income. Moreover, race was the stronger predictor of proximity to a TSDF.

Mohai and Bryant concluded, "Review of 15 existing studies plus results of our Detroit area study provide clear and unequivocal evidence that income and racial biases in the distribution of environmental hazards exist. Our findings also appear to support the claims of those who have argued that race is more importantly related to the distribution of these hazards than income."

18.3.4.4 EPA Study, 1992

At the direction of EPA Administrator William Reilly, an EPA Environmental Equity Workgroup was formed in July 1990 to review evidence that racial minority and low-income communities bore disproportionate burdens of environmental risks. The workgroup conducted a comprehensive evaluation of the scientific literature on environmental justice and related issues, examined environmental and human exposure databases, and reviewed data collected by federal health agencies concerning the health status of minorities. The workgroup also reviewed socioeconomic data pertinent to environmental justice concerns.

Six findings came from these evaluations. Three were specific to risk communication and government policy issues, the other three were recommendations specific to human health and environmental hazards and are therefore more germane for purposes of this chapter. As quoted from the EPA Environmental Equity Workgroup's final report [4]:

1. There are clear differences between racial groups in terms of disease and death rates. There are limited data to explain the environmental contribution to these differences. In fact, there is a general lack of data on environmental health effects by race and income. For diseases that are known to have environmental causes, data are not typically disaggregated by race and socioeconomic group. The notable exception is lead poisoning. A significantly higher percentage of Black children compared with White children have unacceptably high blood lead levels.
2. Racial minority and low-income populations experience disproportionate exposures to selected air pollutants, hazardous waste facilities, contaminated fish and agricultural pesticides in the workplace. Exposure does not always result in an immediate or acute health effect. High exposures, and the possibility of chronic effects, are nevertheless a clear cause for health concerns.
3. Environmental and health data are not routinely collected and analyzed by income and race. Nor are data routinely collected on health risks posed by multiple industrial facilities, cumulative and synergistic effects, or multiple and different pathways of exposure. Risk assessment and risk management procedures are not in themselves biased against certain income or racial groups. However, risk assessment and risk management procedures can be improved to better take into account equity considerations.

The EPA found major limitations in the environmental and health databases pertinent to environmental justice issues. However, for three hazards compelling data supported an EPA finding that environmental exposures were disproportionately borne by minorities. The three hazards, air pollution, children's exposure to lead, and hazardous waste sites, and others in the EPA report are discussed herein.

Air pollution: As EPA noted, air pollution is primarily a problem of urban areas, where pollution emission densities are greatest [4]. The EPA noted that the percentages of various populations living in polluted urban areas differed by ethnic category: White (70.3%), Black (86.1%), Hispanic (91.2%), and Other (86.5%). Citing the work of Wernette and Nieves [26], who analyzed the demographics of areas that the EPA had designated as being out of compliance with the Clean Air Act (CAAct), the EPA concluded that minorities were disproportionately exposed to air pollutants. Data that undergirded EPA's conclusion are contained in Table 18.3. These data show the importance to minorities of attaining urban air quality standards under the CAAct.

TABLE 18.3
Percentages of Populations Living in Air Quality Nonattainment Areas

Air Pollutants	Whites (70.3% Urban)	Blacks (86.1% Urban)	Hispanics (92.2% Urban)
Particulate matter	14.7	16.5	34.0
Carbon monoxide	33.6	46.0	57.1
Ozone	52.5	62.2	71.2
Sulfur dioxide	7.0	12.1	5.7
Lead	6.0	9.2	18.5

Source: EPA (U.S. Environmental Protection Agency), Environmental justice, http://www.epa.gov/ebtpages/environmentaljustice.html, 2005.

The impact of air pollution on Hispanics is also a matter of concern. The National Coalition of Hispanic Health and Human Services Organizations (COSSMHO) has pointed out that reducing exposure to air pollution is a priority issue for Hispanic communities because, in an update of the data in Table 18.3, one organization noted that about 80% of Hispanics live in areas that did not attain air quality standards [27]. These locales failed to meet EPA ambient air quality standards. By updated comparison, about 65% of non-Hispanic blacks and 57% of non-Hispanic whites still live in nonattainment areas. The implication for Hispanics is a greater rate of respiratory morbidity and mortality and other adverse health effects than for other groups.

Children's lead exposure: The EPA concluded that children's exposure to lead was the environmental hazard for which the strongest evidence supported a disproportionate effect on minority populations [4]. Drawing upon data assembled by ATSDR [28], The EPA workgroup concluded that the evidence was unambiguous: children of color had higher blood lead levels (BLLs) than did White children. Moreover, all socioeconomic and racial groups had children with lead in their blood high enough to cause adverse health effects. This was found to be particularly true for African-American children. Lower family income was associated with higher prevalence of elevated BLLs in children.

Subsequent to the EPA report [4], the Centers for Disease Control and Prevention (CDC) updated their data on BLLs in young children [29]. CDC's National Health and Nutrition Examination Survey (NHANES) is a population-based, periodic series of national examinations of the health and nutritional status of the civilian, noninstitutionalized U.S. population. Geometric mean BLLs in the U.S. population, age 1 year and older, declined from 12.8 μg/dL in 1976–1980 to 2.3 μg/dL in 1991–1994, and further declined for the period 1999–2002 to 1.6 μg/dL [30]. This remarkable outcome is attributed largely to (1) removing lead from gasoline, which in turn reduced ambient air levels of lead, and (2) removal (or containment) of lead-containing paint in older housing. The reduction of lead levels in the U.S. population represents the single most successful environmental health outcome.

However impressive the decrease in the national mean BLL, disparities continue to exist across racial/cultural and income lines in the U.S. population. As shown in Table 18.4, the percentages of children, age 1–5 years (the age span of children's greatest BLLs), who have BLLs ≥10 μg/dL (i.e., CDC's action level*) were highest in urban, low-income, Black, non-Hispanic children [29]. Older housing containing lead-based paint accounts for much of this elevation in BLLs. In a subsequent update, CDC reported a continued decrease in the prevalence of BLLs ≥10 μg/dL in children aged 1–5 years living in the U.S. [30] (Table 18.4). CDC's analysis was based on BBL surveillance data for 1997–2001 [31] and 1999–2002 [30], using two data sources: NHANES data and state child blood lead surveillance data. According to CDC's study, the number of children aged 1–5 years in the U.S. reported with confirmed elevated BLLs ≥10 μg/dL decreased from an estimated 930,000 in 1991–1994 [29] to an estimate of about 310,000 in 1999–2002 [30]. As a matter of environmental health policy, having in place surveillance systems like NHANES and state-based reporting systems for collection of health data is an enormous resource for public health officials and decision-makers. Goals for achieving disease and disability prevention goals can be established and monitored through surveillance systems. Unfortunately, health surveillance systems are costly and some decision-makers (e.g., legislators) must be convinced of the systems' efficacy.

TABLE 18.4
Percentages of U.S. Children (1–5 years old) with BLLs ≥10 μg/dL

Race/Ethnicity Percentage	1997–1994	2001–2002
African-Americans, non-Hispanic	11.2	3.1
Mexican-American	4.0	2.0
White non-Hispanic	2.3	1.3
Income		
Low	8.0	
Middle	1.9	
High	1.0	

Source: CDC (Centers for Disease Control and Prevention), *Morb. Mort. Wkly. Rep.*, 46, 141–146, 1997.

Waste sites: EPA's [4] analysis of the impact of environmental hazards on minorities and low-income groups identified residence near CERCLAct sites and operating hazardous waste facilities as a matter of environmental inequity. Their conclusion was based on studies conducted by the United Church of Christ [26] and GAO [12]. These two reports were previously described in this chapter.

Water contamination problems: Scientists from EPA and public health agencies formed a panel to review the impact of contaminants in water on minorities and low income populations [32]. The panel used the Safe Drinking Water Act (SDWAct) and the Clean Water Act as background information against which relevant studies and reports were evaluated. The panel reviewed information about microbial content of water on tribal lands, drinking water quality in migrant worker camps, groundwater contamination from hazardous wastes in poor rural counties, drinking water quality and sanitation along the U.S./Mexico border, lead in drinking water, case studies on water quality problems on Navajo lands, and the consumption of fish from contaminated bodies of water. The panel found that most information was anecdotal or case studies and did not therefore lend itself to quantitative comparisons or analyses. However, the panel concluded, "Despite the sparseness and limitations of the data, the existing data suggest that environmental inequities exist. While the existing data do not support any broad nationwide pattern of inequity, there are, however, clear situations where certain populations

* No safe blood lead level in children has been identified. Even low levels of lead in blood have been shown to affect IQ, ability to pay attention, and academic achievement. And effects of lead exposure cannot be corrected. Experts now use a reference level of 5 μg/dL to identify children with blood lead levels that are much higher than most children's levels [33].

are exposed to higher levels of contaminants in water." The panel did not separate factors of low income and race/ethnicity in arriving at their conclusion. The panel advocated collection of additional data on water contamination and populations at health risk. Amendments to the SDWAct in 1996 contain the statutory directive to collect this kind of data.

Other environmental hazards: In addition to EPA's [4] analysis of air pollution, children's lead exposure, waste sites, and water contamination problems, consideration was also given to minorities' exposure to pesticides and the consumption of fish caught in bodies of water contaminated with toxicants. However, data were generally lacking that might relate those hazards to any inequities experienced by minorities.

In conclusion of their work, EPA's Environmental Equity Workgroup developed recommendations to the EPA Administrator on environmental justice issues [4]. They published their findings in a two-volume report entitled "Environmental Equity: Reducing Risk for All Communities." These findings led to the establishment of environmental justice policies and activities at EPA.

18.3.4.5 *National Law Journal* Study, 1992

Lavelle and Coyle of the *National Law Journal* examined 1177 of the 1206 National Priorities List (NPL) sites as of March 1992 [34]. They found that it took on average 5.6 years from time of waste site discovery until the site was placed on the NPL, but placing uncontrolled hazardous waste sites on the NPL took 20% longer in minority communities than in White communities. The investigators also analyzed outcomes of all environmental lawsuits filed in federal courts over a 7-year period. The average fine imposed for violating federal toxic waste laws in White residential areas, $335,566, was more than six times the average fine imposed in minority residential areas. The disparity occurred by race alone, not income; the average penalty in areas with the lowest median incomes was only 3% greater than the average penalty in areas with the highest median incomes.

18.3.4.6 Metzger et al. Study of Environmental Hazards and Hispanics' Health, 1995

Metzger and colleagues of the COSSMHO used the EPA's ranking to extrapolate the effect of environmental hazards on Hispanics' health [35]. The investigators noted that 22.4 million Hispanics are in the U.S. population, and the number would grow to 31 million by the year 2010. Metzger et al. cited EPA data indicating that Hispanic populations experienced greater health risks. They noted that 80% of Hispanics lived in areas that failed to meet at least one EPA air quality standard compared with 65% of African-Americans and 57% of whites. According to EPA data on air quality nonattainment areas, Hispanics are also more than twice as likely as either African-Americans or whites to live in areas that have elevated levels of particulate matter. Concerning workers' exposure to chemicals, Metzger et al. observed that 71% of all seasonal agricultural workers were Hispanic, compared with 23% who are white and 3% African-American. The use of pesticides in agricultural applications placed Hispanics at elevated health risk. Concerning indoor air pollution, Metzger et al. cited the failure to communicate to Hispanics the risk of radon in indoor air. They noted that 61% of Hispanics had never heard of radon compared with 21% of whites. Metzger et al. included the presence of lead and biologic contaminants in drinking water supplies as two examples of problems that some Hispanic populations face.

18.3.4.7 Maantay Study of Municipal Zoning Laws and Environmental Justice, 2002

How land is zoned for use can have serious environmental health consequences. For example, when polluting industries or waste management facilities are permitted by zoning laws to locate within residential areas, releases of hazardous substances can occur, placing residents at increased risk of adverse health effects. Juliana Maantay of the City University of New York reviewed New York City's zoning decisions between the years 1958–1990 in regard to potential environmental inequities [36]. In particular, changes in land designated as "M" zones (Manufacturing zones), were reviewed for location within the city's boroughs. Maantay's investigation concluded, "[T]hese zoning changes have had the effect of concentrating the noxious uses in the poorest and more minority neighborhoods." For example, the Bronx, the city's least affluent borough, had the most major increases in M zones. This study suggests, but does not prove, that zoning decisions discriminated against residents of poor and minority communities.

18.3.5 Demographics Investigations

The preceding section summarized several key studies that gave impetus to assessing environmental inequity concerns. However, these reports often had important methodological limitations such as the use of ZIP code areas for geographic analyses. Because the U.S. Postal Service developed ZIP codes to facilitate mail delivery, they are subject to change as the Postal Service refines mail delivery patterns. ZIP codes therefore represent variable geographic areas that can lead to uncertainties in demographic analyses. To avoid such methodological shortcomings, several researchers have conducted more in-depth demographic studies on associations among race, ethnicity, and socioeconomic variables as they relate to siting of hazardous waste facilities and location of CERCLAct sites. The key studies are summarized in this section.

18.3.5.1 Hird Study, 1993

John A. Hird, University of Massachusetts, examined three broad equity implications of the EPA CERCLAct program for environmental policy analysis [37]. He examined three elements of environmental justice: geographic distribution of NPL sites (i.e., CERCLAct sites, Chapter 12), who pays

for site cleanups, and the pace of cleanups. Only the first and third elements of his study will be summarized.*

To examine the distributional equity of NPL sites, data were collected on the socioeconomic characteristics of each county in the U.S. ($n=3139$) and the number of current or proposed NPL sites ($n=788$) in each county as of January 1, 1989. This permitted a determination of whether the number of NPL sites in each county was correlated with the socioeconomic characteristics of the surrounding area. Hird argued: "The county is both large enough to include the effects of hazardous waste sites, and small enough to record significant socioeconomic variation." His county-level socioeconomic data were obtained from the U.S. Census Bureau. The number of NPL sites per county was the dependent variable in a multivariate Tobit statistical analysis. Independent variables in the Tobit analysis included quantity of hazardous waste generated in each state; percentage of each county's economy attributable to manufacturing; percentage of college educated residents; percentage of housing units occupied by owners; the median housing value; and percentages of county residents that were unemployed, non-White, and below the mean poverty level.

Results showed the mean number of NPL sites per county was 0.37 (sd=1.28, $n=3139$). Manufacturing presence was strongly associated with more county NPL sites. Hird noted: "[t]he results indicate that more economically advantaged counties (in terms of both wealth and the absence of poverty) are likely to have more Superfund sites." For all 3139 counties, Hird found no statistically significant association nationally between poor counties and the number of NPL sites they contain. However, counties with high concentrations of nonwhites had *more* NPL sites than did others (holding other socioeconomic factors constant), an outcome that Hird characterized as "[c]orroborating the United Church of Christ [23] findings for all hazardous waste sites."

A different picture emerged about distribution of NPL sites when subsets of all counties were evaluated on the basis of their exceeding high rates of poverty ($n=1292$ counties), unemployment ($n=1274$), ethnicity ($n=1195$), or median housing values ($n=1254$). The average number of NPL sites per county was 0.11 in counties highly represented by persons of low income. For counties with high percentages of unemployed, the average number of NPL sites per county was 0.23; for counties with high percentages of nonwhites, the figure was 0.33 NPL sites per county. All three averages are therefore *below* the national average of 0.37 NPL sites per county. For the subset of counties with high median housing value, NPL sites per county was 0.74, which were higher than the national county average. Hird concluded, "Therefore, these results indicate that NPL sites are located predominately in affluent areas, and generally irrespective of race."

Concerning equity in cleanup of NPL sites, three measures of site remediation speed were used. Hird examined data from Remedial Investigation and Feasibility studies, Records of Decision for NPL sites, and actual remedial actions. Because these three events occur in temporal sequence, some indication of the remediation speed can be evaluated. The most important indicator of a site's cleanup stage was found to be the Hazard Ranking Score; that is, the higher the hazard scores, the faster the cleanups. No association was found between pace of site cleanup and the county's socioeconomic characteristics (which included the percentage of non-White population).

18.3.5.2 Anderton et al. Study, 1994

Investigators at the Social and Demographic Research Institute, University of Massachusetts, conducted a comprehensive study of the racial and cultural demographics and income levels of persons living near TSDFs [25,38]. These are commercial sites permitted to operate under the Resource Conservation and Recovery Act (RCRAct) (Chapter 12). Note the important difference between TSDFs, which are controlled hazardous waste facilities, and CERCLAct NPL sites, which are uncontrolled hazardous waste sites.

The Anderton et al. study is noteworthy because investigators examined the effect of using different geographic units on the outcome of demographics analyses. The investigators chose the census tract† as their primary geographic unit to avoid aggregation errors inherent in larger geographic units, such as ZIP code areas.

Commercial TSDFs were identified within census tracts for facilities that had opened for business before 1990 and were still operating in 1992. The investigators defined a TSDF as being privately owned and operated and receiving waste from firms of different ownership; TSDFs were excluded if they were the primary producers of waste. Before the 1990 census, tracts were defined only for Standard Metropolitan Statistical Areas (SMSAs).‡ About 15% of TSDFs are located outside SMSAs and hence were not included in the analysis. Using these criteria, 454 facilities were identified for demographic analysis.

The investigators' first analysis examined how census tracts with TSDFs differ from those without TSDFs. Comparisons were made of census tracts containing TSDFs with tracts that had TSDFs but within SMSAs that contained at least one facility inside their borders. This resulted in analysis of 408 tracts with TSDFs and 31,595 without. The mean percentages of African-Americans were 14.5% in census tracts with TSDFs and 15.2% in tracts without TSDFs; the difference was not statistically significant. The mean percentages of Hispanics were 9.4% in tracts with TSDFs and 7.7% for tracts without facilities, which were not statistically significant. Similarly, no statistically significant difference was found in

* This does not imply that who pays for site remediation is unimportant. Indeed, much of the controversy attending the CERCLAct is about the "polluter pays" principle that undergirds the statute (See [37]). However, who pays for site cleanups has not been part of the debate on environmental justice.

† Generally a census tract is a small statistical subdivision of a county. Census tracts have identifiable boundaries and average about 4000 persons [25].

‡ SMSAs consist of cities with populations of 50,000 or more persons including surrounding counties or urbanized areas but omitting many rural areas and small cities and towns [25].

the median percentage of Blacks residing in tracts with and without TSDFs, which led Anderton et al. [38] to observe, "This single finding is sufficient to raise substantial questions about the previously cited research conducted at a zip code level, and about its substantial influence on national policy."

The investigators found a substantially higher mean percentage of persons employed in precision manufacturing located in TSDF tracts (38.6%) than in surrounding areas (30.6%). This suggested that TSDF facilities are located in industrial areas for reasons unrelated to issues of race and ethnicity.

To determine whether environmental inequities differed for large cities, the census tract comparison was repeated for the 25 largest SMSAs. For these areas, TSDF tracts were found to have significantly lower percentages of Blacks, but larger percentages of Hispanics, compared with census tracts without TSDFs. For the 25 SMSAs, TSDF tracts had significantly higher levels of industrial employment, with less expensive and newer houses.

Anderton et al. next constructed larger areal units of analysis, consisting of all tracts with at least 50% of their areas falling within 2.5-mile radii of the center of tracts in which TSDFs were located. The percentage of Blacks in these larger areas (25.7%) was significantly higher than in other tracts (14.5%). For Hispanics, the comparable numbers were 11% versus 7% for other tracts. Furthermore, in these larger areas, industrial development remained significantly higher than in other tracts. A multivariate analysis using "Being a TSDF Tract" as the dependent measure showed, "[t]he most significant effects in each case are not those of percentage black or percentage Hispanic, but of unemployment and industrial employment within the area. For census tracts, the effects of percentage black and percentage Hispanic are not significant. However, in much larger areas [i.e., 2.5-mile radius areas], both variables appear to be associated with the presence of TSDFs."

In summary, Anderton et al. [38], using census tract-level data, found no nationally consistent and statistically significant differences between the racial or ethnic composition of tracts that contain commercial TSDFs and those that do not. The investigators noted that TSDFs were more likely to be found in tracts with Hispanic groups. In a companion paper [25], they concluded: "We believe our findings show that TSDFs are more likely to be attracted to industrial tracts and those tracts do not generally have a greater number of minority residents."

18.3.5.3 Zimmerman Study, 1993

Rae Zimmerman, New York University, used a unit of geographic analysis different from that used by Anderton et al. [38] to examine equity issues of relevance to NPL sites [39]. She focused on social and economic characteristics at the geographic level of communities, which she defined as U.S. Census "Places," or, where places do not exist, as "Minor Civil Divisions" (MCDs). She observes that these communities represent political subdivisions and are the smallest formal level of political decision-making.

In addition to assessing the demographics of populations living near NPL sites, Zimmerman evaluated whether the time taken to develop a Record of Decision (ROD)* for a site was associated, as a matter of environmental inequity, with minority communities. Zimmerman initially obtained demographics data for the 1090 sites on the NPL at the time of her analysis. Her list excluded sites in extremely rural areas whose community populations in 1980 were fewer than 2500. This resulted in excluding 260 sites, which she asserted, had minimal effect on her overall analysis. Characteristics of NPL communities were compared with the Nation and the four Census regions (Northeast, Midwest, South, West), based on 1990 Census data. Two methods of portraying average percentages for race, ethnicity, and poverty were used. One method was an unweighted averaging of means, counting each community equally regardless of its population. The second method weighted communities according to each community's population (total population as well as minority population). Zimmerman's findings differed according to which method she used.

Using the unweighted averaging method, Blacks represented an average of 9.1% of the population in 1990 for the approximately 800 NPL communities evaluated. This was lower than the national average of 12%. The percentages of Blacks in NPL communities were lower in three of the four U.S. Census regions. In the South census region, percentage of Blacks in NPL communities was 23.7% compared with 18.5% Blacks living in the census region. The percentage of Hispanics in NPL communities was 6.6% compared with 9.0% nationally; no notable regional differences were found. The mean percentage of persons below the poverty level was 10.6% in NPL communities compared with 13.5% for the nation.

When Zimmerman used the alternate approach of weighting minority populations by total population, the mean percentage of Blacks in NPL communities was 18.7% and for Hispanics was 13.7%. This was based on 622 Census Places and MCDs that contained 825 NPL sites. These percentages are greater than national percentages for Blacks (12.1%) and Hispanics (9.0%). She noted that differences in race and ethnicity between the two kinds of population analysis (i.e., nonweighted vs. weighted) reflects the effect of a relative few large communities with NPL sites that have large Black populations. She concluded, "Thus, racial and ethnic disproportionalities with respect to inactive hazardous waste site location seem to be concentrated in a relatively few areas."

18.3.5.4 GAO Study, 1995

The GAO conducted a multipurpose study in 1995 of persons living near nonhazardous municipal landfills [41]. The study was requested by Senator John Glenn (D-OH) and Congressman John Lewis (D-GA). The primary objective of the study was to evaluate demographics and income levels of

* An EPA Record of Decision discusses the various cleanup techniques that were considered for a site and explains why a particular course of action was selected [40].

persons living near the examined facilities. Another objective was to evaluate 10 published demographics studies of persons living near hazardous waste facilities. Other objectives were to examine the EPA's efforts to address environmental justice in their regulations, and to provide information on the extent of data that measure human health effects of waste facilities on minorities and persons of low income. Only findings from the study's first objective are summarized here.

To address demographics and income, GAO identified a potential universe of 4330 landfills in the U.S. This universe was subdivided, using ZIP codes of landfills, into categories of 1498 metropolitan and 2832 nonmetropolitan landfills. GAO used a questionnaire to survey landfill operators with equal probability in each landfill category. The survey elicited information on the geographic location and other characteristics of respondents' landfills. The final sample consisted of 190 metropolitan and 105 nonmetropolitan landfills. The demographics and income levels of persons living within 1 and 3 miles of these 295 landfills were evaluated.

Using a geographic information system (GIS) technique, the latitude and longitude for each site permitted defining two areas that separated landfills from the rest of the county. These areas were within 1 and 3 miles from the boundary of the landfill. To determine the demographics of persons within these two boundaries, GAO used the smallest level of aggregation possible, census block groups*, as their units of geographic analysis. GAO did not use census blocks† as their index because Bureau of Census data do not include information on residential income at the census block level.

The number of minorities and nonminorities living in complete and partial block groups was summed, using 1990 U.S. Census data, to determine the total number of persons living in the 1- or 3-mile areas. GAO found that minorities and persons of low income were not generally over represented near nonhazardous municipal landfills. For 73% of metropolitan landfills and 63% of nonmetropolitan landfills, percentages of minorities living within 1 mile of landfills were lower than percentages of minorities living in the rest of the counties. GAO estimated that people living within 1 mile of about half the landfills analyzed had median household incomes higher than the incomes of residents in the rest of the county. The same result occurred when the 3-mile areas were used for analysis.

GAO noted that actual data on exposure to hazardous substances of minorities and persons of low income were generally lacking. Furthermore, they cautioned that comparing demographics and income data across research studies was difficult, because investigators used U.S. Census databases and geographic units of analysis that differed across studies. Overall, GAO found only marginal support for the argument that minorities and persons of low income are disproportionately located near nonhazardous waste facilities, that is, TSDFs.

18.3.5.5 Been Study, 1995

A set of particularly noteworthy papers on environmental justice was published by Vicki Been, New York University School of Law [42–44]. The papers are noteworthy because of the clarity of writing, clear and logical arguments, and close attention to data analysis. In particular, Been's work on environmental justice issues should be compared with the work of Anderton et al. [25,38] because both investigators used similar databases and methods, but with somewhat different outcomes.

Been compared various characteristics of census tracts with TSDFs versus non-TSDF census tracts. In distinction to Anderton et al. [25,38], Been identified census tracts hosting TSDFs by examining TSDF listings in the 1994 edition of *Environmental Services Directory*, which she supplemented with an EPA database, the *Resource Conservation and Recovery Information System*. She used telephone contacts to verify the location and kind of operation of individual TSDFs. From these efforts, Been identified 608 TSDFs for analysis, which she asserts is more accurate than that used by other investigators.

Been conducted both univariate and multivariate analyses of characteristics between TSDF and non-TSDF census tracts. Landfills, incinerators, and kilns were separated as a group from other kinds of TSDFs to address whether different kinds of TSDFs were associated with racial, ethnicity, or socioeconomic characteristics. The breakout revealed no statistically significant differences in the mean percentages of African-Americans and lower-income persons living near this particular grouping of TSDF facilities.

To determine whether a smaller geographic comparison would change the nature of differences between TSDF and non-TSDF tracts, Been calculated ratios of the demographics of TSDF sites to demographics of all non-TSDF sites within a state and within a metropolitan statistical area (MSA). The mean of the ratios was tested for significance from unity, the ratio that would occur if the TSDF tracts' characteristics were identical to the non-TSDF tracts' characteristics. Using this approach, and using national demographics data, she found that percentages of African-Americans in TSDF tracts did not differ significantly from percentages in non-TSDF tracts. The percentage of Hispanics, however, was significantly greater for TSDF tracts than for non-TSDF tracts. These results for African-Americans and Hispanics maintained when comparisons were made within states. However, when comparisons were made within MSAs, African-American differences remained statistically insignificant and differences in percentages of Hispanics narrowed. Been noted that differences between median housing values in TSDF and non-TSDF tracts narrows considerably when only the host MSA is studied.

* Census block groups can be geographic block groups or tabulation block groups. The former are clusters of blocks having the same first digit of their three-digit identifying numbers within census tracts or block numbering areas. Tabulation block groups and geographic block groups may be split to present data for every unique combination of county subdivision, place, American Indian and Alaska Native area, urbanized area, voting district, urban/rural and congressional district shown in the data product [42].

† Census blocks are small areas bounded on all sides by visible features such as streets, roads, streams, and railroad tracks, and by invisible boundaries such as city, town, township, and county limits, property lines, and short, imaginary extensions of streets and roads [45].

Been extended her own work and that of others by examining not only the means of demographics variables (e.g., racial percentages), but also whether the distribution of TSDF facilities matched the distribution of populations around the mean. Been [44] assumed that a "fair" distribution of TSDF facilities would be proportionate to the distribution of the population. Using this assumption, she calculated the number of facilities that would be located in particular kinds of neighborhoods if distribution of TSDF facilities were proportionate. The results are fascinating. According to Been [44], "In terms of raw numbers, if the distribution of facilities followed the distribution of the population, there would be twenty-four more facilities sited in the neighborhoods with no or very few African-Americans. In neighborhoods where African-Americans made up more than 10% but less than 70% of the population, there would be thirty-four fewer facilities. Neighborhoods with African-American populations of more than 70% would have 10 more facilities. Similarly, neighborhoods with Hispanic populations of more than 20% are bearing more facilities than they should if facilities were distributed in the same way in the population." Been also found that neighborhoods with median family incomes of $10,001–$40,000 bear 62 more facilities than would be proportionate.

Been [44] concluded, "[a] more sophisticated comparison of the distribution of facilities to the distribution of neighborhoods with particular demographic characteristics reveals that certain kinds of neighborhoods—those with median family incomes between $10,001 and $40,000, those with African-American populations between 10% and 70%, those with Hispanic populations of more than 20%, and those with lower education attainment—are being asked to bear a disproportionate share of the Nation's facilities. Analysis of the joint distribution of income and percentage of African-Americans in the population suggests that income explains most of the disparity. Multivariate analysis, however, suggests that race is a better predictor of facilities than income. In total, the analysis reveals that environmental injustice is not a simplistic PIBBY—'put it in Black's backyards.' It suggest, instead, a much more ambiguous and complicated entanglement of class, race, educational attainment, occupational patterns, relationships between the metropolitan areas and rural or non-metropolitan cities, and possibly market dynamics."

18.3.5.6 Heitgerd et al. Study, 1995

Researchers at ATSDR used a GIS approach to assess the demographics of populations living near NPL sites [46]. Racial and Hispanic origin subpopulations living within 1 mile of NPL sites were compared with subpopulations in the same county but living outside the 1 mile border. The investigators extracted census block boundaries from the Bureau of Census' 1990 Topologically Integrated Geographic Encoding and Referencing/Line files and linked them with information on total population, race, and Hispanic-origin data in 1990 census block data. EPA-defined site boundaries were used to specify the boundaries of 1200 NPL sites.

Heitgerd et al. found that 670 counties had parts of their area located within 1 mile of the 1200 NPL sites they examined. This represented 22% of all counties in the contiguous states of the U.S. The areas within 1-mile borders of the 1200 NPL sites comprised 184,191 census blocks, of which 10.6% were within 1 mile of two or more NPL sites. Each site's demographics were derived for each county by summing over all census blocks within the 1-mile range. The investigators assert this shifts the focus of the demographics analysis from NPL sites *per se* to the counties within 1 mile of NPL sites while retaining block-level data. The comparison population was spatially defined as persons living in the 670 impacted counties but at distances greater than 1 mile from NPL sites. Population data for the comparison area were obtained by subtracting the site area data from county totals.

A 3-factor analysis of variance (ANOVA) model served as the investigators' statistical method. The factors used in the ANOVA analysis were NPL (2 levels—within or outside 1-mile buffers of NPL sites), State (48 contiguous states), and County (670 counties).

The investigators found approximately 11 million persons resided within 1-mile boundaries of the 1200 NPL sites they assessed. Fewer NPL sites were in the Great Plains states, and those sites accounted for relatively fewer persons compared with other regions. Additionally, an analysis of 972 NPL sites found that 949,000 children aged 6 years or younger resided within 1 mile of sites' borders, which represented 11% of the population. This is an average of 980 children aged 6 years or younger per NPL site. Given a total of about 1300 NPL sites, one can calculate that approximately 1.3 million young children resided within 1-mile borders of NPL sites.

Heitgerd et al. [46] concluded, "If it is assumed that the NPL sites are representative of all uncontrolled hazardous waste facilities, then the results support existing environmental inequity research that suggests the location of hazardous waste facilities is more burdensome for minority communities."

Because the Heitgerd et al. study relies on a GIS approach and uses county-based comparison data, it is an important contribution to the literature on environmental justice. Its limitations are the lack of control for sociodemographic variables (e.g., are the observed disparities the result of economic conditions?) and uncertainty about whether the demographic results might be a consequence of the 1-mile buffers chosen (e.g., would the results change if some other measure, perhaps, 0.5 mile, had been used?).

18.3.5.7 Oakes et al. Study, 1996

Building upon their previous cross-sectional work [25,38], researchers at the University of Massachusetts conducted the first national longitudinal study of residential characteristics in census tracts that contain TSDFs [47]. This study addresses the central issue in environmental justice as it relates to TSDFs, the issue of alleged racism in the deliberate siting of waste facilities in minority neighborhoods. Because the Oakes et al. study uses rigorous statistical analysis and current demographics databases, it is an important contribution to the scientific literature on environmental justice.

Oakes et al. evaluated community characteristics over a 20-year period before and after new TSDFs were sited. In a follow-up to previous findings [25,38] that indicated a relationship between TSDFs and the level of industrialization in a community, they compared trends within TSDF communities to other similar industrial communities and to less industrialized communities. Data on 476 commercial TSDFs were compiled from the 1992 edition of *Environmental Services Directory*, using a telephone survey of each facility. Analysis was restricted to census tracts within metropolitan statistical areas and rural counties that each contain at least one TSDF. There were 35,208 census tracts without TSDFs. Data on residential communities came from the 1970, 1980, and 1990 tract-level census files. Census data files contained more than 130 census variables that summarized tract composition. Special efforts were made to reconcile any changes in tract locations or TSDF locations due to changes in census track identification.

Oakes et al. first conducted a cross-sectional analysis using 1990 census tract data. They compared racial and economic indicators between tracts that had TSDFs and tracts that did not. Findings showed the average percentages of persons living in TSDF tracts who identified themselves as Black or Hispanic were 17.09 and 10.75, respectively, and for non-TSDF tracts, 16.26% Black and 9.74% Hispanic. These percentages for Blacks and Hispanics were not statistically significant between TSDF tracts and non-TSDF tracks. This result agrees with the researchers' prior report that used 1980 census data [25,38]. Oakes et al. commented, "The largest significant differences that were found between tracts with and without commercial TSDFs were in the average percentage (33.32% in TSDF tracts and 25.28% in non-TSDF tracts) and the median percentage of persons employed in industrial and manufacturing occupations." This again supports the conclusion of Anderton et al. [25,38] that TSDF tracts are somewhat more likely to be found in industrial working-class neighborhoods.

Oakes et al. then analyzed communities' characteristics across two decades, using 1970, 1980, and 1990 census data. They first assessed demographic and socioeconomic characterizations of communities before TSDFs were sited. They found that TSDFs located in the 1970s and 1980s were, on the average, not systematically sited in areas with unusually high percentages of African-American or Hispanic populations, when compared with other areas with significant industrial development. Moreover, results showed the characteristics of communities, after siting of TSDFs, have trends that parallel those in the population at large.

The researchers performed multivariate methods of analysis to examine whether siting of TSDFs was associated with racial or ethnic disparities and other indicators of environmental inequity. No evidence was found to support environmental inequity claims that TSDFs were sited in areas because of racial or ethnic bias. They concluded, "We believe this research, in concert with our earlier findings, suggests that commercial TSDF census-tract communities are best characterized as areas with largely white and disproportionately industrial working-class residential areas, a characterization consistent with what one might historically expect near industrial facilities."

18.3.5.8 Anderton et al. Study, 1997

Investigators at the University of Massachusetts conducted a comprehensive examination of CERCLIS and NPL sites for evidence of environmental injustices. CERCLIS hazardous waste sites are those reported to EPA, but have not been placed on the NPL. In a three-part investigation, demographic characteristics of CERCLIS sites were compared with those without such sites. Second the demographics of neighborhoods with NPL sites were compared to those with CERCLIS sites. Third, possible bias in how CERCLIS sites were prioritized as NPL sites were evaluated. For the purposes of this chapter, only the first study is described [48].

In the first study, 1990 U.S. Census data and EPA CERCLIS records were used to compare neighborhoods with CERCLIS sites against neighborhoods without any such sites. Data analysis showed the percentage of African-Americans residing in census tracts with CERCLIS sites was 11.6%, whereas for non-CERCLIS sites the percentage was 13.7%. Similarly, fewer Hispanics resided in CERCLIS tracts than in tracts without CERCLIS sites. However, the CERCLIS sites in non-metropolitan neighborhoods did contain larger percentages of Native Americans than in comparison tracts. Anderton et al. concluded, "[t]he early discovery of CERCLIS sites in minority neighborhoods does not support the hypothesis of bias in discovery processes."

18.3.5.9 Baden and Coursey Study, 1997

The environmental justice implications of locating waste sites within the city of Chicago were investigated by Baden and Coursey, University of Chicago, through demographic, social, and economic analysis [49]. The investigators examined locations of three kinds of waste sites: all CERCLIS sites and TSDFs within the city limits, RCRAct hazardous waste generators, and historical hazardous waste sites. Sites were examined with regard to racial, ethnic, and income variables; access to transportation; and waste disposal. Sites were linked with corresponding census tract information. Regression analysis was the primary statistical method used to associate geographic and demographic variables. Different kinds of regression analyses were used to investigate which demographic and physical features predicted the location of sites within limited communities, the location of sites within larger neighborhoods, and the geographic concentration of sites. Census and waste site data were specific to the years 1960 and 1990 for comparison.

Baden and Coursey found that waste sites in 1990 tended to be located in Chicago areas of low-population density near commercial waterways and commercial highways. They found no evidence of environmental racism against African-Americans for either CERCLAct sites or TSDFs. There was no indication that African-Americans lived in areas with higher concentrations of hazardous waste than did whites or Hispanics. Evidence showed that the percentage of Hispanics in an area was significant with regard to the location of CERCLAct sites and solid waste disposal facilities, perhaps because of recent migration of Hispanics into white ethnic

neighborhoods. Baden and Coursey observed: "Surprisingly, areas where RCRAct and solid waste disposal sites are located tend to have higher incomes; this is likely the result of the recent trend in construction of high price river-front residences in previously industrial areas." In summary, Baden and Coursey found little to no indication of environmental injustice in the location of hazardous waste sites and facilities within Chicago census tracts.

18.3.5.10 Carlin and Xia Study, 1999

Carlin and Xia, School of Public Health, University of Minnesota, used Bayesian hierarchical models to investigate geographic and racial associations between ambient ozone levels and rates of pediatric asthma emergency room (ER) visits in Atlanta, Georgia, for years 1993 through 1995 [50]. Local ozone air quality data were used to calculate 1- and 8-h (maximum) averages. Results showed "[t]he association between pediatric asthma ER visits and the percent blacks in a zip (i.e., ZIP code) is significant and positive; the fitted relative risk shows that a theoretical all-black zip would have relative risk nearly three times that of a comparative all-non-black zip." Further, an increase of about 2.6% for every 20 ppb increase in ozone level (8-h max value) was found. This study's design did not permit the identification of factors that might explain the racial disparity in asthma ER visits.

18.3.5.11 Davidson and Anderton Study, 2000

Davidson and Anderton, University of Massachusetts, investigated the association between RCRAct-governed facilities and indicators of environmental inequity [51]. This work extended previous work by Anderton and associates by considering additional TSDFs beyond their prior investigations. The census tract locations of 6550 RCRAct facilities were examined according to minority community composition and other demographic data. Tracts with at least one RCRAct facility were compared with tracks without an RCRAct facility. The authors found, "[t]hese findings suggest that tracts with RCRAct facilities may be described as working-class neighborhoods with a lower percentage of Hispanic and black residents (except in nonmetropolitan regions), higher levels of industrial employment, lower average levels of education, and more modest housing." This study's findings are similar to previous investigations of TSDFs, suggesting no environmental inequities according to racial and ethnic criteria.

18.3.5.12 Morello-Frosch et al. Study, 2002

Morello-Frosch and associates, San Francisco State University, summarized the findings of environmental justice investigations undertaken by an academic and community-based collaborative. In one study, the locations of TSDFs in Los Angeles, California, were examined for evidence of environmental inequalities [52]. Results showed those census tracks containing a TSDF or located within a 1-mile radius of a TSDF had significantly higher percentages of residents of color, lower per capita and household incomes, and a lower proportion of registered voters. In a second study of similar design and purpose, an analysis was conducted of air emissions reported to EPA's Toxics Release Inventory (TRI)* by sources in southern California. The study distinguished between all TRI facilities and those facilities releasing toxicants classified by EPA as being priority hazardous substances. Logistic regression analysis that controlled for income, industrial land use, and population density found that proportion of minority residents was significantly associated with proximity to a TRI facility. Potential biases in the study due to the nature of the collaborative project were not discussed.

18.3.5.13 Mohai and Saha Study, 2015

Paul Mohai, University of Michigan, and Robin Saha, University of Montana, conducted the first national-level environmental justice study to conduct longitudinal analyses using distance-based methods, an approach the investigators contend will help resolve the conflicting findings from other studies that used varying geographic scopes in their analyses. The investigators used a national database of commercial hazardous waste facilities (TSDFs) sited from 1966 to 1995 and examined the demographic composition of host neighborhoods around the time of siting and demographic changes that occurred after siting. Results indicated strong evidence of disparate siting for facilities sited in all time periods. The investigators noted that although some evidence of post-siting demographic changes was found, they were mostly a continuation of changes that occurred in the decade or two prior to siting, suggesting to the investigators that neighborhood transition serves to attract noxious facilities rather than the facilities themselves attracting people of color and low income populations. Mohai and Saha concluded, "[…] our findings show that rather than hazardous waste TSDFs 'attracting' people of color, neighborhoods with already disproportionate and growing concentrations of people of color appear to 'attract' new facility siting" [53].

18.3.6 Tabulation of Studies

The environmental justice findings from the demographic and other studies described in this chapter are summarized in Table 18.5. The table is broadly structured into investigations that focused on uncontrolled hazardous waste sites (HWS) and those focused on TSDFs. As shown in the table, the Anderton et al. [48] study, which examined CERCLIS sites, was unique and is highlighted in gray. Above it are studies of HWS; below are investigations of TSDFs. If one disregards those studies that were not independently peer reviewed (which is an expectation of contemporary science), the remaining studies cited in Table 18.5 point to a difference in environmental justice findings between HSW and TSDFs. There is an indication of excess numbers of minorities who reside near HWS. No similar pattern exists in regard to TSDFs. Of the studies that attempted to assess evidence of environmental injustice, i.e., determine if waste sites had been deliberately located in

* The TRI database was established under provisions of Title III of the Superfund Amendments and Reauthorization Act of 1986, as discussed in Chapter 12.

TABLE 18.5
Key Waste Site Studies Bearing on Environmental Justice

Author (Year)	Scope/Sites Studied	Geographic Unit	Excess in Minorities?	Environmental Injustice?[a]	External Peer Review?	Published?
CSJ (1987)	National/HWS, TSDFs	ZIP code	Yes	NI	No	No
Lavelle and Coyle (1992)	National/HWS (NPL)	None	NI	Yes?	?	Journal
Hird (1993)	National/HWS (NPL)	Counties	Yes	NI	Yes	Journal
Zimmerman (1993)	National/HWS (NPL)	Census places	Yes	NI	Yes	Journal
GAO (1995)	National/HWS	Census block group	No	NI	No	No
Heitgerd et al. (1995)	National/HWS (NPL)	Census block	Yes	NI	Yes	Journal
Anderton et al. (1997)	CERCLIS sites	Census tract	No	No	Yes	Journal
GAO (1983)	Regional/TSDFs	Census area	Yes	NI	No	No
Mohai and Bryant (1992)	Local/TSDFs (Detroit)	Individual TSDFs	Yes	NI	No?	Journal
Anderton et al. (1994)	National/TSDFs	Census tract	No	No	Yes	Journal
Been (1995)	National/TSDFs	Census tract	No	NI	Yes	Journal
Oakes et al. (1996)	National/TSDFs	Census tract	No	No	Yes	Journal
Baden and Coursey (1997)	National/HWS, TSDFs	Census tract	Yes (Hispanics)	No	Yes	Journal
Davidson and Anderton (2000)	RCRAct facilities	Census tract	No	No	Yes	Yes
Morello-Frosch et al. (2002)	TSDFs (Los Angeles)	Census tract	Yes	NI	Yes	Journal
Mohai and Saha (2015)	National/TSDFs	Distance-based	Yes	Yes	Yes	Journal

[a] Environmental justice refers to whether waste sites were deliberately sited in minority communities.

NI, not investigated; HWS, uncontrolled hazardous waste sites; NPL, National Priorities List; TSDFs, treatment, storage, and disposal facilities; ?, *uncertain action*.

minority or low-income areas, only the Mohai and Saha study of 2015 reported deliberate siting of waste facilities in minority communities.

In summary, the tabulated studies cited in Table 18.5 point to environmental inequity in regard to minorities who reside near HWS, but not for TSDFs. Further, the matter of environmental injustice, at least on a national scale, has generally yielded little compelling evidence, a conclusion that seems based on investigators' choice of the metrics of population exposure and location.

18.4 PRESIDENT CLINTON'S EXECUTIVE ORDER ON ENVIRONMENTAL JUSTICE

Any injustices that occur across cultural and racial groups related to exposure to environmental hazards must be prevented as a matter of fairness and social justice. On February 11, 1994, at the urging of environmental justice advocates, U.S. President Bill Clinton signed Executive Order 12898 entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations." Clinton's executive order is a prime example of the PACM policymaking model, as discussed in Chapter 2. As with all executive orders, this order applies only to federal agencies. Although state and local governments and private sector entities are not directly subject to executive orders, actions that federal agencies take under executive order can have substantial ripple effects on other levels of government and the private sector.

The Clinton Executive Order directs each federal agency to "[m]ake achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations" [54]. The several responsibilities prescribed in the executive order for federal agencies are outlined in the following section.

Creation of an interagency working group—The Administrator of EPA was directed to convene and chair an interagency federal working group on environmental justice. Members of the group include EPA, the Departments of Defense, Energy, Health and Human Services, Commerce, Housing and Urban Development, Agriculture, Transportation, Labor, Justice, Interior, and various White House offices.

Development of agency strategies—The executive order directs each federal agency to develop an agency-wide environmental justice strategy. Each agency's strategy must identify and address disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations.

Federal agency responsibilities for federal programs—Each federal agency is directed by the executive order to conduct its programs, policies, and activities that substantially affect human health or the environment in a manner that ensures against the effect of excluding persons from participation on the basis of race, color, or national origin.

Research, data collection, and analysis—The executive order mandates each federal agency, whenever practicable and appropriate, to collect, maintain, and analyze information assessing and comparing environmental and human health risks borne by populations identified by race, national origin, or income.

Subsistence consumption of fish and wildlife—The executive order requires federal agencies, whenever practicable and appropriate, to collect, maintain, and analyze information on the consumption patterns of populations who principally rely on fish and/or wildlife for subsistence. Agencies are directed to communicate to the public the risks of these consumption patterns.

Perspective: Although the federal government's environmental justice strategies are in place in compliance with the executive order, their impact on issues of environmental injustices are unclear.

18.5 GLOBAL PERSPECTIVE

As described in this chapter, environmental justice has developed as an agenda within the U.S. civil rights movement. On reflection, linkage between social justice and environmental justice seems a natural relationship within the U.S. political arena because both movements are rooted in issues of fairness and social change. But is environmental justice confined to the U.S. landscape? Do similar concerns exist in other countries about the impact of hazardous waste on the health and well-being of minority groups and persons of low income? To seek answers to these questions, an analysis was conducted of the single, most comprehensive international statement on environmental protection, which is known as *Agenda 21* (Chapter 2).

Agenda 21 was developed at the United Nations Conference on Environment and Development, which was held in Rio de Janeiro in 1992. *Agenda 21* is a document of 40 chapters, consisting of about 600 pages. A review of relevant chapters that might address environmental justice as a matter of national or international policy reveals no statements specific to this issue. In particular, *Agenda 21*'s Chapter 20, entitled "Environmentally Sound Management of Hazardous Wastes Including Prevention of Illegal International Traffic in Hazardous Wastes," makes no mention of the importance of ensuring that hazardous waste generation, transportation, storage, and disposal do not cause environmental injustices. A review of *Agenda 21*'s other chapters reveals a concern for the rights of indigenous peoples and acknowledges their historical commitment to protecting the environment, although this support for respecting the rights of indigenous peoples was not couched in the language of environmental justice.

It is curious why environmental justice did not elicit concern in the major international statement on the environment. However, assuming that environmental inequities can be prevented through the actions of informed persons who have access to political processes, *Agenda 21* provides some tangential support for environmental justice concerns. Specifically, the Preamble to §III of *Agenda 21* states [55]: "One of the fundamental prerequisites for the achievement of sustainable development is broad public participation in decision-making. Furthermore, in the more specific context of environment and development, the need for new forms of participation has emerged. *This includes the need of individuals, groups and organizations to participate in environmental impact assessment procedures and to know about and participate in decisions, particularly those which potentially affect the communities in which they live and work* (emphasis added). Individuals, groups, and organizations should have access to information relevant to environment and development held by national authorities, including information on products and activities that have or are likely to have a significant impact on the environment, and information on environmental protection measures."

Adherence to the philosophy highlighted in this statement from the United Nations Environment Program would help prevent environmental injustices.

Environmental justice has become a subject of concern in Australia, according to Lloyd-Smith and Bell [56]. To them, "[T]he term 'environmental justice' refers to the distribution and impacts of environmental problems as well as the policy responses to address them." Further, they assert "[E]nvironmental injustice focuses on the inequitable distribution of those who bear the risks." Both definitions, unlike those in the U.S., are not restricted to environmental hazards that are specific to racial or ethnic populations. Lloyd-Smith and Bell present two case studies of "toxic disputes" in Australia. One dispute pertains to residents' concerns about the effects of living near a hazardous waste dump. The other dispute pertained to the destruction of a huge stockpile of hazardous hexachlorobenzene waste. The authors' analysis of the two "toxic disputes" assert that both represented cases of environmental injustice, primarily because residents at each site did not have information equal to that of the government and private industry. Further, inequalities were manifest because residents living distant from the two hazardous waste sites derived benefits from industrial operations formerly on the sites, whereas those living near the sites had not.

The Australian authors' [56] notion of environmental justice and inequality illustrate how difficult it is to transfer the environmental concerns, policies, and practices of one country (e.g., the U.S.) to another. Each country, certainly those with democratic governments, will likely need to develop its own legal and ethical structure to address environmental justice and injustice issues. One country's issues may be quite different from those of another country. What constitutes "environmental justice" will be a key policy issue. Consider, e.g., the "environmental justice" issues in Central and Eastern Europe, where one source asserts that "[N]ational minorities are often subjects of environmental injustice" [57]. They claim that residents frequently became second class citizens when their traditional national borders changed and they became minority populations with a new country, citing such areas in the Balkans. These demographic changes occurred because of wars within the region.

Varga et al. [57] also cite "manipulated industrialization" as a characteristic feature of the fallen national communist regimes in Central and Eastern Europe, leading to non-remediated environmental hot spots that impact local residents and, sometimes, adjacent countries. The national governments in this region of Europe currently lack the political

imperatives and socioeconomic resources to develop and implement environmental justice infrastructure. Such an infrastructure will appear only when environmental activists and community groups bring sufficient pressure on their governments.

18.6 POVERTY AND ENVIRONMENTAL JUSTICE

Poverty is antithetical to good health. While this dictum may seem obvious to modern specialists in public health, in fact, the association between health and social conditions is a rather modern association. Public health historians credit Edwin Chadwick, a British lawyer of the early nineteenth century as one of the first persons to recognize that social conditions such as poverty, crowding, lack of social support systems, draconian work conditions, and limited educational opportunities are interrelated with disease and disability [58]. Among his many accomplishments was overseeing the construction of London's first sanitary sewer system, an accomplishment of significant public health benefit.

Modern public health practitioners recognize that conditions in the places where people live learn, work, and play affect a wide range of health risks and outcomes. As noted by CDC, "These conditions are known as social determinants of health (SDOH). We know that poverty limits access to healthy (sic) foods and safe neighborhoods and that more education is a predictor of better health. We also know that differences in health are striking in communities with poor SDOH such as unstable housing, low income, unsafe neighborhoods, or substandard education. By applying what we know about SDOH, we can not only improve individual and population health but also advance health equity" [59].

Given the preceding definition of SDOH, one might consider poverty (or low income) as a social determinant of environmental health. This assertion, framed in different words, is a reason why poverty is considered a component of environmental justice. Recalling EPA's definition of environmental justice, "[t]he fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies" [1], one notes the inclusion of income as a component.

One can assert that at the heart of environmental justice is resistance to the imposition of unwanted environmental hazards. But low income communities are often strapped in mobilizing the resources necessary to form resistance, leaving them vulnerable to placement of environmental hazards within their communities it is argued [e.g., 53]. Indeed, investigators of allegations of environmental injustice often relate their findings as low income communities of minority populations. For example, Mohai and Saha (2016) present their findings in terms of "targeting minority, low-income neighborhoods for hazardous waste sites." Similarly, Johnston et al. reported, "Wastewater disposal wells in southern Texas are disproportionately permitted in areas with higher proportions of people of color and residents living in poverty, a pattern known as "environmental injustice" [60].

18.7 TRIBAL ISSUES OF ENVIRONMENTAL JUSTICE

The social history of indigenous people in the U.S., Canada, Australia, and elsewhere reveals struggles of conflict and pursuit of cultural survival as majority populations, often via European colonization, imposed sociopolitical control. As but one example, the indigenous people of the Americas were forced to accommodate the sociopolitical control established by European governments (England, France, Holland, Portugal, Russia, and Spain). Tribal governments were permitted to form and function, but generally only within colonial policies and control. In the U.S., tribal nations (e.g., Sioux, Navajo) were considered sovereign, but within strictures of the U.S. Constitution.

Issues of environmental justice for U.S. tribal nations were not a feature of the early, formative days of the environmental justice movement. However, over time, tribes have become increasingly active in presenting environmental justice concerns. An illustration is the 2016 struggle surrounding proposed construction of the Dakota Access pipeline, which is a 1134-mile oil pipeline from North Dakota to Iowa. A section of the pipeline would cross the Missouri River at Lake Oahe, which would be half a mile upstream of the Standing Rock reservation. The Standing Rock Sioux tribe of North and South Dakota had sought a temporary halt to construction, which they said threatens water supplies and cultural sites. After a federal district court refused to grant an injunction to block the pipeline, the Obama administration reacted in 2016 by withholding construction permits required of three federal agencies. The Obama administration also said it would reassess how tribal input is taken into account in future similar project reviews, and whether the whole approval process needs a comprehensive overhaul [61]. However, the Trump administration in 2017 issued federal construction permits by the U.S. Army Corps of Engineers, thereby clearing the way for pipeline construction to proceed [61a].

The Dakota Access pipeline dispute contributed to U.S. Native American tribes and Canadian First Nations banding together to "collectively challenge and resist" proposals to build more pipelines from the tar sands in Alberta, Canada. At least 50 First Nations and tribes signed a treaty on September 22, 2016 at ceremonies held in Vancouver and Montreal. In the treaty, the native groups say the proposed projects "threaten many Indigenous Nations' territories, waterways, shores, and communities with the very real risk of toxic and hazardous oil spills." The alliance vows to work toward a "more equitable and sustainable future" [62].

In the U.S. awareness and concern of Native Americans for preservation of their cultural resources has resonated with many tribes. An example is a cultural resources issue faced by the Menominee tribe of Wisconsin. Downstream from the White Rapids, on the Menominee River, part of the former home of the tribe, is a proposed open-pit copper, gold, and zinc mine along the river on the Michigan side of the border. The Michigan Department of Environmental Quality announced their mining permit approval. The river and mine

are both off the Menominee reservation, but the river and land around it remain central to Menominee culture. As stated by one source, "That's the crux facing tribes across the nation today: Cultural resources—both on and off reservation—get sullied, destroyed, defaced by activities happening off reservation and forces beyond Native Americans' control." The tribe has appealed to the federal government for assistance in disallowing the mining site [63].

Perspective: Environmental justice has not often been a rallying cry by Native American tribes in the U.S. Concerns about protection of native lands, traditions, and cultural resources were voiced by tribal leaders, but not often in the context of environmental justice. This seems to be changing, as the three preceding examples imply. Tribes are banding together to garner support for protecting cultural resources such as rivers and burial grounds. One potential success of tribal efforts may be revisions in federal environmental permit policies such as dam constructions in order to require consideration of tribal traditions and cultural resources.

18.8 TITLE VI OF THE CIVIL RIGHTS ACT, 1964

On issues of environmental justice and other matters of civil rights, the EPA and other U.S. government agencies are accountable to the provisions of Title VI, 42 U.S.C. § 2000d et seq., which was enacted as part of the Civil Rights Act of 1964. Title VI prohibits discrimination on the basis of race, color, and national origin in programs and activities receiving federal financial assistance.

If a recipient of federal assistance is found to have discriminated and voluntary compliance cannot be achieved, the federal agency (e.g., EPA or FDA) providing the assistance should either initiate fund termination proceedings or refer the matter to the Department of Justice for appropriate legal action. Aggrieved individuals may file administrative complaints with the federal agency that provides funds to a recipient, or the individuals may file suit for appropriate relief in federal court. Title VI itself prohibits intentional discrimination. However, most funding agencies have regulations implementing Title VI that prohibit recipient practices that have the effect of discrimination on the basis of race, color, or national origin.

At the request of some U.S. states, the EPA developed and published guidance for recipients of EPA assistance who implement environmental permitting programs. The guidance discusses various approaches, and suggests tools that recipients can use to enhance the public involvement aspects of their current permitting programs. It also addresses potential issues related to Title VI of the Civil Rights Act of 1964 (Title VI) and EPA's regulations implementing Title VI at 40 C.F.R. Part 7. On March 21, 2006, EPA published in the *Federal Register* the final version entitled "Title VI Public Involvement Guidance for EPA Assistance Recipients Administering Environmental Permitting Programs (Recipient Guidance)." EPA's Office of Civil Rights has primary responsibility for administering the agency's Title VI programs and actions [64].

Pertaining to EPA's responsibilities under Title VI, the U.S. Commission on Civil Rights reviewed the agency's programs and outcome and issued findings critical of EPA. The Commission stated that EPA has a history of being unable to meet its regulatory deadlines and experiences extreme delays in responding to Title VI complaints in the area of environmental justice. Also noted was EPA's Office of Civil Rights had never made a formal finding of discrimination and has never denied or withdrawn financial assistance from a recipient in its entire history, and has no mandate to demand accountability within the EPA. The Commission noted that of the 25 complaints lodged with EPA's Office of Civil Rights between December 2015 and July 2016, 14 were rejected due to lack of jurisdiction, 2 were withdrawn by complainants and 2 were closed for lack of evidence. Further, as of June, the office had 32 cases pending jurisdictional review, the oldest from 2013, the Commission found. The Commission recommended that the EPA should add additional staff to its Office of Civil Rights in order to improve responsiveness to Title VI complaints [65]. The EPA voiced disagreement with the Commission's findings, asserting that the Commission's report contained errors of fact and interpretation.

18.9 NAACP ENVIRONMENTAL AND CLIMATE JUSTICE PROGRAM

Founded February 12, 1909, the NAACP is the oldest, largest and most widely recognized grassroots-based civil rights organization in the U.S. The NAACP Environmental and Climate Justice (ECJ) Program was created to provide resources and support community leadership in addressing this human and civil rights issue by advocating for these three objectives [65a]:

- Reduce Harmful Emissions, Particularly Greenhouse Gases: We combine action on shutting down coal plants and other toxic facilities at the local level, as well as building of new toxic facilities, with advocacy to strengthen development, monitoring, and enforcement of regulations at federal, state, and local levels. Also includes a focus on corporate responsibility and accountability.
- Advance Energy Efficiency and Clean Energy: We work at the state level on campaigns to pass renewable energy and energy efficiency standards while simultaneously working at the local level with small businesses, unions, and others on developing demonstration projects to ensure that communities of color are accessing revenue generation opportunities in the new energy economy, while providing safer, more sustainable mechanisms for managing energy needs for our communities and beyond.
- Strengthen Community Resilience and Livability: We work to ensure that communities are equipped to engage in sustainability/climate action planning that integrates policies and practices on advancing food justice, advocating for transportation equity, upholding civil and human rights in emergency management, and facilitate participatory democracy [65a].

18.10 PERSPECTIVE ON EVOLUTION OF ENVIRONMENTAL JUSTICE

The conferences, studies, reports, and policies cited in this chapter resulted from serious questions about inequities along racial and low-income groups in siting TSDFs and in remediating CERCLAct sites. Bullard [9,17], who conducted sociologic evaluations of several communities near waste sites and waste disposal facilities, concluded: "[t]here is mounting empirical evidence that people-of-color and low-income communities suffer disproportionately from facility siting decisions involving municipal landfills, incinerators, and hazardous-waste disposal facilities." Studies by the GAO [15] and the United Church of Christ [23] raised similar concerns about racially or culturally discriminatory actions that allegedly led to locating waste facilities in minority and low-income communities. Given that more than 30 years have passed since the GAO study of 1983, what do the data now suggest about environmental inequities and hazardous waste sites and other environmental hazards?

First, data are sufficient to show that some environmental hazards are not shared equally across racial, ethnic, and low-income groups in the U.S. For example, data are compelling that African-American and Hispanic children are exposed to environmental lead sources in percentages that exceed their White counterparts. The presence of lead in the paint of older housing is a primary reason, and older housing is associated with low household income. As the problem of lead exposure for young children illustrates, race and ethnicity are intertwined with socioeconomic factors for some environmental hazards. From a public health perspective, these intertwined relationships should be understood and factored into public health interventions that eliminate or minimize health risks.

Second, environmental justice issues about the location of hazardous waste sites have led to several demographic studies conducted since the late 1980s. The siting of hazardous waste TSDFs has stimulated a debate about the equity of site locations. Research on the demographics and socioeconomic characteristics of populations near hazardous waste sites has led to a better picture of what kinds of hazardous waste facilities and sites disproportionately impact minority groups and persons of low income.

The work of several investigators indicates that the method of selecting the geographic unit of analysis and the comparison data will determine how environmental justice questions are answered. Investigations that used large geographic units (e.g., ZIP code areas) generally show that African-American and Hispanic populations live near hazardous waste facilities (TSDFs and uncontrolled hazardous waste sites) in percentages that exceed their percentages in the U.S. population.

As the geographic unit of analysis is reduced in size from ZIP code areas to census tracts and census blocks, the question of minorities and low-income populations living near uncontrolled hazardous waste sites and TSDFs becomes clearer. Minorities appear to reside disproportionately near uncontrolled hazardous waste sites [37,39,46]. The finding of inequity in the percentages of Blacks, and to a lesser extent, Hispanics, living near NPL sites may, however, be primarily attributable to a subset of NPL sites with large minority populations [39].

However, in distinction to uncontrolled hazardous waste sites, using geographic units smaller than ZIP code areas—primarily census tracts—investigators found no disproportionate association of minorities residing near TSDFs versus living elsewhere [9,17,41].

Moreover, how investigators of environmental justice communities develop toxicity indicators of putative exposure to hazardous substances can lead to different study outcomes. For example, Cutter et al. [66] evaluated six different toxicity indicators, as applied to substances released from hazardous waste sites. Indices included Threshold Limit Values®, EPA Priority Chemical List, and the Environmental Defense Fund's Toxicity Equivalent Potential. Using the six toxicity indices, relative risk scores were calculated for the 426 facilities in South Carolina that comprised the state's Toxics Release Inventory. Findings from the study showed that the choice of toxicity indicator can result in different statistical and spacial variations in the results of investigations such as those investigating environmental justice claims.

The association between household income and persons' residential proximity to hazardous waste sites does not appear to be particularly significant. That is, household income is not a good predictor of a population's proximity to uncontrolled hazardous waste sites and TSDFs. The most consistent socioeconomic characteristic of communities near hazardous waste facilities and waste sites is the presence of manufacturing facilities, that is, hazardous waste facilities are located in industrial areas. What this finding portends for questions of environmental justice is unclear.

Two studies summarized in this chapter directly addressed the matter of racism and discriminatory actions putatively related to how TSDF facilities were sited. Oakes et al. analyzed communities' characteristics across two decades, using 1970, 1980, and 1990 census data. When they assessed the composition of communities before TSDFs were sited, they found, on average, that TSDFs sited in the 1970s and 1980s were not systematically in areas with unusually high percentages of African-American or Hispanic populations, compared with other areas that had significant industrial development. Moreover, results showed that characteristics of communities, after siting of TSDFs, have trends that mirror those in the population at large.

Conversely, Mohai and Saha conducted the first national-level environmental justice study to conduct longitudinal analyses using distance-based methods. The investigators used a national database of commercial hazardous waste facilities (TSDFs) sited from 1966 to 1995 and examined the demographic composition of host neighborhoods around the time of siting and demographic changes that occurred after siting. Mohai and Saha concluded "[…] our findings show that rather than hazardous waste TSDFs 'attracting' people of color, neighborhoods with already disproportionate and growing concentrations of people of color appear to 'attract' new facility siting" [53].

Other reviewers have assessed the adequacy of the environmental health literature cited in this chapter and presented their conclusions. One reviewer, who examined the literature on race, class, and environmental health, including much of the material described in this chapter [67], overlaid his review with editorial comments and recommendations on study designs and future research directions pertaining to environmental justice concerns. Brown concluded, "The overwhelming bulk of evidence supports the 'environmental justice' belief that environmental hazards are inequitably distributed by class, and especially race." He recommends that investigations into class and race issues move away from traditional epidemiological designs and toward in-depth ethnographic analysis of communities and neighborhoods. Brown's recommendation is predicated on the belief that traditional epidemiological designs exclude community input as a means of minimizing bias in the conduct of the epidemiological investigation. He offered no data to support his belief.

18.11 POLICY IMPLICATIONS OF ENVIRONMENTAL JUSTICE

Environmental justice has become an integral part of social justice policy and practice in the U.S. and elsewhere. The deliberate placement of environment hazards in communities of minority populations and/or low income is a breach of any framework of ethics. Although there is no comprehensive federal statute to prevent environmental injustices, litigation can be brought under civil rights statutes, both criminal and civil, and also litigated under common law. For example, some communities have successfully litigated against chemical companies that desired to expand their production facilities, thereby potentially increasing pollution in adjacent residential communities.

In addition to federal environmental justice policies, as expressed in Executive Order 12898, states have adopted various environmental justice policies. These policies vary according to each state's needs and conditions, although it is unclear if all states have developed environmental justice policies and resources. The following examples from the states of California, Illinois, Maryland, New York, and Washington will illustrate state-developed environmental justice policies.

California—"The Department of Toxic Substances Control is committed to ensuring that all of the state's population, without regard to color, national origin or income, are equally protected from adverse human or environmental effects as a result of the Department's policies, programs or activities. The Department will: 1. Ensure that, to the extent feasible, its decisions, actions and rulemaking avoid adding to disproportionate environmental and/or health impacts on affected communities and reduce disproportionate environmental and related health impacts on such communities. […] 4. Allocate its permitting, enforcement and clean-up resources, to the extent feasible, so as to reduce disproportionate environmental and related health impacts on ethnic minority and low-income communities. […]" [68].

Illinois—"The Illinois Environmental Protection Agency (Illinois EPA or Agency) is committed to protecting the health of the citizens of Illinois and its environment, and to promoting environmental equity in the administration of its programs to the extent it may do so legally and practicably. The Illinois EPA supports the objectives of achieving environmental justice for all of the citizens of Illinois. Key goals of this policy are as follows: 1) to ensure that communities are not disproportionately impacted by degradation of the environment or receive a less than equitable share of environmental protection and benefits; 2) to strengthen the public's involvement in environmental decision-making, including permitting and regulation, and where practicable, enforcement matters; 3) to ensure that Agency personnel use a common approach to addressing EJ issues; and 4) to ensure that the Illinois EPA continues to refine its environmental justice strategy to ensure that it continues to protect the health of the citizens of Illinois and its environment, promotes environmental equity in the administration of its programs, and is responsive to the communities it serves. […]" [69].

Maryland—"In March 2001, the Governor created the Commission on Environmental Justice and Sustainable Communities […]. The Commission advises State agencies on issues related to environmental justice and sustainable communities. With the Children's Environmental Health and Protection Advisory Council, it coordinates recommendations on such issues. The Commission analyzes and reviews what impact current State laws, regulations, and policy have on the equitable treatment and protection of communities threatened by development or environmental pollution, and determines what areas in the State need immediate attention. The Commission assesses the adequacy of current statutes to ensure environmental justice, and develops criteria to pinpoint which communities need sustaining. […]" [70].

New York—"This policy provides guidance for incorporating environmental justice concerns into the New York State Department of Environmental Conservation (DEC) environmental permit review process and the DEC application of the State Environmental Quality Review Act. The policy also incorporates environmental justice concerns into some aspects of the DEC's enforcement program, grants program and public participation provisions. The policy is written to assist DEC staff, the regulated community and the public in understanding the requirements and review process. […] It is the general policy of DEC to promote environmental justice and incorporate measures for achieving

environmental justice into its programs, policies, regulations, legislative proposals and activities. This policy is specifically intended to ensure that DEC's environmental permit process promotes environmental justice. […]" [71].

Washington—"The Washington State Board of Health's Environmental Justice Committee recognizes the progress that many community organizations, businesses, industries, and agencies have made in reducing pollution sources and minimizing the impact these sources have on human health. These guidelines are intended to build on these successes and promote and even more healthy and equitable environment for everyone. […] The Board's Environmental Justice guidelines ask that: 1. All environmental and public health laws and regulations are equitably enforced in all communities. 2. Policymakers use a combination of scientific evidence, traditional knowledge, and public testimony in their decision-making process. […]" [72].

Although these five states are but 10% of all states, some interesting policy observations can be gleaned from their environmental justice policies. First, environmental justice responsibilities are housed in different administrative offices across states, reflecting each state's sense of its environmental justice responsibilities. It is also noteworthy that three of the five states use their permit authorities as a means to identify environmental justice issues. This is an example of how a regulatory mechanism, permits, can be used for larger social purposes.

18.12 SUMMARY

If one accepts the premise that the search for environmental justice, framed as a political and societal movement, leads inevitably to confrontation raises the question whether a better approach might exist. A lesson from the CERCLAct is instructive. The statute contains the "polluter-pays" principle, which necessarily leads to assessing blame; that is, identifying which parties are responsible for paying the costs of remediating hazardous waste sites (Chapters 1 and 8). This has resulted in assessing blame, which has caused confrontation, conflict, and litigation. Will environmental justice, with its tendency to assign blame for allegedly targeting minority communities as sites for hazardous waste sites, suffer the same fate as the CERCLAct? The question cannot be answered yet, but some would argue that a philosophical focus on equity rather than justice might achieve better results.

Given the level of concern that environmental injustices be prevented, the policies and actions already set in motion will likely result in fewer minorities and persons of low income being exposed to environmental hazards. This is a very desirable outcome in terms of both public health and social justice. Government efforts to collect data on the impacts of environmental hazards on minorities and to ensure that federal policies do not create environmental inequities will be important. Furthermore, strengthening the training and education programs that inform communities about their environmental status will be required. A commitment to enhance the number and diversity of environmental justice and environmental professionals must be allied with such efforts.

The importance of fairness will be the centerpiece of whatever gets done. The U.S. public gives strong support to actions predicated on what is fair. Changes in voting rights legislation and fairness in job opportunities are examples of fairness translated into statutory action. Having minorities and persons of low income experience a disproportionate burden of environmental health hazards is unfair and antithetical to social advancement. Environmental justice can redress many of these inequities through improved data collection, culturally-sensitive environmental policies, and heightened consciousness.

Culturally-sensitive environmental policies could become an important strategy in preventing instances of environmental injustice. In particular, since the establishment of new or modified environmental hazards such as landfills and incinerators generally requires permits from a state or municipal authority, permit policies that include analysis of potential environmental injustices are encouraged.

18.13 POLICY QUESTIONS

1. Using the material in Chapter 18, together with any auxiliary material, discuss which of these terms is preferable: *environmental racism, environmental justice*, or *environmental equity* for each of the following situations: (a) Assume you are a member of a community group that is concerned about a local landfill, (b) assume you are a senior policymaker at the EPA, and (c) assume you are a local public health official. Use critical thinking (as described in Chapter 1) for each of these three cases.
2. Examine the 17 elements of Principles of Environmental Justice (Table 18.2), as developed in 1991 at the First People of Color Environmental Leadership Summit. Select any 3 of the 17 elements and critically discuss how they could be made into policy by local governments, e.g., county commissioners. Discuss how the selected elements could be made operational as county policy.
3. Draw a random sample of five U.S. states, and then use Internet resources to determine each state's environmental justice/justice (EJ) resources and policies. Rank the five states in terms of their commitment to achieving EJ goals.
4. Select three federal government agencies and query their websites for material on their actions in compliance with Presidential Executive Order 12898. Compare and rank each agency's responsiveness to the Order.
5. Using Internet resources assess the policies and products of EPA's National Environmental Justice Advisory Committee (NEJAC). What policies seem particularly important to you in regard to preventing environmental injustices to minority and/or low-income populations?

6. Assume that you are a senior environmental health advisor to the director of the local health department. A community EJ group has asked to meet with the director for purpose of presenting health concerns about odors emanating from a local landfill. The director has asked for your advice as how to respond to the group's request. Detail your advice. Be specific, stating reasons for each recommendation that you provide to the director.
7. How do the demographics investigations of persons residing near hazardous waste sites differentiate between residential proximity to NPL sites and RCRAct facilities?
8. Several reports on EJ were not peer reviewed nor published in the peer-reviewed scientific literature (Table 18.5). Yet these reports had in their time a great impact on EJ concerns and directions. Given their lack of peer review, should the reports have been ignored?
9. Choose any one of the demographics investigations described in Chapter 18 and evaluate its strengths and limitations.
10. How would you strengthen *Agenda 21* for relevance to EJ? Provide details.
11. Are there any federally recognized Native American tribes residing in your state of residence? If yes, choose one tribe and investigate whether they have publicly expressed any environmental justice concerns. If there are no tribes in your state of residence, select an adjacent state and conduct the requested investigation.
12. Poverty (or low income) is considered by CDC as one of several social determinants of health (SDOH). Using data from CDC and other sources, prepare an essay of appropriate depth that summarizes how specific SDOHs impact young children's health.
13. Using the essay you developed in response to Question 12, describe how each of the SDOHs can be made more severe through experiencing environmental injustice.
14. As noted in Chapter 12, the federal SWAct, as amended, requires states to issue permits for the placement of new landfills and incinerators prior to their placement. Examine your state's permit regulations and procedures and ascertain if concerns for preventing environmental injustice are incorporated in the regulations.
15. In your opinion, does the EPA's definition of environmental justice need revision? If so, how? If not, why not? Be specific.
16. Using Internet resources, research other definitions of environmental justice. List each source and quote each definition. Which definition do you prefer? And why? Be specific.
17. The requirements of Title VI of the U.S. Civil Rights Act were summarized in this chapter. Using Internet resources, access the website of the U.S. Department of Justice and examine their published procedures for investigating Title VI complaints of civil rights violations. Have any complaints been based on environmental justice allegations? Do the DoJ's procedures seem adequate to you, assuming that you are a member of a community group that is protesting the proposed placement of a new incinerator in your community?
18. Both Canada and Australia are countries with large, important populations of native people. Select one of these countries and research that country's policy on assuring environmental equity. Contrast the chosen country's policy with that of the U.S.
19. The Flint, Michigan, water contamination crisis was presented as a case study in Chapter 9. Some critics of the events that led to the crisis have alleged that the Flint water crisis is an example of environmental injustice. Using Internet resources, research news clips of sources that made such allegations. Do you agree with their allegations and characterization? If so, why? If not, why not? Be specific.
20. After considering the material in this chapter, discusses the three most important lessons you learned. Was your personal environmental health behavior changed by the content of this chapter? If so, how? If not, why not?

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19 Policy Impacts of Risk Assessment

19.1 INTRODUCTION*

The development of a comprehensive set of federal laws to protect the environment and human health was discussed in Chapters 6 through 12. The key laws are built upon a regulatory structure, most often using a command-and-control approach. In particular, the Clean Air Act (CAAct), Clean Water Act (CWAct), Safe Drinking Water Act (SDWAct), Superfund Act, and their amendments, direct the EPA to establish standards for pollutants in air, water, and soil, respectively. Over time, the EPA and other regulatory agencies (e.g., OSHA, FDA) have turned to risk assessment as the method of choice for developing their standards and guidelines for exposure to hazardous substances. The evolution of health and ecological risk assessments from a regulatory method of convenience to becoming a driver of national environmental policies is best appreciated by reviewing how risk assessment evolved in U.S. regulatory agencies, followed by how risk assessment is applied to reducing the consequences of environmental hazards.

This chapter describes the evolution of risk assessment as a means to facilitate the development and implementation of environmental health policy, the different kinds of risk assessments currently in practice, the uses of risk assessment for management of environmental hazards, and the debate between risk assessors and public health practitioners on how best to assess and manage environmental hazards. Of particular importance will be a description of the four-step health risk assessment process, as illustrated in Figure 19.1. Application of risk assessment as a means to compare the importance of individual environmental hazards is discussed, along with differences in perception between public health specialists and risk assessors as to the applicability of risk assessment for public health purposes. This chapter is oriented around the evolution of risk assessment policy, rather than a "how to" chapter on conducting risk assessments. Several sources are available elsewhere that describe how to perform risk assessments (e.g., [1,2]).

Hazard: Potential for radiation, a chemical, or other pollutant to cause human illness or injury [3].

Risk: A measure of the probability that damage to life, health, property, and/or the environment will occur as a result of a given hazard [3].

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19.2 KEY DEFINITIONS AND ABBREVIATIONS

Before proceeding further, it is important to define key terms used throughout this chapter. The following set of definitions are those used by the EPA and were chosen for use in this chapter [3], unless cited to the contrary. However, it should be noted that other definitions are available for some of these terms. Key definitions pertaining to risk assessment include the following:

- *Hazard*: Potential for radiation, a chemical, or other pollutant to cause human illness or injury
- *Hazard assessment*: Evaluating the effects of a stressor or determining a margin of safety (MOS) for an organism by comparing the concentration which causes toxic effects with an estimate of exposure to the organism
- *Hazard evaluation*: A component of risk evaluation that involves gathering and evaluating data on the types of health injuries or diseases that may be produced by a chemical and on the conditions of exposure under which such health effects are produced
- *Hazard identification*: A process used to identify possible situations where people may be exposed to injury, illness, or disease; the type of injury or illness that may result from these; and the way in which work is organized and managed
- *Hazard quotient*: The ratio of the potential exposure to the substance and the level at which no adverse effects are expected. A hazard quotient less than or equal to 1 indicates that adverse noncancer effects are not likely to occur, and thus can be considered to have negligible hazard
- *Risk*: A measure of the probability that damage to life, health, property, and/or the environment will occur as a result of a given hazard
- *Risk assessment*: Qualitative and quantitative evaluation of the risk posed to human health and/or the environment by the actual or potential presence and/or use of specific pollutants
- *Risk estimate*: A description of the probability that organisms exposed to a specific dose of a chemical or other pollutant will develop an adverse response, e.g., cancer

Regarding the definition of risk assessment, the National Research Council (NRC) previously defined it as, "[r]isk assessment means the characterization of the potential adverse health effects of human exposures to environmental hazards" [4]. This definition was developed for application to

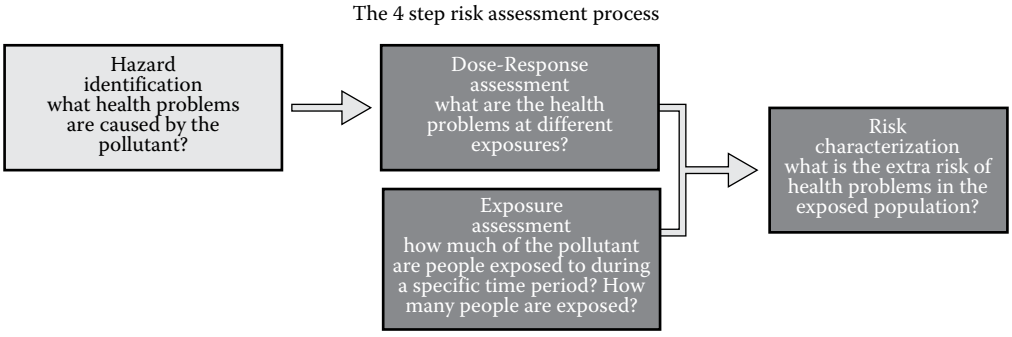

FIGURE 19.1 The four elements of health risk assessment. (From EPA, https://www.epa.gov/risk/conducting-human-health-risk-assessment, 2016.)

situations of human exposure. As the concept and methods of risk assessment expanded to include ecological situations and occupational injuries, other definitions have emerged that are specific to their situations. These condition-specific situations of risk assessment will be discussed later in this chapter.

Regarding key definitions and abbreviations, it is important to present two other definitions of hazard and risk. A non-EPA source defines "*Hazard* is a factor or exposure that may adversely affect health. *Risk* is the probability that an event will occur" [5]. Examples of environmental hazards are air pollutants, adulterated food, and radiation. We all experience some environmental hazards in our everyday life, e.g., minute or trace amounts of air or water contaminants. Whether hazard causes harm to human or ecological health depends on such factors as extent of exposure, potency of a toxicant, and susceptibility factors such as age and health condition. The extent to which exposure to a hazard has the potential to cause harm can be expressed as the risk, i.e., the probability that the exposure will be harmful.

Risk assessment is the qualitative and quantitative evaluation of the risk posed to human health and/or the environment by the actual or potential presence and/or use of specific pollutants [3].

It needs to be noted that risk assessments and hazard evaluations heavily rely on toxicologic data as the primary source of information upon which to base calculations and inferences. Data and findings from epidemiological investigations are equally or more important, but are often less available than toxicologic data.

19.3 EVOLUTION OF RISK ASSESSMENT IN THE U.S.

While the term *risk assessment* is a relatively new term in regard to environmental regulations and public health practice, the concept of trying to determine the consequences of exposure to environmental hazards and their potential impact on human health is not new. Indeed, as humankind evolved, our distant ancestors had to constantly assess the consequences of hazards around them. Will wild animals harm us? Will the tribes migrating into our area be warlike? Will forest fire destroy us? These kinds of questions relate to survival of individuals and groups of people, and assessment of hazards still remains a human endeavor today.

Hazards to public health have long been of great interest to governments and health specialists. Problems of contaminated water, in particular, and waste management were issues of concern in the U.S. in the eighteenth century and continued thereafter. More recently, in the twentieth and twenty-first centuries, health hazards from industrialization, pests (e.g., West Nile fever from migratory mosquitoes), and biological weapons of terror have been added to the public health agenda. These kinds of threats to the public's health have historically been approached using the traditional public approach of hazard evaluation (i.e., assess the nature and severity of a hazard but not necessarily calculate a risk estimate).

Public health hazard evaluations conducted by federal authorities consist of: assess the relevant scientific findings, develop consensus about the threat to public health, and provide services to potentially affected populations, particularly through assistance to state and local health departments. In distinction, federal regulatory risk assessment consists of: risk assessment, risk management via regulatory actions, and services to affected populations, particularly state environmental departments.

The professional disciplines of risk assessors have expanded over time. Probably the earliest risk assessors (although not called such) were radiation biologists, persons interested in the biological hazard of radiation. This kind of risk assessment began early in the twentieth century and continues today. As U.S. industry expanded during and following World War II, concerns about workplace hazards grew, but at a rate slower than industrial expansion. Industrial hygienists, persons with specialty training in chemistry, toxicology, and industrial processes, conducted safety assessments of workplace substances and workers' exposure conditions. Such assessments considered the toxicology of a substance of concern, sometimes using the results from their company's own toxicology studies, and workplace exposure data.

The need for assessment of occupational hazards contributed to the creation in 1938 of a key organization, the National Conference of Governmental Industrial Hygienists. The organization originally limited its membership to two representatives from each federal government agency containing industrial hygiene programs. The Threshold Limit Values Chemical

Substances Committee was established in 1941 [6]. This group was charged with recommending exposure limits for chemical substances in the workplace. This remains this committee's primary work. In 1946, the parent organization changed its name to the American Conference of Governmental Industrial Hygienists (ACGIH) and has broadened its membership from only industrial hygienists to other relevant disciplines, e.g., toxicologists. Moreover, government employees who served on ACGIH's committees represented only themselves, not the government agencies with which they were affiliated.

ACGIH's Threshold Limit Values (TLVs)* are developed by scientists from government, private industry, and academia. They are advisory guidelines, i.e., they do not carry the weight of law. However, the TLVs have had a significant impact on workplace standards. They were adopted by the newly-created OSHA in the early 1970s as Permissible Exposure Limits (PELs), owing to OSHA's quick need for legally enforceable workplace standards for workplace hazardous substances. PELs are legally enforceable by OSHA under authorities in the OSHAct (Chapter 4). Some states and other countries have adopted specific TLVs for their own uses, although ACGIH cautions that TLVs should not be adopted as standards without an analysis of other factors necessary to make risk management decisions [6]. Some persons have questioned the substantial role of industry representatives in the work of TLV committees [7,8]. They assert that industry scientists were given primary responsibility for developing TLVs on proprietary chemicals produced by their employers, suggesting a possible conflict of interest. However, it is worth mentioning that in general TLVs are more conservative (i.e., lower) than PELs and TLVs can be updated more quickly than PELs, which require public review and comment, providing TLVs with considerable flexibility in application.

As a matter of policy, should government agencies such as OSHA adopt exposure limits (e.g., TLVs) that are developed by nongovernmental organizations (e.g., ACGIH) that do not provide opportunities for public participation to review and comment on proposed exposure limits? This is a difficult question, because a case can be made for either adoption or rejection of nongovernment derived exposure limits. Adoption *en masse* of the TLVs gave a nascent OSHA a set of PELs circa 1970 that could be enforced by the agency. Rejection of the TLVs would have forced OSHA to establish, working through a process that would allow the public's involvement, PELs for individual chemicals on a case-by-case basis. This mechanism would have been met with industry opposition and fallen victim to protracted litigation, one chemical at a time.

19.4 U.S. FEDERAL GOVERNMENT'S INVOLVEMENT

Though the early 1950s, federal public health authorities conducted hazard evaluations (i.e., the qualitative evaluation of the adverse health effects of a substance(s) in animals or in humans), which were advisory to states and local health departments. The advisories did not bear the weight of regulatory imperative, but were effective to some degree because they emanated from a trusted source, often the Office of Surgeon General. This lack of legal authority began to change with the enactment of the Air Pollution Control Act Amendments of 1963. The federal DHEW† was directed to develop air quality criteria that were to be "an expression of the scientific knowledge of the effect of various concentrations of pollutants depending on the intended use of a particular [m]ass of air" [9]. However, these criteria were merely advisory and U.S. states' air pollution control agencies were not mandated to adopt the air quality criteria. Nevertheless, the die had been cast, with later Congressional environmental legislation that mandated the EPA to develop environmental standards, using risk assessment methods.

The concepts of hazard and risk are nothing new. However, what is new is the development and formalization of risk assessment as a body of both scholarship and practice used to aid policy decisions on the consequences of exposure to individual hazards in the environment. In particular, federal government regulatory agencies such as the EPA and OSHA use risk assessment to evaluate the importance of various levels of toxicants in the atmosphere and the workplace, respectively.

Current risk assessment policies and practices at EPA have evolved over two decades. With the establishment of the EPA in 1970 came the statutory responsibility to set air and water quality standards for toxicants in the environment. Similarly, the OSHAct of 1970 required OSHA to regulate workplace conditions, including control of workplace hazards through PELs. PELs are enforceable under federal and state laws, i.e., employers can be fined if PELs are exceeded. The same act directed the National Institute for Safety and Health (NIOSH)‡ to develop and disseminate criteria documents that would contain Recommended Exposure Levels (RELs) for specific toxicants and physical agents in U.S. workplaces. Therefore the EPA, NIOSH, and OSHA were all faced with how to evaluate environmental hazards and develop exposure recommendations (NIOSH) or standards (EPA, OSHA). An early challenge to the EPA and OSHA was how to establish standards in ways that would withstand judicial review. Other federal regulatory agencies had the same need in 1977, leading to the formation of the Interagency Liaison Regulatory Group (ILRG).

The ILRG consisted of representatives from the four primary regulatory agencies involved with particular environmental hazards: the EPA, OSHA, FDA, and the CPSC. The ILRG was an attempt by the Carter administration to coordinate federal government programs and to develop and implement consensus policies and procedures on matters of interagency common interests. The ILRG's mission "was to coordinate the activities of its members and help them reach

* TLV is a registered trademark of the American Conference of Governmental Industrial Hygienists, Cincinnati, Ohio.

† This department was split in 1979 into the Department of Health and Human Services and the Department of Education.

‡ See Chapter 3 for a discussion of the administrative relationship between NIOSH and OSHA.

their common goals more effectively" [10]. The ILRG formed work groups around particular issues. Each group's effort was supervised through surrogates by one of the heads of the four member agencies comprising the ILRG.

One of the ILRG work groups was the Risk Assessment Work Group (RAWG). Composed of scientists from the four member agencies, this group undertook the task of developing a document that would be a state-of-the-science discussion on cancer risk assessment. Despite political challenges inherent in the work group's efforts, primarily differences between OSHA and EPA on matters of risk assessment practices, the RAWG produced a document entitled "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks," which was published in the *Federal Register* in 1979 [10]. The ILRG guidelines on cancer risk assessment later appeared in the *Journal of the National Cancer Institute* in 1979. The guidelines, which were developed over a period of 2 years, were a product of compromise between ILRG member agencies but, in the end, had limited impact on the cancer risk assessment policies of the EPA, OSHA, and other agencies responsibilities for environmental health policies. Each agency simply adopted its own cancer risk assessment policies, as they interpreted their particular statutory responsibilities.

With the passing of the Carter administration, the incoming Reagan administration tried to revise federal policies and practices on environmental regulations. Reagan's presidential campaign of 1980 included a goal of eliminating several federal departments and agencies, including the Department of Education (DOE), the EPA, and OSHA, as matters of "regulatory reform." With Democrats in control of both houses of Congress, elimination of these federal agencies did not occur. While some of the Reagan agenda can be ascribed to campaign rhetoric, in fact, political appointees at the EPA and OSHA were able to make significant changes in how environmental and workplace regulations and standards were determined, respectively [11]. In particular, policy and procedural changes made standards setting more problematic through protracted reviews of documents and reduction in regulatory agencies' staff and budgets. The second Reagan term in office saw the appointment of officials more willing to harmonize their political agenda with the statutory requirements of standards development and regulatory implementation. Likewise, in 2016 the incoming Trump administration also vowed to implement their version of "regulatory reform," but the specifics and dimensions of that administration await definition and implementation.

19.5 HUMAN HEALTH RISK ASSESSMENT

Beginning in the mid-1970s, U.S. federal regulatory agencies were legislated to develop policies to control workplace and environmental hazards. As discussed in Chapters 8 through 12, federal legislation such as the CAAct, the CWAct, the RCRAct, the OSHAct, and the FDCAct directed the EPA, OSHA, and FDA, respectively, to promulgate regulations and standards to control various hazards. Not the least of the challenges has been how to regulate chemical carcinogens. The task undertaken by federal regulators was—and remains—daunting: how to extrapolate findings from chemical-specific laboratory toxicology studies (and occasional epidemiological investigations, e.g., workers' health studies) to apply to humans in occupational or community conditions. In the late 1970s, OSHA's cancer policy embodied both hazard evaluation and control strategies. Regulatory action was predicated on hazard identification—usually a positive laboratory animal carcinogenesis study—coupled with supporting evidence such as a positive mutagenicity assay [12]. Hazard control was then triggered, targeted at determining and regulating the lowest feasible workplace exposure to the carcinogen under regulatory consideration [13]. As described in Chapter 2, Section 2.6.2.1, a Supreme Court decision set the course for risk assessment by U.S. regulatory agencies. OSHA, EPA, and other federal regulatory agencies interpreted the Court's decision as a mandate for them to undergird their regulatory actions through use of risk assessment. But how should this occur was the key question facing the agencies circa 1980. Congress was aware of this challenge and intervened by asking advice from the National Research Council (NRC).

A 1980 U.S. Supreme Court decision changed how U.S. regulatory agencies developed risk assessment in support of environmental and workplace standards, ruling that the law demanded that OSHA must first establish that current allowed exposures posed a significant risk to workers' health.

In 1982, the NRC was directed by Congress to conduct a study of how federal regulatory agencies should manage their risk assessment processes. The ensuing NRC report "Risk Assessment in the Federal Government: Managing the Process" [4] provided the framework being sought by the federal regulatory agencies. According to the NRC, risk assessment should consist of four elements:

- *Hazard identification*—The qualitative evaluation of the adverse health effects of a substance(s) in animals or in humans
- *Dose–response assessment*—The process of estimating the relation between the dose (i.e., the amount of the substance received by the target organism) of a substance(s) and the incidence of an adverse health effect
- *Exposure assessment*—The evaluation of the types (routes and media), magnitudes, time, and duration of actual or anticipated exposures and of doses, when known; and, when appropriate, the number of persons who are likely to be exposed
- *Risk characterization*—The process of estimating the probable incidence of an adverse health effect to humans under various conditions of exposure, including a description of the uncertainties involved

The four-step risk assessment paradigm and other recommendations in the 1983 NRC report set into motion a policy

change in how federal agencies regulate environmental hazards. In some sense, this was serendipitous. In 1983, William Ruckelshaus returned to become EPA Administrator, following the resignation of an administrator who had become a political liability to the Reagan administration. Ruckelshaus inherited a demoralized EPA staff and a legacy of adverse public opinion about the attempted elimination of the agency by the Reagan administration. According to one source, he realized the need to reorient the EPA around a process that would reinvigorate the science base of the agency and reposition the EPA to resume its statutory mandates of regulating environmental hazards, as required by existing environmental statutes [14]. The process that Ruckelshaus chose was the risk assessment and risk management paradigm outlined in the NRC report. It became EPA policy to conduct risk assessments of environmental hazards in accord with the NRC four-step paradigm, and to keep risk management separate from the risk assessment process so that the science of risk assessment would not be unduly influenced by the political and societal aspects of risk management. Ruckelshaus's policy decision served the EPA well and righted the policy structure of the agency.

19.5.1 Methods for Quantifying Human Health Risks

Human health risk assessment has evolved as a bifurcation between noncancer and cancer health endpoints. This bifurcation stems from the EPA's understanding of different toxic mechanisms associated with the two endpoints, mixed with the agency's policy decisions regarding threshold mechanisms of chemical toxicity. In their 1993 concept paper on health risk assessments, the EPA states, "Chemicals that give rise to toxic endpoints other than cancer and gene mutations are often referred to as 'systemic toxicants' because of their effects on the function of various organ systems. In addition, chemicals that cause cancer and gene mutations also commonly evoke other toxic effects (i.e., systemic toxicity). Based on our understanding of homeostatic and adaptive mechanisms, systemic toxicity is treated as if there is an identifiable exposure threshold (both for the individual and for populations) below which there are no observable adverse effects. This characteristic distinguishes systemic endpoints from carcinogenic and mutagenic endpoints, which are often treated as no threshold processes" [15]. These comments regarding threshold processes can be interpreted as a statement of policy by the EPA. In sum, these 1993 concept statements from the EPA helped set the agency's course of conducting health risk assessments for cancer separate from that of noncancer substances.

Human health risk assessment has evolved as a bifurcation between noncancer and cancer health endpoints. This bifurcation stems from EPA's understanding of different toxic mechanisms associated with the two endpoints.

19.5.1.1 Traditional Regulatory Approach to Characterizing Noncancer Risks

Regulatory agencies such as the EPA and OSHA are required by authorizing statutes such as the CAAct and the OSHAct, respectively, to develop and promulgate standards for protection of human health. The agencies have utilized risk assessment procedures as a principal method for the development of the exposure standards. As described in the ensuing section, the procedures have evolved over time as regulatory agencies implemented updated risk assessment procedures.

19.5.1.1.1 Acceptable Daily Intake and Safety Factor

In the EPA's early years, risk decisions on systemic toxicity were sometimes made by the agency using the concepts of the "acceptable daily intake (ADI)," "safety factor (SF)," and "margin of safety (MOS)." The ADI is commonly defined as the amount of a chemical to which a person can be exposed on a daily basis over an extended period of time (usually a lifetime) without suffering a deleterious effect. The ADI concept was often used as a tool in reaching risk management decisions (e.g., establishing allowable levels of contaminants in foodstuffs and water). However, application of ADI, SF, and MOS for risk decisions was gradually replaced by the EPA due in part to the EPA's view that each of these terms represented "value-laden" terminology and replaced them with "reference dose (RfD)," "uncertainty factor (UF)," "margin of exposure (MOE)," and "regulatory dose (RgD)." These new terms were thought to be less "value-laden" and helped distinguish between aspects of risk assessment and risk management, a recommendation from the previously discussed NCR's 1983 report on risk assessment [15]. These new terms' uses in risk assessment are discussed in the ensuing sections.

19.5.1.1.2 Reference Dose and Reference Concentration

The EPA establishes noncancer criteria for most chemicals within the agency's statutory purview. These criteria include reference doses for exposure to chemicals via ingestion and reference concentrations for exposure to chemicals via inhalation. According to the EPA's definition, "oral risk dose (RfD) is the amount of a chemical that one can ingest every day for a lifetime that is not anticipated to cause harmful noncancer health effects. The RfD can be compared to an estimate of exposure in mg/kg-day" [2]. Similarly, the EPA's "inhalation reference concentrations (RfC) is the concentration of a chemical that one can breathe every day for a lifetime that is not anticipated to cause harmful noncancer health effects. The RfC can be compared to an estimate of exposure concentration in mg/m^3" [2]. As will be subsequently demonstrated, reference doses and concentrations can be used as denominators to derive hazard quotients, which can then be interpreted as risk assessments of noncancer chemical hazards.

19.5.1.1.3 MOE and MOS

The EPA defines a MOE as being the ratio of the no-observed adverse-effect-level (NOAEL) to the estimated exposure dose. A MOE is calculated to determine human health risk from exposure to the substance of interest. This "margin" is essentially the established "safety buffer" between the toxicity effect level dose (in this case the no observed effect concentration [NOEC]) and the predicted exposure dose. The MOE is a ratio of the toxicity effect level to the estimated exposure dose. UFs are used to determine the acceptable MOE. An acceptable MOE for a NOAEL/NOEC-based assessment is 100 and for a lowest-observed adverse-effect level (LOAEL)/lowest observed effect concentration (LOEC)-based assessment add an additional factor of 10 to give an acceptable MOE of 1000 for a LOAEL/LOEC-based assessment. The lower the MOE (margin between the toxicity effect level and the exposure dose), the more likely a chemical is to pose an unreasonable risk. For example, if the margin indicates that a particular toxicity effect level is 10,000 times higher than the expected exposure dose there is little concern that concentrations will reach levels where toxicity is possible. However, considering potential uncertainty in experimental measurement, if the toxicity level is only 1 time higher than the exposure dose there is a significant chance the exposure dose may reach the toxicity effect level [2].

19.5.1.1.4 Calculations of Noncancer Health Risks

Estimates of noncancer health risk are based on the assumption that there is a threshold of exposure below which it is unlikely that adverse health effects will occur. In this context, a common method of evaluating noncancer risks is to generate a "hazard quotient" (HQ), which is the ratio of exposure to toxicity. The HQ is calculated as follows [2]:

$$HQ = E/RfD$$

where E is the exposure level or intake (mg/kg/day) and RfD is the reference dose (mg/kg/day).

As stated by EPA, "HQs greater than 1 are not statistical probabilities of harm occurring. Instead, they are a simple statement of whether (and by how much) an exposure concentration exceeds the reference concentration (RfC). Moreover, the level of concern does not increase linearly or to the same extent as HQs increase above 1 for different chemicals because RfCs do not generally have equal accuracy or precision and are generally not based on the same severity of effect. Thus, we can only say that with exposures increasingly greater than the RfC, (i.e., HQs increasingly greater than 1), the potential for adverse effects increases, but we do not know by how much. An HQ of 100 does not mean that the hazard is 10 times greater than an HQ of 10. Also an HQ of 10 for one substance may not have the same meaning (in terms of hazard) as another substance resulting in the same HQ" [2a]. Put more simply, an HQ value is an indicator that requires further consideration as a component of a risk characterization.

Estimates of noncancer health risk are based on the assumption that there is a threshold of exposure below which it is unlikely that adverse health effects will occur.

19.5.1.2 Regulatory Approaches to Characterization of Cancer Risks

The EPA considers cancer risk to be the probability of contracting cancer over the course of a lifetime, assuming continuous exposure over 70 years for the purposes of risk characterization [2a]. Estimates of cancer risk from exposure to toxic agents of interest to regulatory agencies are often based on the simplifying assumption that the dose–response relationship is linear at low dose levels. Under this assumption, risk is directly related to dose intake and risk can be estimated using the following equation, with key assumption of linearity of response at low doses [2]:

$$\text{Risk} = \text{LADD} \times \text{CSF}$$

where Risk is the probability (units) of an individual's developing cancer

LADD is the lifetime daily dose of the toxicant (mg/kg day)

CSF is the cancer slope factor $(\text{mg/kg day})^{-1}$

It merits mentioning that LADD is also used for noncarcinogenic health risk characterization as well as for carcinogens. Also, in most cases there is a lot of policy associated with the derivation of the LADD. This is often accomplished with the EPA's exposure factors handbook and relies on standard exposure and demographic assumptions.

The slope factor in the equation usually represents the 95% upper confidence limit (UCL) of the probability of response based on experimental animal data used in the multistage model of carcinogenicity. The slope factor therefore represents an "upper bound" value. According to the EPA, use of the 95% UCL permits regulators and risk managers to be "reasonably confident that the 'true risk' does not exceed the risk estimate derived through use of this model and is likely to be less than that predicted" [2a]. The EPA's policy is to consider any cancer risk less than 10^{-6} (i.e., one chance in a million) to be an initial indication of unlikely adverse health effect, while any risk greater than 10^{-6} to be cause for concern and merits further review and assessment. For example, an estimated cancer risk of 10^{-4} would be of potential health concern, whereas 10^{-8} would not. However, in practice the acceptable risk range is 10^{-6}–10^{-4}. For instance, the Levels of Concern in seafood following the Deepwater Horizon oil spill were based on a risk level of 10^{-5}. While 10^{-6} is preferred, 10^{-5} and 10^{-4} would not by default indicate potential health concern. In fact, there are several instances in which the acceptable risk level was set at 10^{-4} by the FDA, EPA, and state agencies, a decision often based on risk management considerations such as the nature and availability of intervention strategies.

Over time, increasingly sophisticated cancer risk estimates have been developed. An example is the unit risk estimate (URE). According to the EPA, "The URE is the upper-bound

excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 μg/m^3 in air. The interpretation of the URE would be as follows: if the URE = 1.5×10^{-6} μg/m^3, 1.5 excess tumors are expected to develop per 1,000,000 people if exposed daily for a lifetime to 1 μg of the chemical in 1 m^3 of air. UREs are considered upper bound estimates, meaning they represent a plausible upper limit to the true value. (Note that this is usually not a true statistical confidence limit.) The true risk is likely to be less, but could be greater" [2b]. Listings of UREs for individual toxicants are available from EPA [2b].

* * *

It is also worthwhile to observe that government agencies update their cancer policies in accord with the availability of new scientific data and when improved risk management methods become available. As an example, in 2016 NIOSH revised its cancer policy, stating "[…] the policy by which NIOSH classifies chemicals as carcinogens, identifies control levels, and addresses analytical feasibility is being updated because of advances in science and with the intent of providing transparent guidance on how NIOSH assesses and addresses cancer risks. Underlying this policy is the recognition that there is no known safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer. Accordingly, this policy no longer uses the term recommended exposure limit (REL) for chemical carcinogens; rather NIOSH will only recommend an initial starting point for control, called the Risk Management Limit for Carcinogens (RML-CA). For each chemical identified as a carcinogen, this level corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. Keeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended. When measurement of the occupational carcinogen at the RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ) of the analytical method. In addition, NIOSH will continue to evaluate available information on existing engineering controls and also make that information available when publishing the RML-CA" [2c]. Because NIOSH is not a regulatory agency, its cancer policy applies to its own programs of risk assessment and management, but the agency's recommendations have influence on those agencies, e.g., OSHA, that do have regulatory authority.

Perspective: In the early 1990s EPA toxicologists, statisticians, and other staff scientists were faced with developing a risk assessment process that would stand up to both contemporary scrutiny by non-government scientists as well as surviving litigious challenges. EPA toxicologists, in particular, met this challenge by building upon traditional toxicological principles (e.g., threshold exposure, and systemic effects) and modifying the principles and terminologies (e.g., less value-laden terms) to suit the agency's regulatory responsibilities. These early beginnings of what might be called "regulatory toxicology" have stood the test of about 30 years of application, an endorsement of the efforts and insight attributable to the EPA staff of those years.

19.5.2 Case Study: Arsenic Risk Brouhaha

Reassessing the U.S. arsenic standard is an example of a risk assessment that got caught in the political thickets of environmental politics and policies. Arsenic is a well-known poison when ingested in a sufficient dose. Avoidance of exposure to arsenic is good health advice, but in many areas of the world, including the U.S., arsenic occurs naturally in soil and thereby can contaminate groundwater supplies. The concentration of arsenic in soil varies widely, generally ranging from 1 to 40 ppm*, with an average of 5 ppm [16]. The concentration of arsenic in natural surface and groundwater is generally about 1 ppb†, but may exceed 1000 ppb in mining areas or where arsenic levels in soil are high [16]. Groundwater supplies are primary sources of drinking water, whether ancient wells in Mongolia or municipal water supplies in some areas of the western U.S. As a hazard to human health, the question arises, how much arsenic in drinking water presents an unacceptable risk to the public's health?

In the U.S., the arsenic in drinking water standard was set at 50 ppb by the Public Health Service in 1942, which precedes the establishment of the EPA in 1970 (Table 19.1). This PHS recommendation was based on total dietary intake of As and for noncancer health effects [16a]. This level was maintained in the U.S. for more than 50 years, even though scientific evidence had mounted that lower levels of arsenic in drinking water were necessary to protect the public's health. Decreasing the standard from 50 ppb to a lower level led to a lengthy and heated debate that involved EPA, Congress, two Presidents' administrations, environmental groups, and business associations.

In 1993, the World Health Organization (WHO) recommended that arsenic levels in drinking water not exceed 10 ppb, based on carcinogenic health concerns. The EPA chose not to follow WHO's recommendation, an outcome not favored by environmental groups. The EPA chose not to act upon WHO's recommendation, believing they had higher priority water contaminants for which to develop standards, together with pressure being brought upon the agency by mining companies opposed to any revision of the arsenic standard in the U.S. In response to the EPA's inaction, environmental groups, joined by public health advocates, brought pressure on Congress to force the EPA to revise its arsenic standard. Opposed to any change in the arsenic standard were mining companies and some municipal water suppliers in western states. Their opposition was based on the economic impact of a lower arsenic standard. Because arsenic in mining waste can be a source of groundwater contamination; remediation of the waste would be costly. Water suppliers objected to a lower

* 1 part arsenic in 1 million parts of soil

† 1 part arsenic in 1 billion parts of water

TABLE 19.1
Key Events in the Revision of EPA's as in Drinking Water Standard

Year	Event
1942	U.S. Public Health Service set As standard for drinking water at 50 ppb
1993	WHO decreased from 50 to 10 ppb
1995	EPA chose not to adopt WHO's recommendation
1996	Safe Drinking Water Act Amendments directed EPA to update their As standard by January 1, 2001
1999	NAS recommended that the As standard be lowered from 50 ppb
2001 (January)	Clinton administration published a rule to lower As standard to 10 ppb
2001 (March)	George H.W. Bush administration withdrew EPA's As rule
2001 (July)	U.S. House Representatives voted to support an As standard of 10 ppb
2001 (September)	NAS issues a report, declaring As in drinking water to be a carcinogen at 10 ppb
2001 (November)	George H.W. Bush administration announced it reinstatement of the Clinton administration's proposed As standard of 10 ppb
2002 (November)	EPA announces industry's voluntary action to phase out pressure-treated wood products containing As as a preservative
2003 (June)	U.S. Federal Circuit Court upholds EPA's revised As standard of 10 ppb

arsenic standard because new, costly equipment would need to be purchased to remove arsenic from drinking water.

Congress sided with those groups advocating a lower arsenic standard. The Safe Drinking Water Amendments of 1996 directed the EPA to update the arsenic standard by January 1, 2001. As a matter of science, the EPA asked the U.S. National Academy of Sciences (NAS) to review the toxicology and human health literature on arsenic and recommend courses of action. In 1999, the NAS recommended that the EPA standard be lowered from its then current level of 50 ppb, based on concerns for As carcinogenicity. Two years later, in January 2001, as the Clinton administration was preparing to leave office, the EPA published rules that would lower the arsenic standard to 10 ppb. On January 20, 2001, Democrat Bill Clinton was succeeded in office by Republican George W. Bush. In March, as its first environmental policy action, the new administration withdrew the proposed arsenic rule. What followed was considerable criticism of the Bush administration's action, providing environmental and public health groups with an easy platform to criticize the new administration. Remarkably, the ensuring clamor led the U.S. House of Representatives, under Republication control, to support the Clinton-era 10 ppb proposed rule on arsenic in drinking water. In July 2001, the NAS issued a second report on arsenic, finding it to be carcinogenic and recommending a level of less than 10 ppb as a standard. Subsequent to the NAS report, the Bush administration reversed itself and in November 2001 reinstated the arsenic rule proposed by the Clinton administration.

The revised EPA water quality standard of 10 ppb for arsenic in drinking water was litigated by the state of Nebraska and the city of Alliance, Nebraska. They argued that regulating drinking water quality was a state, not federal, responsibility. In June 2003, a three-judge panel of the U.S. Court of Appeals, District of Columbia Circuit, held in favor of the EPA, concluding that plaintiffs had failed to show that the EPA's actions were in violation of the U.S. Constitution [17]. The EPA arsenic standard was defended before the court by the Justice Department and the Natural Resources Defense Council, a national environmental advocacy organization. The court's decision removed barriers to enforcing the new, lower arsenic standard adopted by EPA, ending the political clash between the Clinton and Bush administrations.

In addition to the public health concern over arsenic levels in drinking water supplies, environmental groups have expressed concern about arsenic contamination of soil attributable to pressure-treated wood. Pressure treating wood is a way to extend its life through introduction of preservatives that protect against termites, molds, fungi, and dry rot. Chromated copper arsenate (CCA) has been used as a preservative in wood, but as the wood ages, CCA migrates into soil, causing focal areas of arsenic contamination. The EPA determined that CCA-containing products cannot be produced after January 2004, announcing that industry voluntarily agreed to phase-out such products [18].

As a matter of environmental health policy, risk assessment was used by the EPA, and earlier by WHO, to develop the standard for arsenic in drinking water supplies. However, changes in political direction at EPA led to conflicts in whether or not to accept a lower standard. This raises the question of whether risk-based standards should be spared the political gauntlet of partisan politics. Is it possible to isolate the standards process from pressure from vested interest groups? The arsenic in drinking water issue illustrates the difficulty in revising existing environmental standards and the intrusion of changed political bases. This case study also illustrates the problem when naturally occurring hazards exist. Aside from a few industrial examples of releases of As into soil and/or water, Mother Nature is the responsible party for the vast majority of exposures to As. Risk assessment of a hazard—arsenic, in this case—that results in a significantly lower standard will be a challenge if economic impacts on the regulated parties are sufficiently great.

19.5.3 What Is the Value of a Human's Life?

In the mid-1990s, Congress began adding cost/benefit analysis as a requirement for federal regulatory agencies when developing proposed environmental regulations and standards.

In theory, benefits of a proposed regulation, e.g., a lowered standard for arsenic in drinking water, should outweigh its costs of implementation. Regulated entities were the principal advocates of cost/benefit analysis. While cost/benefit analysis seems, on the surface, a reasonable and prudent public policy, in fact, it has become a matter of some controversy when put into practice. Much of the controversy concerns how costs and benefits of a proposed regulation are calculated. An example is the calculation of the value of a human life.

What is the value of your life? Or that of a child? Or an elderly person? Is the value of an elected official's life different from, say, a young medical doctor? Or should all human life be valued as equal? These are questions, without easy answers, inherent in the calculus of cost/benefit analyses. The controversy arising from these kinds of questions divides into two camps of supporters. One camp considers, for regulatory purposes, all human life to be equal in value. One could call this the *egalitarian* camp. An egalitarian approach was developed and subsequently practiced by the George H.W. Bush administration and continued as policy by the Clinton administration. Using the egalitarian approach, the EPA determined that each life saved by a change in a regulation was worth $6.1 million per life [19].

The *utilitarian* approach attempts to value human life on the basis of an individual's age and health status. This approach, advocated by the Office of Management and Budget (OMB) of the George W. Bush administration, produces life value estimates that differ across age and statistical lines. In one permutation of the utilitarian approach, OMB advocated that $3.7 million should be allocated for the life of a person younger than 70 years old and $2.3 million for persons older than 70 [20]. Critics of this approach quickly labeled it as the "senior death discount." In 2003, the EPA used both the egalitarian and the utilitarian approaches to estimate the health benefits of proposed changes in the CAAct. The EPA estimated that approximately 12,000 lives would be saved by the proposed changes. But what would be the economic impact? Using the egalitarian approach ($6.1 million per life saved) resulted in an overall health benefit of $93 billion by year 2020. Using OMB's utilitarian approach yielded an estimated health benefit of $14.1 billion, a figure reasonably close to EPA's cost estimate of $6.5 billion [19]. Of note, when costs of projected regulations are close to the value of benefits, policymakers are loath to support regulatory actions, given that policymakers prefer situations where the outcome is more clear cut, thereby lessening the possibility that an unpopular regulatory decision will be made.

It will be a matter of policy not science that decides which approach, egalitarian or utilitarian, will be adopted by federal regulatory agencies. It can be predicted that regulated communities will bring pressure to bear on legislative bodies to adopt the utilitarian approach, predicating their argument on the cost savings of such an approach.

Perspective: The calculus of cost–benefit analysis is complex for several reasons. Policy considerations abound. One such policy just described is how to estimate the worth of a human life. Another policy is what and how to choose the length of a person's exposure lifetime. Does one choose a default value of 70 years of duration of exposure to a carcinogen or other form of hazardous substance? How are children's mortality and morbidity data factored into the cost–benefit analysis? How are vulnerable populations, for example, persons who are elderly or possess infirmities, factored into the cost–benefit analysis? And not the least of policy decisions is what constitutes a benefit? For example, is it a benefit if a person or a population experiences an improved quality of life due to a regulatory decision?

Further, should the cost–benefit analysis include considerations of the economic impact of tighter regulations on human well-being? For example if a manufacturing facility in a small town employs many people and is closed due to regulatory decisions, what happens to their families' ability to meet their basic needs? There are not always other employment opportunities available and there is no guarantee that people have the resources to relocate. Despite various social nets (e.g., Medicaid, Women, Infants, and Children programs), peoples' health status can be put in jeopardy by limiting their access to income. Stated differently, poverty is antithetic to good health and well-being. This kind of indirect economic impact is not a factor in the regulatory risk calculations because it is not directly related to hazard exposure but it is enormously important to acknowledge.

The policies inherent in regulatory agencies' cost–benefit analyses are neither always stated nor evident. Regulatory agencies have published guidelines on their analyses and are available via agency databases and some social media. However, communication of an agency's cost–benefit methods and outcomes for a specific environmental hazard represents a challenge to both the agency and the public.

19.6 ECOLOGICAL RISK ASSESSMENT

Risk assessment was first directed to hazards to human health. This was due to the need for the EPA to set air and water quality standards under the CAAct, CWAct, and SDWAct, and their amendments. Similarly, the OSHAct directed OSHA to promulgate standards to protect workers' health and control of hazards in order to provide safe workplace conditions. As noted in Chapter 4, where no specific standards exist for a workplace condition, the OSHAct directs each employer to provide "[a] place of employment which is free from recognized hazards that are causing harm to employees." This "general duty" clause is used by OSHA to control workplace hazards that are obvious but for which no specific standard exists.

Also, the FDA's regulatory responsibilities under the Food and Cosmetic Act were specific to controlling hazards to human health. However, the passage of the CERCLAct, as amended, expanded federal environmental policy to include assessment of hazards to natural resources and ecosystems. This created the need for ecological risk assessment.

The passage of the CERCLAct expanded federal environmental policy to include assessment of hazards to natural resources and ecosystems. This created the need for ecological risk assessment.

Distinct from human risk assessment, ecological risk assessment has evolved into a discipline of its own [21], not merely as an adjunct to human risk assessment—even though some methodological approaches are in common. In the most common situation, ecological risk assessment is used to estimate the impact of a hazard (e.g., waste site toxicants that leached into a lake or river) on a natural resource. The Superfund Law, as amended, requires polluters to pay for the consequences of damage to ecosystems. The damages can be considerable and quite costly. For example, waste released into a river can reduce or eliminate fish populations, causing long-lasting loss of commercial and recreational fishing. Remediation of the river's water and sediment can bring huge expenses to those responsible for the pollution. As an example, remediation of a 40-mile section of the Hudson River for removal of PCBs has cost the General Electric Corporation approximately $1.6 billion [19a].

EPA defines ecological risk assessment as "The application of a formal framework, analytical process, or model to estimate the effects of human actions(s) on a natural resource and to interpret the significance of those effects in light of the uncertainties identified in each component of the assessment process. Such analysis includes initial hazard identification, exposure and dose-response assessments, and risk characterization" [22].

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19.7 ECOLOGICAL RISK OF CHLORPYRIFOS

In 2001 Solomon et al. conducted an ecological risk assessment of the use of chlorpyrifos, an insecticide, to determine the probability and significance of effects to wildlife from chlorpyrifos use in terrestrial ecosystems, particularly corn agrosystems [23]. The following were the features of their risk assessment:

- *Hazard identification*: Chlorpyrifos is an organophorphorus insecticide. Under the environmental conditions of most agricultural use, it is not considered persistent in the environment. In the context of the risk assessment, chlorpyrifos was used for insect control in corn agrosystems. Under certain conditions of exposure, chlorpyrifos can be toxic to birds and mammals. Young birds and animals are more susceptible to chlorpyrifos toxicity than adults of their species.
- Exposure *assessment*: Birds and mammals are exposed to chlorpyrifos through food contamination (insects, worms) and through contact with soil and water contaminated with the insecticide.
- *Risk characterization*: Using toxicity data and assessment of various acute and chronic exposure scenarios, risk characterization of both granular and liquid administration of chlorpyrifos showed overall negligible consequences to exposed birds and mammals. Granular chlorpyrifos was less hazardous than liquid administration. Liquid application was found to present greater risks to young birds than adult birds feeding on insects from fields treated with chlorpyrifos.

The findings from this assessment have the potential to improve how farmers apply chlorpyrifos to their fields. If lesser amounts of this hazardous substance are applied to crop fields, the public's health will benefit because less of the substance will enter environmental pathways, including those portending human exposure, such as groundwater used as drinking water sources.

19.8 OCCUPATIONAL INJURY RISK ASSESSMENT

The methods and practices of risk assessment were originally applied to assess the risk of radiation and later applied to human exposure to chemicals. A more recent development has been the use of risk assessment in programs of occupational injury control. NIOSH states that "occupational injury risk assessment concerns the estimation of risk in hazardous occupational environments that lead to traumatic injury," noting, "The risk assessment paradigm provides a useful framework to address problems resulting from workplace exposures that cause traumatic disabling and fatal injuries" [24]. For instance, occupational injury risk assessment has been applied to workplace conditions that produce musculoskeletal injuries [25], cause occupational fatalities [26], affect machine design [27], and produce injuries from farming [28]. At the heart of occupational injury risk assessment is the prevention of traumatic injury and fatalities.

Occupational injury risk assessment concerns the estimation of risk in hazardous occupational environments that lead to traumatic injury.

According to one source, the National Academy of Sciences' four-step risk assessment paradigm (Figure 19.1) must be modified as follows when used in assessing the risk of occupational injuries [24]:

- *Hazard identification*—it requires an evaluation of data on injuries or fatalities associated with specific workplace factors such as tools, workplace practices, or environmental conditions.

- *Exposure assessment*—the frequency, variability, and duration of workplace conditions associated with occupational injuries are represented through the use of statistical distributions.
- *Dose–response assessment*—exposure for injuries can be based on duration and frequency of such factors as biomechanical stress, workers' fatigue, and workplace practices.
- *Risk characterization*—probability models "[p]rovide the basis to describe the random nature of injuries and define a stochastic mechanism for injury incidence that can be useful for measuring and characterizing risk" [24].

These four steps provide a framework for systematic assessment of occupational injuries. An example of an occupational injury risk assessment follows.

Kines assessed the risk of injuries in the Danish construction industry for the period 1993–1999 [29]. Hazard identification was conducted by examining lost-time injury incidents reported by employers to the National Working Environment Authority in Denmark for the period of interest. From this database, injury incidents resulting in amputations, bone fractures, and multi-trauma injuries in construction work were extracted for analysis. Risk analyses included calculations of proportions, relative rates, fatal injury incidence rates, nonfatal injury incidence odds ratios, and injury severity odds ratios. These statistics were used for both exposure assessment and risk characterization. Findings from the study showed the following: (1) carpenters had excessively high proportions, rates, and hazards for falls from heights, compared to the entire Danish construction industry, and (2) rates of serious injury falls from heights increased with increasing age of workers. From such findings, programs of injury prevention can be designed and implemented.

19.9 OTHER APPLICATIONS OF RISK ASSESSMENT

Risk assessment, as previously discussed in this chapter, has become the most frequently applied method for estimating the potential harm from exposure to environmental hazards. It has been utilized to assess both human health risk and risk to ecological systems. But other applications of risk assessment have arisen. The following section discusses (1) the use of risk estimates for comparing and ranking individual environmental hazards, (2) the application of risk assessment to make risk management actions, and (3) the process of deriving data-driven SFs. Each of these three applications of risk assessment has implications for policymakers, because each application has implications for risk management. Risk management, in turn, has such societal impacts as technology costs (e.g., pollution controls), levels of regulated pollutants, and how risk is communicated to the public.

19.9.1 Comparative Risk Assessment*

How individuals and societal structures, such as legislatures, compare environmental hazards has become a subject of great interest. As individuals, we make personal decisions that, knowingly or not, constitute a comparison of health risks. Some persons unwisely choose to smoke tobacco, perhaps unaware that nicotine in tobacco smoke is addictive. How persons select their living arrangements can result from comparing health risks. Some locales, such as in urban areas, present higher health risks because of higher levels of air pollutants there than in rural areas. However, health risks due to urban environmental pollution may be outweighed by risks that come with commuting to work from less environmentally polluted suburban or rural areas. Sometimes these personal choices are deliberate and based on factual information; other times, personal choices stem from fears or perceptions not based on scientific data or fact.

Comparative risk analysis is an environmental decision-making tool used to systematically measure, compare, and rank environmental problems or issue areas.

As will be subsequently discussed, comparing health and other forms of risk has become important to public health and environmental agencies, medical care providers, policymakers, government programs, and legislative bodies. Further, comparative risk analysis has become a discipline of considerable importance to these aforementioned groups. However, considerable differences exist between groups as to how they define and perform comparative risk analysis. These differences will be discussed and illustrated with examples of different forms of comparative risk analysis. Comparative risk analysis of environmental hazards is discussed first.

What priorities exist for evaluating the nation's environmental hazards? Is there a consensus method for ranking them? These two questions have on occasion become increasingly important to legislators, government officials, and public service groups. Legislators, in particular, assert their need to match legislative actions with environmental priorities. One approach, called *comparative risk assessment*, compares risks across various environmental hazards. Some persons consider this the best approach to establishing priorities for environmental and public health programs. For example, an expert in risk assessment presented testimony in 2000 to a Congressional committee that asserted, "Comparative risk assessment (CRA) is an important analytical tool that deserves the attention this committee is giving it. The fundamental goal of most of our environmental programs is to reduce or prevent risk. Thus, identifying and comparing risks is a logical starting point for evaluating progress and identifying future directions and priorities" [31a].

How did comparative risk assessment become a prominent method of setting priorities for environmental hazards? In 1987, the EPA released its "Unfinished Business" report.

* Material in this section is adapted from Johnson [30,31].

The report was prepared by 75 career EPA managers who ranked 31 environmental hazards for which EPA had regulatory jurisdiction [32]. Because of lack of jurisdiction, EPA did not rank some key environmental hazards that state and local governments later considered important in their comparative risk assessments, including food safety, lead contamination, and natural hazards.

For the 31 environmental hazards, the EPA assessed four different kinds of risk: cancer, noncancer health effects, ecologic effects, and welfare effects (e.g., materials damage, aesthetic degradation). Quantitative cancer risk estimates were developed where possible; other risks were qualitatively estimated through a process involving professional judgment and consensus development. An overall risk assessment priority for each environmental hazard resulted when rankings from the four risk criteria were combined. Shown in Table 19.2 are the 10 top-ranked (not in ranked order, according to the EPA report) environmental hazards in terms of overall risk.

In 1989 and again in 1990, the EPA's Science Advisory Board examined both the methods and findings of the "Unfinished Business" report and gave the Board's endorsement to the comparative risk approach to setting environmental priorities [33]. The gist of the EPA report was that the nation's environmental priorities were failing to address many of the most serious risks. One source indicates that with EPA funding, since 1990 more than 100 states, territories, counties, cities and other local communities have conducted their own comparative risk projects of environmental hazards [33]. However, as a matter of policy relevance, data on the utility and application of these various risk analysis are lacking. This situation may be due to the reality of how environmental programs are funded by government and some private entities.

Like individuals, societal structures such as legislatures must make decisions about environmental hazards. This occurs when legislators craft environmental and public health legislation and appropriate budgets to government programs.

TABLE 19.2
Top-Ranked Environmental Hazards in EPA's Comparative Risk Assessment Study (Not Listed in Rank Order)

Criteria air pollutants
Hazardous air pollutants
Other air pollutants
Radon—indoor
Indoor air pollutants other than radon
Radiation from sources other than indoor radon
Substances suspected of depleting the atmospheric ozone layer
CO_2 and global warming
Direct, point-source discharges to surface waters
Indirect, point-source discharges to surface waters

Source: EPA (U.S. Environmental Protection Agency), Unfinished Business: A Comparative Assessment of Environmental Problems, xix, Office of Media Affairs, Washington, DC, 1987.

Private industry performs similar comparisons of environmental hazards. Companies must budget according to their own environmental priorities and those required to meet government regulations and community concerns. Because environmental protection and remediation programs are costly, legislators must seek better methods on which to predicate legislative actions. Comparative risk assessment has most often been suggested as the lamp to light the way to improved legislative decisions. This stems from the belief that because risk assessment is a quantitative and systematic approach to characterizing risks, using it to compare individual environmental hazards would lead to more precise ways of prioritizing hazards.

Two examples illustrate how some government officials have viewed comparative risk assessment of environmental hazards. In 1992 Governor John Engler of Michigan said, "Too often in the past, Michigan's environmental priorities have been set by the crisis of the moment, budget uncertainties, media attention, or conflicting data. I am convinced that it is time to carefully review and evaluate our priorities and base those priorities on careful thought and scientific information. We must do this in order to efficiently apply our limited resources to addressing the most serious environmental risks that our state faces" [34]. In a similar vein, in 1991 Jan Eastman, Secretary, Agency of Natural Resources, Vermont, stated, "The Agency will seek to reduce risks to Vermont and Vermonters by exploring approaches to environmental management, including pollution prevention, toxics reduction, market incentives, and the continued use of public information and education. These approaches may help the Agency make the best possible use of its increasingly scarce resources. The Advisory Committee's ranking of the relative severity of Vermont's environmental problems helps to provide a useful foundation for action" [35]. In both examples, linkage between government resources and ranking of environmental hazards is evident, but data are lacking as to whether this linkage was actually implemented.

> The comparative risk process attempts to identify those aspects of the environment which both technical and public groups feel are of top priority [33].

A perception that "low priority" risks have received too much attention and too many resources underlies the desire for better legislative decisions on environmental hazards. Proponents of this thesis often cite the cost of remediating uncontrolled hazardous waste sites as an example of the imbalance between environmental benefits and costs. They assert that the multibillion dollar costs of remediating uncontrolled hazardous waste sites outweigh the beneficial effects to human health, ecologic systems, and environmental quality. To what extent is this assertion legitimate and, for example, where do the risks of hazardous waste sites rank in comparison to those of other environmental hazards? For example, do hazardous waste sites present greater risks to human health than do indoor air pollutants? These and similar questions are fuel for conducing comparison risk assessments.

Lee Thomas, when serving as EPA Administrator, summarized his views on risk comparison by observing, "Although EPA's mission enjoys broad public support, our agency nonetheless must operate on finite resources. Therefore, we must choose our priorities carefully so that we apply those resources as effectively as possible. While we have made much progress to date, the cost of further environmental improvements in many areas will be high. For example, removing additional increments of toxics from industrial effluents or cleaning up contaminated groundwater to background levels can be enormously expensive. The unit cost of moving ever closer to the point of zero discharge, zero contamination, and zero risk increases exponentially. Yet this agency must proceed to carry out its mandates and to set its priorities" [36]. This statement by the EPA Administrator in 1987 can be considered a policy statement in support of use of comparative risk assessment as a means for setting EPA's program priorities. However, this policy seems not to have been implemented due to budgeting priorities by Congress and changes in EPA leadership. As an example, in *EPA's Strategic Plan for FY 2014–2018*, five strategic goals are stated: "Addressing climate change and improving air quality; Protecting America's waters; Cleaning up communities and advancing sustainable development; Protecting human health and the environment by enforcing laws and assuring compliance" [37]. The EPA report does not indicate that the agency used comparative risk assessment as the basis for their five strategic goals. Whether the EPA strategic plan will be implemented by the Trump Administration is unknown. It is important to know that agency-derived comparative risk assessments are subject to revision by legislative appropriations determinations.

* * *

A somewhat different definition and approach comparative risk assessment is provided by WHO, which states, "Comparative risk assessment is defined as the systematic evaluation of the changes in population health which result from modifying the population distribution of exposure to risk a risk factor or a group of risk factors" [38]. Two illustrations of this method of comparative risk assessment follow. In one study, Danaei et al. estimated mortality from 12 types of cancer in seven World Bank regions for 2001 [39]. The investigators analyzed data from WHO's Comparative Risk Assessment project and from new sources to assess exposure to risk factors and relative risk by age, sex, and region. Of the seven million deaths from cancer worldwide in 2001, an estimated 2.43 million (35%) were attributable to nine potentially modifiable risk factors. Smoking, alcohol use, and low fruit and vegetable intake were the leading risk factors for death from cancer worldwide and in low-and-middle-income countries. In high-income countries, smoking, alcohol use, and overweight and obesity were the most important causes of cancer.

In a second study of this kind of comparative risk assessment, Danaei et al. estimated the mortality effects of 12 modifiable dietary, lifestyle, and metabolic risk factors in the U.S. [40]. Investigators used data on risk factor exposures in the U.S. population from nationally representative health surveys and disease-specific mortality statistics from the U.S. National Center for Health Statistics. Investigators obtained the etiological effects of risk factors on disease-specific mortality, by age, from systematic reviews and meta-analyses of epidemiological studies that had adjusted (1) for major potential confounders and (2) where possible for regression dilution bias. Findings revealed that in 2005, tobacco smoking and high blood pressure were responsible for an estimated 467,000 and 395,000 deaths, respectively, accounting for about one in five or six deaths, respectively, in U.S. adults. Overweight–obesity (216,000 deaths) and physical inactivity (191,000) were each responsible for nearly 1 in 10 deaths. High dietary salt (102,000), low dietary omega-3 fatty acids (84,000), and high dietary trans-fatty acids (82,000) were the dietary risks with the largest mortality effects. These kinds of health-focused comparative risk assessments provide valuable data for the design of public health interventions and for allocation of resources to address priority health problems.

In summary, comparative risk analysis is an environmental decision-making tool used to systematically measure, compare, rank, and act upon environmental hazards or issues. The process typically focuses on the risks an environmental problem poses to human health, the natural environment, and quality of life. The outcome is a list of environmental hazards or issues that are ranked in terms of relative risks. Comparative risk analysis typically investigates what are called "residual risks," the risks remaining after an environmental problem is addressed by current regulatory controls or other administrative means. For example, a state environmental department may determine that its current food safety actions may leave little residual risk to the public's health, as compared to higher level of residual health risk presented by uncontrolled hazardous air pollutants. As a matter for environmental health policymakers, it is important that effective programs (and that have a low residual risk) not be shorted in resources and authorities in deference to environmental hazards that have a higher residual risk. What is working effectively to protect the public's health should be changed or revised only with great caution.

19.9.2 Risk-Based Corrective Action

Another practical use of risk assessment appeared in the mid-1990s as the result of Congressional concern about underground storage tanks (USTs). The EPA estimates that more than 1 million USTs have been in service in the U.S., primarily used for fuel storage at gasoline stations [41]. Of these, more than 400,000 have been confirmed as leaking USTs. The median cost to investigate and remediate a leaking UST is more than $100,000 [41]. In addition to gasoline, USTs hold such liquid hazardous substances as pesticides, fertilizers, and industrial chemicals. The public health relevance is that leaking USTs contaminate the environment, including groundwater and surface waters used as sources of drinking water.

Under Subtitle I of the RCRAct, Congress directed the EPA to establish regulatory programs that would prevent, detect, and remediate releases from USTs. In 1988, EPA released the required regulations and directed their implementation by state and local agencies. The EPA regulations

do not specify cleanup levels or administrative procedures that the states must follow, requiring only that state or local remediation programs must be protective of human health and the environment. The EPA's regulations allow states to make choices about how they will design and conduct their corrective action programs. As applied to corrective action at UST release sites, risk-based corrective action (RBCA) is a process that utilizes risk and exposure assessment methodology to help UST implementing agencies to make determinations about the extent and urgency of corrective action and about the scope and intensity of their oversight of corrective action by UST owners and operators [41].

In 1993, in large measure because individual states were struggling to develop their UST programs, the American Society of Testing and Materials (ASTM) began work on development of a streamlined process for assessment and response to subsurface contamination associated with petroleum hydrocarbon releases. The standard was reissued in final form in December 1995 as ASTM E 1739-95 *Standard Guide for Risk-Based Corrective Action Applied at Petroleum Release Sites* [42] and was later expanded and reissued as ASTM PS 104-98 *Provisional Standard Guide for Risk-Based Corrective Action* [43], addressing all types of chemical releases to the environment. The RBCA process, as defined in the ASTM Standard, is a flexible, science-based, decision management framework that may be customized by individual regulatory agencies to design or revise their corrective action programs [43]. In simple terms, the RBCA process entails (1) the identification of applicable risk factors on a site-specific basis and (2) the implementation of appropriate corrective measures in a time frame necessary to prevent unsafe conditions.

The goal of RBCA programs is to identify those leaking USTs of greatest hazard to human health and the environment, relegating those of lesser risk to categories of environmental monitoring or inactivity. To examine the performance of states' RBCA programs that utilize the ASTM standard (or similar standard), Connor and McHugh [44] conducted detailed evaluations of five state environmental agencies. Comparison of pre-RBCA to post-RBCA program management statistics found an increase in the number of case closures (ranging from 46% to 134%), reduced environmental cleanup costs (e.g., in Texas the median cost was reduced from $250,000 to $107,000 for low-risk groundwater sites), and more effective targeting of resources toward responding to higher-risk sites.

As a matter of environmental health policy, risk-based correction action has been developed and applied to the problem of leaking underground storage tanks. In principle, this approach emulates the process of risk assessment and management of Superfund sites. In theory, those sites (USTs or Superfund sites) that are of greatest hazard to human and ecological health are remediated before sites of lesser risk are remediated. As policy, this makes sense in a public health context. The sites of greatest urgency are responded to first, lessening the likelihood that humans will be exposed to hazardous substances released from the sites. However, what is lacking is any retrospective analysis that proves that the worst sites were accurately characterized in the first place. Public policies that are constructed on theoretical constructs or "common sense" bases require an evaluation of their effectiveness. This is infrequently done by public agencies due to lack of interest and sometimes, limited resources needed to conduct policy effectiveness reviews. One possible fix for this lack of assessment would be for periodic policy reviews conducted by committees of Congress or state legislatures, depending on whether the policies are federal or state based.

19.9.3 Data-Derived SFs

Another example of risk assessment being used for practical purposes is the evaluation of SFs used to calculate toxicity thresholds. Thresholds occur for noncarcinogenic substances. For science policy purposes, carcinogens are generally considered to have no threshold exposure, but this is a policy decision that varies between regulatory agencies, as will be subsequently described. Two kinds of threshold studies have been developed by toxicologists and the study results used in risk assessment calculations. A no observed adverse effect level (NOAEL) is the point on a dose-effect curve at which a threshold is reached. A LOAEL is the lowest level for which a toxic response is observed. NOAELs and LOAELs are usually determined from laboratory animal toxicology studies that use a range of exposure levels. As background, the risk assessment process involves the extrapolation to humans of toxicological animal data and associated science. Because there may be a range of sensitivities in humans to a specific toxic exposure, UFs are used to account for scientific uncertainties in underlying databases. How the UFs are determined has changed over time. The overall goal has been to reduce the range of UFs, relying less on default values,* leading to more precise risk estimates. Some background on how UFs have evolved is instructive.

> The policy of using data-derived uncertainty factors (UFs), rather than default values of 10 or other values, leads to science rather than speculation.

Government agencies historically have been responsible for developing recommendations or regulations to protect against human consumption or exposure to hazardous substances. An early concept used for substances with toxicity thresholds is called an acceptable daily intake (ADI). According to one source [33], the concept of using UFs in risk assessment was first proposed by Lehman and Fitzhugh [45]. They advocated a "100-fold MOS" to provide SFs when extrapolating animal toxicological data to sensitive human populations. In 1977, the National Research Council's Safe Drinking Water Committee recommended that the SF be increased from 100-fold to 1000-fold when

* Default values are those used in lieu of values otherwise available.

toxicity data are found inadequate (as cited in [15]). The committee's recommendation was an expression of concern that in the absence of satisfactory data, water quality standards should be conservatively based. Later, the use of RfD and UF replaced ADI and SF, respectively [15]. The RfD is equal to the NOAEL divided by the product of UFs (i.e., factors of 10) and an additional modifying factor (MF). This can be expressed as

$$\mathrm{RfD} = \frac{\left[\mathrm{NOAEL}\ (\text{or LOAEL})\right]}{\left[(\mathrm{UF})(\mathrm{MF})\right]}$$

The UF components have been categorized as follows: subchronic to chronic exposure extrapolations, interspecies differences between animals and humans, and variability in sensitivity among humans, and incomplete database [46]. The variability in humans is thought to be due to the outbred human populations' inherent genetic variability. Inbred animal models lack this genetic component, leading to the understanding that humans have variable responses while inbred animal models usually do not. This understanding influences the evaluation of relevant databases, e.g., data from animal carcinogenicity studies, where risk assessors will assign the 10-fold default factor, unless data indicate a lesser value.

Similar in concept to EPA's RfDs, ATSDR has developed Minimal Risk Levels (MRLs) under that agency's responsibilities under the CERCLAct. ATSDR's MRL for chronic exposure to ethylene glycol, a compound used in many industrial products (e.g., automotive antifreeze) is shown herein as an example.

1. ATSDR used the study of DePass et al. [51] of rats fed diets with EG at 0, 40, 200, or 1000 mg EG/kg/day.
2. Rats exhibited chronic nephritis at 1000 mg EG/kg/day; no effects at lower doses.
3. NOAEL = 200 mg EG/kg/day UFs applied by ATSDR: 10 for extrapolation from rats to humans and 10 for human variability.
4. MRL = 200/(10)(10) = 2 mg EG/kg/day for chronic oral dose of EG.

One UF, the extrapolation of toxicological data to account for differences between and within species, has become the subject of data-derived methodology. To be more specific, the relative magnitude of toxicokinetic and toxicodynamic variations between or within species have been examined (e.g., [47–49]). In one study, composite factors were all lower than 10 for six pharmaceuticals and 8 of the 12 composite factors were less than 5.5. When UFs are less than the default value of 10, RfD is increased, which, in effect, is a lessening of the risk estimate. This observation means that, in a public health context, it is vital to ensure that accurate and unbiased estimates of UFs are derived.

The policy implications of using data-derived UFs, rather than default values of 10 or other value, are considerable. It can be argued that data-derived factors, which are based on findings from experimental research, reduce the uncertainty that attends default values. In other words, science replaces speculation. On the other hand, what are the guarantees that data-derived UFs are unbiased and accurate? How regulatory agencies incorporate data-derived UFs into their regulatory processes remains to be determined, but will likely be influenced by the requirements of the Information Quality Act of 2001, which was discussed in Chapter 4.

19.10 PUBLIC HEALTH CONCERNS ABOUT RISK ASSESSMENT

Risk assessment in the U.S. has evolved since the 1970s. It has become the engine that drives much of environmental policymaking. But this has not occurred without criticism. In particular, some public health specialists and some environmentalists have questioned whether risk assessment has failed to advance public health goals. It is therefore useful to reflect on the relationship between risk assessment, as practiced by regulatory agencies, and its impact on the public's health.

> Some have asserted that regulatory risk assessments have suffered from lack of depth in epidemiological and health surveillance perspectives [52,53].

The public health community, i.e., public health officials and practitioners, has been slow to embrace risk assessment [52]. The reasons are complex, but can be distilled into three broad categories: the public health tradition, prevention ethos, and public health resources.

The public health tradition can be stated to comprise science, consensus, and services. In this context, science includes laboratory and field research, epidemiological investigations, and studies of causal mechanisms of disease. Findings from contemporary research, when added to an existing body of knowledge, can create a science foundation that can be applied to a public health problem at hand. For example, findings from studies of children exposed prenatally to lead released from maternal tissues revealed a public health problem. The children evidenced developmental disorders (e.g., delays in cognitive processes) due to their fetal exposure to lead. In the public health tradition, science of import, such as the lead findings in children, must be vetted through peer reviewed publications of research findings and disclosure to the scientific community. Consensus formation on the gravity of a body of science is a key step in the public health tradition. This is necessary because public health resources are limited and must be directed to prevention of significant, not trivial, public health problems. Consensus is often pursued by reliance on advisory organizations, e.g., the National Academy of Sciences, or issue-specific advisory committees, e.g., CDC's Advisory Committee on Childhood Lead Poisoning Prevention. When

a public health problem has been identified, it becomes essential to obtain cooperation among health agencies on to prevent or contain the problem. A significant part of public health agencies' cooperation is the sharing of resources and services. For example, federal health agencies can provide states with grants, e.g., childhood lead exposure surveillance, for purpose of disease prevention, assuming that the federal agencies have granting authority under their authorizing statutes.

In distinction to the public health approach, the regulatory approach comprises science, regulations, and enforcement. Much like in the public health tradition, regulatory agencies require a body of science in order to develop regulations and standards. As with public health organizations, regulatory agencies cannot act on a whim (i.e., in the absence of scientific data). Regulatory agencies utilize scientific data (e.g., findings from toxicology studies) to develop proposed regulations and standards. Enforcement of regulations, when authorized by law, completes the regulatory approach to controlling environmental hazards.

Unlike those public health agencies that lack regulatory authority, environmental regulatory agencies have the weight of law buttressing their actions, such as environmental standards. Strictly speaking, regulatory agencies do not require consensus on their proposed regulatory actions. Rather, federal regulatory agencies hold public meetings and public notices in the *Federal Register* to solicit comments from the public and the targets of proposed regulations. A consequence of these meetings and public notices is often the revision of proposed regulations. Therefore, to some extent, such actions constitute a kind of consensus formation.

In summary, the public health tradition differs from the regulatory approach in response to control of environmental hazards. This duality in approach has been uncomfortable for some public health practitioners, contributing to a slow acceptance or outright rejection of quantitative risk assessment. The second area that contributes to the public health community's slow acceptance of risk assessment concerns the ethos of prevention of disease and disability, the centerpiece of public health theory and practice. Some persons with experience in both public health practice and regulatory agency responsibilities [52,53] have opined that prevention (in a public health context) is not prominent in the regulatory approach. Goldman [53] has observed that prevention as a possible anchor for risk assessment was not addressed in the NRC's seminal report "Risk Assessment in the Federal Government: Managing the Process" [4]. Because federal regulatory agencies adopted the NRC's recommendations on how to conduct risk assessments, any lack of prevention perspective was passed along to regulatory agencies.

Whether or not risk assessment lacks a prevention thrust is open to interpretation. It must be acknowledged that risk assessment of a hazard generally occurs with the hazard already present in the environment. Risk assessment is employed to address whether existing levels of exposure to a hazard should be lowered or eliminated because the risk of adverse health effects is unacceptable. This is a kind of *post hoc* disease prevention. However, it is possible to use risk assessment in a prospective manner. For example, some business enterprises, as they develop new products, conduct risk assessments during the product development process. Company risk assessors attempt to determine if their product could harm humans or ecosystems. Keeping harmful products out of commerce is a matter of primary prevention. However, it is unknown to what extent this kind of self-censoring of products under development occurs, since such actions are usually considered "business confidential." The belief by some public health practitioners that risk assessment does not readily comport with the principle of disease prevention has led them to recommend that it be replaced by application of the Precautionary Principle, which was discussed in Chapter 2. However, such a replacement should be accompanied by a cautionary analysis of its consequences. For example, would an action predicated on precaution produce any undesired impacts on economic or other social systems?

The third area that contributes to public health authorities' skepticism about risk assessment can loosely be termed "lack of public health resources" found in the risk assessment process. In the context used here, public health resources refers to both people and databases. Goldman [53] observed, referring to the establishment of regulatory agencies, "[p]ublic health decision-making was moved into realms where there were very few people with public health training and experience." This situation has changed little over the years following the EPA's and OSHA's establishment. Although both agencies employ epidemiologists and public health specialists, their numbers are few in comparison to the numbers in public health agencies. As a consequence, some have asserted that regulatory risk assessments have suffered from lack of depth in epidemiological and health surveillance perspectives [52].

In regard to public health databases, some public health spokespersons have lamented the absence of epidemiological databases and health surveillance systems both within regulatory agencies and in individual risk assessments. Burke [52], commenting on the adoption of risk assessment by federal and state agencies, stated, "On the Federal level EPA support for epidemiology declined, and on the state level the traditional roles of health agencies, including epidemiology and health surveillance, became more distant from the evaluation of population health to the quantification of population risk." As a consequence, fewer data from epidemiological investigations and health surveillance systems are available for risk assessments of environmental hazards.

19.11 OTHER CRITICS OF RISK ASSESSMENT

In addition to the community of public health specialists, others have also expressed concerns about the use of risk assessment in aspects of environmental health policymaking. For example, the United Kingdom's Royal Commission on Environmental Pollution advocated that risk assessment, as currently practiced, be replaced [54,55]. The commission concluded that current risk assessments were inadequate,

cumbersome, and slow. Moreover, they expressed criticism of current risk assessment methodologies, as practiced within the EU, that involve "[a] range of criteria, including toxicity, persistence, bioaccumulation and, importantly, exposure as a basis for management" [54]. In lieu of the current methodology, the commission recommended a new paradigm that focuses on environmental persistence of a toxicant and its bioaccumulation, leading to decision-making that is hazard-based, not risk-based. Further, the commission recommended that qualitative structure–activity relationships (QSARs) be used to predict toxicity results, based on chemical structures, rather than conducting toxicity tests directly. However, caution must be exercised in the adoption of QSARs for specific risk assessments. In particular, data from application of QSARs must comport with biological reality.

The commission's recommendations, if adopted in lieu of risk assessment, would, they assert, reduce delays in policymaking that is currently based on risk assessment. As noted by Calow and Forbes [55], the commission's new paradigm seems willing to accept less scientific information in order to reduce delays in decision-making. This approach is in the spirit of a precautionary approach for dealing with environmental hazards. Whether or not the commission's recommendations become policy in Europe remains to be seen.

19.12 SUMMARY

Quantitative risk assessment did not just drop from the sky into the awaiting nets of U.S. regulatory agencies. Rather, risk assessment of toxicants in community and workplace environments evolved in reaction to court decisions in the early 1980s that required regulatory agencies to quantify levels of risk posed by specific federal regulations. The court decisions set into motion ongoing efforts at the EPA and OSHA to systematize how risk assessment and risk management policies and practices are developed and implemented. In this regard, a study conducted by the U.S. NRC [4] was particularly influential on how risk assessment was systematized by EPA and other regulatory agencies, federal and state, as discussed in this chapter. The NRC risk assessment structure of hazard identification, dose–response assessment, exposure assessment, and risk characterization was widely accepted in the U.S. as a sensible roadmap for use by regulatory agencies and remains in current use.

Systematization of regulatory risk assessment policies (e.g., inter-agency cancer policies and methods) and practices (e.g., public hearings on proposed regulations) is important. It informs both a regulatory agency's staff and the general public about what to expect. This is laudable in the context of the public's right-to-know policy, but has also contributed to almost automatic litigation over environmental regulations and standards. All risk assessments require that risk assessors deal with uncertainties in scientific data, leading to choices that can be litigated.

Risk assessment, as the core of regulatory agencies' programs to control environmental hazards, has given rise to criticism by some public health practitioners and environmentalists. Critics have voiced concern about the inordinately long time to establish a regulation, e.g., the OSHA ergonomics rule that was in development for 10 years. Moreover, the litigious nature of current risk assessments and the politicalness of proposed regulations can delay promulgation of risk-based exposure standards. These concerns have led public health advocates and environmentalists to propose using the Precautionary Principle, which was discussed in Chapter 2, in lieu of risk assessment for control of environmental hazards, believing that less time would be required to take action to control environmental hazards. However, given the U.S. investment in risk assessment-based regulations and standards, it is unlikely that the Precautionary Principle will soon be adopted as a replacement.

19.13 POLICY QUESTIONS

1. Compare the merits and drawbacks of the use of risk assessment-based regulatory strategies versus a precautionary-approach strategy, as discussed in Chapter 2. Which of these two strategies do you prefer, and why?
2. Does ecological risk assessment have any relevance for public health? If so, discuss why. If not, discuss why.
3. What is the dollar value of your life? How did you determine the value? Do you favor the utilitarian or the egalitarian approach to determining the value of human life? Defend your selection.
4. Discuss each of the four elements of the NAS risk assessment paradigm in terms of importance to public health practice.
5. Assume that you are a member of a local health department. The director of the department asks for your advice on the following two topics: (a) How could the county's hazards be compared and ranked? (b) Should a survey of the public's risk perceptions be undertaken and used as a factor on which to allocate scarce budgetary funds?
6. Discuss the relevance of the U.S. Supreme Court's benzene decision on public health.
7. How does hazard differ from risk? Discuss the hazards that you face in your daily activities. How do you decide on which ones pose the most significant risk to your health?
8. Discuss how the ACGIH's TLVs have had a substantive impact on occupation health.
9. How could the arsenic brouhaha (Table 19.1) been avoided?
10. A public health specialist has stated some criticism of the NAS four-step method of risk assessment, as was discussed in this chapter. Your assignment is to modify the NAS paradigm to include the element of prevention. Be sure to justify your modification of the NAS proposal.

11. Generally speaking, regulatory agencies are vested with the authority to issue legally enforceable regulations. Nonregulatory agencies, e.g., WHO, can issue nonbinding guidelines. In an essay of appropriate depth, discuss the pros and cons of each method.
12. What do you estimate to be the value of your life? What about the value of your eldest living relative? Should value of human life be a component of cost–benefit analysis as required for development of federal regulations? And what about value of life present in ecological systems?
13. Do you personally conduct comparative risk analysis of the hazards you face in daily life (e.g., food choices)? If so, how? If not, why not? Be specific.
14. In your opinion, should any risk assessments utilize SFs that are not data driven? In an essay of appropriate depth, present the pros and cons of use of SFs not based on data. Conclude your essay with a paragraph that presents your conclusion on data-driven SFs.
15. RBCA is described in this chapter and its application discussed in the context of actions to be taken at sites of environmental contamination, hazardous waste sites in particular. In your opinion, should RBCA be required for any environmental hazard problem, e.g., air pollution control? Provide details on your decision.
16. In 2016, NIOSH released a new carcinogens policy. RELs for carcinogens were replaced by RML-CAs. Discuss the practical implications of this change in policy. Are RML-CAs legally enforceable?
17. Assume that you are a senior member of a county health department. A neighborhood committee brings to your attention that a small chemical plant is discharging noxious fumes into the neighborhood. They are concerned about possible cancer causation. The group has heard about something called "cancer risk analysis." What is your reply and what actions to you take? Be specific.
18. Good news! You have been appointed to the position of senior toxicologist at an EPA regional office. On your first day of the new job, a junior toxicologist brings her analysis of an air contaminant being released by a new paint company. The HQ was calculated to be 1.3. What do you do with this information, for which a decision by the paint company is needed ASAP.
19. Access the EPA website and ascertain the inhalation carcinogenic URE for benzene. What is the estimated range of number of persons with hematologic cancers per one million benzene-exposed people?
20. Congratulations! You have completed another chapter. We trust the experience was not unduly hazardous to you. Discuss in an essay of appropriate depth the most important new information you learned that will aid you in making risk assessment and management decisions.

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20 Lessons Learned and Authors' Reflection

20.1 INTRODUCTION

We have endeavored in this book to present the key environmental policies and their public health foundations. In this regard, the book provides an important perspective on the public health issues that buttressed the development of almost all environmental policies. We are of the belief that these two bodies of information, environmental policies and public health foundations, must be presented as companion sets of knowledge. To have knowledge, based on persuasive science, of the health consequences of specific environmental hazards and to do nothing about the science would be unethical and inexcusable. For example, shown in Table 20.1 is a tabulation of deaths associated with the specific environmental hazards described in this book. The mortality data in the table illustrate that the health consequences are real and will present formidable challenges to their mitigation.

In this second edition of the book, we have found it necessary to add additional perspectives to the prior work. First, it is now abundantly clear that environmental hazards in the physical environment are a global problem. For instance, today's air pollution in North America is tomorrow's air pollution in Asia, Europe, and elsewhere on our planet. The second perspective added in this update is ecosystem health. We believe, as do many others, that human health and ecosystem health are intrinsically intertwined. As but one example, warmer global temperatures due to carbon-fueled climate change has already influenced the distribution and pattern of mosquito-bearing viruses, bacteria, and parasites that will result in human diseases in geographic locations previously free of them. Public health specialists, as but one profession, will need to understand the relationship between these kinds of ecosystem changes on public health. Third, we had added hazard interdictions as new material in this edition of the book. We realized that to merely describe various environmental hazards and not to present hazard interdictions would have been an inadequate risk communication.

The broadest definition of the environment encompasses four domains: the physical domain, which includes the chemical and built components; the biological domain, which addresses pathophysiological processes in the human body; the social domain, often exemplified by nonchemical stressors such as community violence; and the policy domain. This book uses the lens of policy to focus more heavily on the components of the traditional physical environment and its key elements (air, water, food, and waste) as well as emerging hazards associated with genetically modified organisms, loss of biodiversity, energy production, environment-related infectious diseases, and the built environment. The biological and social domains are indirectly addressed through the content discussed in the chapters on environment-related infectious diseases, and environmental justice, respectively.

We also recognize two broader concepts linking environment and health: One Health is an "approach that considers the connections between the environment, plant, animal, and human health" [1]. Planetary Health is defined as the "health of human civilizations and the ecosystems on which they depend" [2]. Both are emerging fields and are not yet associated with robust policies or regulations that could be included in our book.

20.2 SUMMARY OF LESSONS LEARNED

Reflecting on the environmental policies presented in this book provides an opportunity to glean some lessons that have portent for the future. The following lessons are those of the book's authors, both of whom have had considerable experience in environmental policies and pertinent public health programs at federal and state governments and academic levels. We invite others to supplement the following lessons.

1. Environmental policies have evolved from humankind's experience with physical hazards in the environment. Who knows when this awareness began? Perhaps with our primordial hunter-gather ancestors, but one can assert with some surety that environmental policies slowly emerged, often from experience due to natural or anthropomorphic disasters or epidemics of disease. As larger societies such as towns and cities formed from smaller groups such as tribes and villages, dealing with the physical environment became increasingly important, if for no other reason than survival. Decisions were made for the social good; decisions such as how to defend the population, how to acquire food, and how to deal with nonsocial behavior. Decisions emerged on how to avoid or manage environmental hazards such as impure food, unsanitary waste, and nonpotable water. These kinds of decisions can be considered as policies, and policymaking became an activity in its own right, with attendant rules, procedures, and resources. A lesson from this bit of history is that policymaking occurs in a social structure because it is must. Societies eschew chaos and policymaking is but one way to structure order out of complex, vexing challenges to a society's welfare.
2. As evident from the content of Chapter 18, the burden of environmental hazards is not equally shared across social, cultural, and global boundaries. In industrialized countries, the poor and ethnic minority populations are exposed to disproportionate

TABLE 20.1
Mortality Associated with Specific Environmental Hazards

Environmental Hazard	Estimated Deaths	Time	Source	Chap./Cite
	Air Pollution			
Air pollution (total)	7–8 million global	Annual	WHO	8/[1]
Air pollution (outdoor)	Approx. half of total	Annual	WHO	8/[1]
Air pollution (indoor)	Approx. half of total	Annual	WHO	8/[1]
Climate change	150,000 global 250,000 additional global	Year 2000 2030–2050 annual	WHO	6/[25]
Consumer products	23,900	Annual	CPSC	4/[18]
	Food			
Food safety	420,000 global 3,000 U.S.	Annual Annual	WHO CDC	10/[17] 10/[19]
	Infectious Diseases			
Cholera	21,000–143,000 global	Annual	WHO	13/[10]
Ebola virus disease	11,000 global	Year 2013	CDC	13/[39]
HINI influenza	300 U.S.	Year 2010	CDC	13/[33]
Malaria	600,000 global	Year 2012	WHO	13/[59]
Vector-borne diseases	1 million global	Annual	CDC	13/[50]
Tobacco	6 million global 480,000 U.S.	Annual Annual	WHO CDC	7/[25] 7/[28]
Water	2 million (unsafe water, sanitation, and hygiene) global	Annual	WHO	9/[14]
Work/Job-Related	5,071 (injuries) U.S. 49,000 (illnesses) U.S.	Year 2008	CDC	4/[15]
Total global deaths (all causes)	55 million	Annual	WHO	5/[27]

CDC, Centers for Disease Control and Prevention; CPSC, Consumer Product and Safety Commission; WHO, World Health Organization.

burdens of environmental pollution. This disproportionality can be the direct result of racial discrimination or a disenfranchisement from social justice. While some policymakers in the U.S. have chosen to place their waste processing facilities (e.g., landfills or recycling plants) in poor or minority communities, this is an example of intentional discrimination. In developing countries, the burden of environmental hazards may be borne more equally, as the difference between poor and affluent populations may be smaller than in industrialized countries. Sadly, young children and the unborn can also experience a disproportion response to exposure to some environmental hazards. This can occur because of the effects of environmental stressors, such as lead and other toxicants, on the developing body of fetal and neonatal bodies. A child who lives in poverty and is a victim of environmental injustice can face a lifetime of impaired development and function.

3. The historical record indicates that essential environmental municipal policies such as sanitary management of human waste began to occur in the early years of the nineteenth century, when Edwin Chadwick, a British attorney and policymaker, led the financing and construction of a sanitary sewer system in London. He was a person of passionate energy and absolute conviction that the public's health would be improved via installation of his sanitary sewers. He was correct in his prescient vision. And that is but one lesson worthy of note: Be willing to wage the sociopolitical battles that attend the public good.
4. Development of environmental policies by government entities is vital for forging the political will, resources, and platform for democratic debate. And by government we speak broadly: federal, state or province, or tribal and local levels of government. That is not to infer that nongovernment entities aren't important—they are—but the private sector and nongovernment organizations don't often offer the same forums for making decisions on environmental policies. Further, nongovernment entities can provide valuable perspectives and persuasion, but lack the authority to craft legal policies such as the Clean Air Act (CAAct).
5. Development and enactment of environmental policies at any level from a household to a global treaty must be undergirded by a body of persuasive science. And by persuasive we are referring to science based on the scientific method or a body of common

knowledge. For the former, the current body of independent, peer-reviewed science concerning the morbidly and mortality consequences of exposure to air pollution, presented in objective journals has driven global policies on control of air contaminants. Concerning common knowledge, humankind learned, without benefit of published science, that some unwelcome household invaders such as rodents could be vectors of disease.

6. Commercial product development has inadequately assessed the potential consequences of products released into the environment. The addition of lead, a long known toxic element, to paint and gasoline is but one example of public health disaster due to commercial drive to "improve" a product, but without seminal attention to environmental consequences. A more current story is the release of plastics into the global environment. Government agencies have been inadequate to the task of forecasting dire environmental effects of new products that will find their way into the environment. Environmental groups have been more attuned to the environmental consequences of new products.
7. The field of toxicology has been slow to adjust to the adverse effects of agents released into the physical environment. This is unfortunate, since that toxicology is one of the key pillars of policymaking science. In the early days of pharmacology, attention was focused on adverse effects of new pharmaceutical substances, with due attention given to assessing mortality of laboratory animals administered new pharmaceuticals. In time, the examination of the adverse effects of substances morphed into the field of toxicology. But the emphasis on mortality remained, with LD50 studies often used to assess the "toxic effects" of some substances. As toxicology grew as a field separate from pharmacology, attention to mortality turned to organ systems, with cancer as the principal focus. In time, attention enlarged to include the toxic properties of substances on reproduction and reproductive systems. This was subsequently followed by attention on the immune and nervous systems, with the latter gradually incorporating study of behavioral aspects of toxic substances such as lead and polychlorinated biphenyls (PCBs). Each of these additions to toxicological inquiry was met with resistance from both within and outside the field of toxicology. Perhaps the best example of resistance to an emerging area of toxicology is endocrine disruption, an area of science that examines the effects of environmental substances on hormone function. This science was a tough sell to traditionally trained toxicologists and was vigorously opposed by commercial interests that produced some of the substances under examination for hormone disruption properties. But the persistence of one scientist, Dr. Theo Colborn, with commensurate science from academic researchers, overcame obstacles within the toxicology community. A lesson here was the vital needs for a persistent advocate of a public health and ecosystem cause, resourced with good science.
8. It is obvious to our species that we share our planet with other living organisms. Indeed, our living partners sustain our life and well-being, providing us with food, shelter, clothing, education, and entertainment, as but a few of many benefits. One might argue that not all of our "partners" are necessary. Mrs. Mosquito comes to mind, but even there one must understand the ecological consequences of mosquito eradication. Unfortunately, over time, many species have disappeared from our planet due to many factors, not the least of which is human intervention. As described in Chapter 16, one example is the elimination in the U.S. of the passenger pigeon due to municipal policies of pigeon eradication and from hunting forays. We will never know what the benefits of the passenger pigeon were. A lesson from experience with policies on environmental health is the need for consideration of ecological consequences of human actions. Put simply, what we do affects our planet's partners and vice versa. That is why we have endeavored to provide an ecosystem complementary perspective on environmental health policies.
9. An American political leader once proclaimed, "All politics is local." By that he encapsulated the principle that a politician's success is directly tied to the person's ability to understand and influence the issues of their constituents. A corollary for environmental policy might be "All pollution is local." For instance, a local power plant can be a source of particulate air pollution, agricultural runoff of fertilizers occurs locally and from a choice made by a farmer or farm business, cosmetics one chooses may contain microbeads as abrasives, household food waste can become food for disease-carrying vermin, the vehicles we choose for transportation can determine air pollution levels, and so forth. So the choices that we individuals make can collectively shape local pollution and environmental hazards. The lesson is to realize that we as individuals make our own environmental policies that in the aggregate can shape larger environmental hazards. This is a matter of education, beginning with youth education.
10. The global increase in human population will present enormous challenges to policymakers of many disciplines, not the least of whom will be environmental health policymakers. Each and every new human addition will impact the planet's fragile balance of natural and anthropogenic resources. Not the least of these resources will be food and water. And as described in Chapter 6, climate change will adversely affect both these vital resources. In the extreme, whole populations of human and nonhuman life will face a nonsurvival fate if climate

change has not been contained via global environmental policymaking. The lessons of history reveal that humankind is rather resilient in the face of catastrophic challenges, whether in the form of epidemic disease or from natural disasters. But a global challenge as presented by climate changes that were not adequately contained via global cooperation and agreement will be a challenge that will severely test the resiliency of humankind.

11. At the core of much of our planet's environmental woes is mismanagement of waste. As noted in Chapter 12, waste is material or an action that is discarded. Discarding can be intentional, as in kitchen waste, or unintentional, as in an effort wasted trying to solve a puzzle without solution. We assert here that waste is at the heart of air pollution, water contamination, food security, climate change, energy production, vehicle design, and waste management. To elaborate on this theme, air pollution occurs from release of incomplete combustion of materials; water pollution is a product of unwanted materials released into bodies of water, including the planet's oceans; food security is threatened by significant amounts of food that are discarded during transportation, marketing, or preparation of foodstuffs; climate change occurs due to humans' release of excessive amounts of carbon into the atmosphere; waste from the generation of energy occurs from how we mine, drill, transport, and use different forms of energy supply; our vehicles designed and built for transportation began with, and remain now, primarily powered by polluting internal combustion engines; and waste management itself can be a wasteful process if methods of recycling or reuse are not integral to the management process. This thesis of waste as a core environmental problem argues for better education, training, and implementation of waste minimization strategies and policies.
12. A lesson from the Flint, Michigan, municipal water catastrophe (Chapter 9) of municipal inattention to lead in the city's water supply concerns the loss of public trust in government agencies that were supposed to protect the public from impure water. As presented in Chapter 9 as a case study, the introduction of nonpotable water into the municipal water supply of Flint, Michigan, was a failure by federal, state, and local levels of government. It is alleged that the Michigan Department of Environmental Quality, the EPA, and the Flint water authorities had either ignored or refused to act on what had emerged as lead poisoning in young children. As a consequence, public trust in government diminished according to local news media. Loss of trust is akin to loss of virtue; it is quite difficult to reclaim. To whom or what does a community or an individual turn if government agencies fail? The lesson should be to inculcate into environmental and public health agencies the fundamental principle of responding to the public, regardless of the political fences placed in the way.
13. Recall that the Precautionary Principle addresses making decisions about the best ways to manage or reduce risks that reflect a preference for avoiding unnecessary health risks instead of unnecessary economic expenditures when information about potential risks is incomplete. Bearing this thesis in mind, we consider much of the U.S. policymaking on environmental health derives from the precautionary principle, though not usually explicitly stated. Major U.S. statutes such as the CAAct, the CWAct, the FDAct, and the CERCLAct became policies based on the precautionary principle, since each of these statutes was formulated on public health concern, but often without foundational science.

20.3 CLOSURE

The authors do not assert that these lessons learned are unique to us, nor do they convey any special insight nor wisdom. Rather, the lessons are what they are: Ideas and reflections gleaned from our collective life experience as teachers, administrators, researchers, and students of environmental science. If these lessons and, moreover, the content of this book find their way into the minds and hands of policymakers who can make or aid in making the globe a sustainable home for living creatures, we authors will have achieved satisfaction. The authors hope that this second edition of *Environmental Policy and Public Health* will be useful to those persons who care about the public's health and the control of hazards in our physical environment. If the material herein aids in establishing new or revised environmental health policies, either personal or institutional, our goal for this work will have been met.

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Section V

Support Material

Appendix 1

LIST OF ABBREVIATIONS

ATSDR	Agency for Toxic Substances and Disease Registry, DHHS
BAT	Best Available Technology
BPT	Best Practicable Control Technology
CAAct	federal Clean Air Act
CBAN	Canadian Biotechnology Action Network
CBD	Center for Biological Diversity
CCEHRP	Committee to Coordinate Environmental Health and Related Programs, DHHS
CCR	Consumer Confidence Report
CDC	Centers for Disease Control and Prevention, DHHS
CEQ	Council on Environmental Quality
CERCLAct	federal Comprehensive Environmental Response, Compensation, and Liability Act (also called the Superfund Act)
CPSAct	federal Consumer Product Safety Act
CPSC	Consumer Product Safety Commission
CTP	Center for Tobacco Products
CWAct	federal Clean Water Act
DHEW	U.S. Department of Health, Education, and Welfare (predecessor of DHHS)
DHHS	U.S. Department of Health and Human Services
DHLS	Department of Homeland Security
DoC	U.S. Department of Commerce
DoW	Defenders of Wildlife
ECHA	European Chemicals Agency
EEA	European Environmental Agency
EFSA	European Food Safety Authority
EIC	Earth Institute, Columbia University
EIS	Environmental Impact Statement (required by the NEPAct)
EPA	United States Environmental Protection Agency
ESAct	federal Endangered Species Act
FAO	Food and Agriculture Organization, United Nations
FCCC	Framework Convention on Climate Change (United Nations)
FDA	Food and Drug Administration, DHHS
FDCAct	federal Food, Drug and Cosmetic Act
FEMA	Federal Emergency Management Agency, DHLS
FHA	Federal Housing Authority
FHSAct	Federal Hazardous Substances Act
FIFRAct	Federal Insecticide, Fungicide, and Rodenticide Act
FMIAct	Federal Meat Inspection Act
FQPAct	Federal Food Quality Protection Act
FSMAct	federal Food Safety Modernization Act
GAO	Government Accountability Office, née General Accounting Office (name changed July 7, 2004)
Hazmat	Hazardous Materials
IARC	International Agency for Research on Cancer, WHO
IEA	International Energy Agency
ILO	International Labour Organization, United Nations
IMO	International Maritime Organization
IPCS	International Programme on Chemical Safety, WHO
IUCN	International Union for Conservation of Nature
JGCRI	Joint Global Change Research Institute
MACT	Maximum Available Control Technology
MCL	Maximum Contaminant Level

MCLG	Maximum Contaminant Level Goal
MHS	Medical Hospital Service
MMPAct	Marine Mammal Protection Act
NAAQS	National Ambient Air Quality Standard
NAS	National Academy of Sciences
NASA	National Aeronautics and Space Agency
NCI	National Cancer Institute, NIH
NCP	National Contingency Plan
NCTR	National Center for Toxicological Research, FDA
NEPAct	federal National Environmental Policy Act
NIAID	National Institute of Allergy and Infectious Diseases, NIH, DHHS
NIEHS	National Institute of Environmental Health Sciences, NIH, DHHS
NIH	National Institutes of Health, DHHS
NIOSH	National Institute for Occupational Safety and Health, CDC, DHHS
NOAA	National Oceanic and Atmospheric Administration, DoC
NRC	National Research Council of the National Academies
NRCS	Natural Resources Conservation Service, USDA
OCS	Ocean Conservation Society
ODAct	federal Ocean Dumping Act
OPA	federal Oil Pollution Act
OPAct	Oil Pollution Act
OSHA	Occupational Safety and Health Administration, U.S. Department of Labor
PELs	Permissible Exposure Limits
PHS	U.S. Public Health Service, DHHS
PHSAct	Public Health Service Act
PPA	federal Pollution Prevention Act
PPAct	Pollution Prevention Act
PRP	Potentially Responsible Party under CERCLA provisions
QSAR	Quantitative Structural Activity Relationship
RCRAct	federal Resource Conservation and Recovery Act
RELS	Recommended Exposure Limits
ROD	Record of Decision
SDWAct	federal Safe Drinking Water Act
SIP	State Implementation Plan
TEDX	The Endocrine Disruption Exchange
TRI	Toxics Release Inventory (required by Title III of CERCLA, as amended)
TSCAct	Toxic Substances Control Act
TSDF	Treatment, Storage, and Disposal facility
UN	United Nations
UNCED	United Nations Conference on the Environment and Development
UNEP	United Nations Environment Programme, UN
USACE	United States Army Corps of Engineers
USFWS	U.S. Fish and Wildlife Service
WHO	World Health Organization, UN
WTO	World Trade Organization
WWF	World Wildlife Fund

Appendix 2

LIST OF KEY WEBSITES

Site	Resource	Web Address
3GF	Global Green Growth Forum	http://3gf.dk/en/about-3gf/
Bagheera	An Education Website about Endangered Species and the Efforts to Save Them	http://www.bagheera.com/endangered-species-laws-a
BIF	Birds in Flight for protection of bird species	http://www.partnersinflight.org/
CBAN	Canadian Biotechnology Network	http://www.cban.ca/
CBD	NGO advocate for biodiversity	http://www.biologicaldiversity.org/
CDC	Lead U.S. agency for disease control	www.cdc.gov
CDCWDOS	Waterborne disease surveillance	http://www.cdc.gov/healthywater/surveillance/index.html
CFS	Nonprofit public interest and environmental advocacy organization	http://www.centerforfoodsafety.org/about-us
CTP	FDA's principal center for information about tobacco products	http://www.fda.gov/TobaccoProducts/
DoW	NGO wildlife conservation	http://www.defenders.org/
ECHA	EU chemicals regulatory agency	http://echa.europa.eu/
EEA	Lead EU environmental agency	http://www.eea.europa.eu/about-us/who
EFSA	Food safety in the EU	https://www.efsa.europa.eu/en/about/people
EIC	Academic source of Earth's data	http://www.earthinstitute.columbia.edu/
EPA	Lead U.S. federal agency for environmental protection	https://www3.epa.gov/
FAO	Lead U.N. agency for food and agriculture	http://www.fao.org/home/en/
FDA	Lead U.S. federal agency for safety of food, drug, cosmetics, and devices	www.fda.gov
IARC	WHO's cancer research program	http://www.iarc.fr/
IEA	OECD's energy agency	http://www.iea.org/
IMO	Global maritime organization	http://www.imo.org
IPCS	This WHO program provides chemical safety recommendations	http://www.who.int/ipcs/en/
IUCN	NGO concerned with conservation of nature	http://www.iucn.org/about/
JGCRI	Global change research institute	http://www.globalchange.umd.edu/
Just Name It!	NGO Product Labeling Organization	http://www.justlabelit.org/right-to-know-center/labeling-around-the-world/
NAACP ECJ	NAACP Environmental and Climate Justice Program	www.naacp.org/environmental-climate-justice-about/
NAS	A nonprofit society of scholars that provides advice to the nation on matters related to science and technology	http://www.nasonline.org/about-nas/mission/
NASA	Summary data on the causes and effects of global climate change	http://climate.nasa.gov/
NIEHS	Lead NIH institute for environmental research	http://www.niehs.nih.gov/
NIH	Lead U.S. federal agency for biomedical research	http://www.nih.gov/
NIOSH	Lead U.S. federal agency for health and safety workplace research	http://www.cdc.gov/niosh/
NRCS	U.S. soil conservation service	http://www.nrcs.usda.gov/wps/portal/nrcs/main/national/about/
OCS	NGO for ocean conservation	www.oceanconservation.org
OSHA	U.S. federal agency for workplace safety and health	https://www.osha.gov/
TEDX	Website for endocrine disruption info	http://www.TEDX.org
UN	Global organization for international affairs	http://www.un.org/en/index.html
UNEP	Lead U.N. agency for environmental research, education, services	http://www.unep.org/default.asp
USACE	U.S. Army Corps of Engineers	http://www.usace.army.mil/About/
USAID	Agency for international development	https://www.usaid.gov/
WHO	Lead U.N. agency for health response	http://www.who.int/about/en/
WWF	NGO wildlife advocacy organization	http://www.worldwildlife.org

Appendix 3

GLOSSARY OF KEY TERMS

Absorbed dose	The amount of a substance that penetrates across the exchange boundaries of an organism through either physical or biological processes after contact (exposure) [1].
Absorption	The process of taking in, incorporation, or reception of gases, liquids, light, or heat [2].
Acute	Occurring over a short time, usually a few minutes or hours. An *acute* exposure can result in short-term or long-term health effects. An *acute* effect happens a short time (up to 1 year) after exposure.
Administered dose	The amount of a substance given to a human or test animal. Administered dose is a measure of exposure because absorption is not considered [1].
Agency	A government office or department that provides a specific service.
Agent	An entity (chemical, radiologic, mineralogic, or biologic) that may cause effects in an organism exposed to it.
Ambient	Surrounding; pertaining to the air, noise, temperature, etc., in which an organism or apparatus functions [2].
Analytic epidemiologic study	Investigations that evaluate the causal nature of associations between exposure to hazardous substances and disease outcome by testing scientific hypotheses [3].
Anemia	A decreased ability of the blood to transport oxygen; Low numbers of red blood cells or hemoglobin.
Anthropogenic	Of, relating to, or resulting from the influence of human beings on nature.
Applied dose	The amount of a substance given to a human or test animal, especially through dermal contact. Applied dose becomes a measure of exposure because absorption is not considered [1].
Assessment	The process of determining the nature and extent of hazards and health problems within a jurisdiction.
Background level	A typical or average level of a chemical in the environment. *Background* often refers to naturally occurring or uncontaminated levels.
Biologic indicator	A chemical, its metabolite, or another marker of exposure that can be detected or measured by biomedical testing of human body fluids or tissues to validate human exposure to a hazardous substance.
Biologic monitoring	Measuring chemicals in biologic materials (e.g., blood, urine, breath, hair) to determine whether chemical exposure has occurred in living organisms.
Biologic uptake	The transfer of substances from the environment to living organisms.`
Blood lead level	The concentration of lead in a sample of blood.
Body burden	The total amount of a chemical in the body. Some chemicals accumulate in the body because they are stored in fat or bone or other tissues.
Bully pulpit	A prominent public position (as a political office) that provides an opportunity for expounding one's views [4].
Carcinogen	A substance that can cause cancer.
Carcinogenicity	Capacity to cause cancer.
Census block group	A geographic block group or tabulation block group. The former is a cluster of blocks having the same first digit of their three-digit identifying numbers within a census tract or block numbering area. A tabulation block group is a geographic block group that may be split to present data for every unique combination of county subdivision, place, American Indian and Alaska Native area, urbanized area, voting district, urban/rural and congressional district shown in the data product [5].
Census block	Small geographic areas enclosed by visible features such as streets, roads, streams, and railroad tracks, or by invisible borders such as city, town, township, and county limits; property lines; or short, imaginary extensions of streets and roads [5].
Chromosome	The structure (normally 46 in humans) in the cell nucleus that is the bearer of genes.
Chronic	Occurring over a long period of time (e.g., more than 1 year).
Climate change	A condition that can be caused by an increase in the atmospheric concentration of greenhouse gases, which inhibits the transmission of some of the sun's energy from the earth's surface to outer space.
Climate	The weather in a region or city averaged over many years. This is usually different for different seasons [20].
Command-and-control regulation	A regulation that requires polluters to meet specific emission-reduction targets.
Community	A group or social class having common characteristics.
Concentration	The amount of one substance dissolved or contained in a given amount of another.
Confidence interval	An interval of values that has a specified probability of containing a given parameter or characteristic [1].
Contaminant	Any substance or material that enters a system (e.g., the environment, human body, food) where it is not normally found.

Cost–benefit analysis	An economic technique applied to public decision-making that attempts to quantify in dollar terms the advantages (benefits) and disadvantages (cost) associated with a particular policy.
Cost-effectiveness analysis	An analysis that measures the net cost of providing a service as well as the outcomes obtained.
Demographics	The statistical study of human populations.
Dermal	Referring to the skin. *Dermal* absorption means absorption through the skin.
Developing countries	Those countries that are in the process of becoming industrialized but have constrained resources.
Diagnostic test	A laboratory test used to determine whether a person has a particular health problem.
Disease incidence	The rate of new occurrences of a disease.
Disease surveillance	A data collecting system that monitors the occurrence of specific diseases (e.g., cancer).
Disease	Illness; sickness; an interruption, cessation, or disorder of body functions, systems, or organs [2].
Dose–response study	A toxicological study of the quantitative relationship between the amount of a toxicant administered or taken and the incidence or extent of the adverse effect [6].
Dose	The total amount of radiation or toxicant, drug, or other chemical administered or taken by the organism (adapted from [6]).
Ecology	The branch of biology that deals with the relations of organisms to one another and to their physical surroundings [7].
Ecosystem	A community of living organisms in conjunction with the nonliving components of their environment (things like air, water and mineral soil), interacting as a system.
Effluent	Waste material discharged into the environment.
Emissions	Pollutants released into the air or waterways from industrial processes, households, or transportation vehicles.
Environment	The circumstances, objects, and conditions by which one is surrounded [8].
Environmental contamination	The presence of hazardous substances in the environment.
Environmental equity	The proportionate and equitable distribution of environmental benefits and risks among diverse economic and cultural communities [9].
Environmental health	Comprises of those aspects of human health, including quality of life, that are determined by physical, chemical, biological, social and psychosocial factors in the environment. It also refers to the theory and practice of assessing, correcting, controlling, and preventing those factors in the environment that can.
Environmental justice	Concern about the disproportionate occurrence of pollution and potential pollution-related health effects affecting low-income, cultural, and ethnic populations and lesser cleanup efforts in their communities [10].
Environmental medium	Material in the outdoor natural physical environment that surrounds or contacts organisms (e.g., surface water, groundwater, soil, air) and through which substances can move and reach organisms (adapted from [1]).
Epidemiologic surveillance	The ongoing, systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to persons who need to know.
Epidemiology	The study of the occurrence of disease in human populations.
Ergonomics	An applied science concerned with the characteristics of people that need to be considered in designing and arranging things that they use in order that people and things will interact most effectively and safely [8].
Exposure assessment	Determination of the sources, environmental transport and modification, and fate of pollutants and contaminants, including the conditions under which people or other target species could be exposed, and the doses that could result in adverse effects [10].
Exposure investigation	The collection and analysis of site-specific information to determine whether human populations have been exposed to hazardous substances. The site-specific information may include environmental sampling, exposure-dose reconstruction, biologic or biomedical testing, and evaluation of medical information.
Exposure pathway	The path by which pollutants travel from sources via air, soil, water, or food to reach living organisms (adapted from [10]).
Exposure route	The way a substance enters an organism after contact (e.g., inhalation, ingestion, dermal absorption).
Exposure–response relationship	The relationship between exposure level and the incidence of adverse effects.
Exposure	The amount of a stressor (e.g., a hazardous substance) that living organisms contact over a defined period of time.
Federalism	A kind of government in which power is divided between a central government and independent regional (*e.g.*, states) governments.
Fibrosis	Formation of fibrous tissue as a reparative or reactive process [2].
Fossil fuel	A fuel that is formed in the earth from animal or plant remains.
Fungicide	A substance that kills molds.
Gene	The functional unit of heredity that occupies a specific place or locus on a chromosome [2].
Genotoxicity	An effect on the genetic material (DNA) of living cells that, upon replication of the cells, is expressed as a mutagenic or a carcinogenic event [6].
Geographic information system (GIS)	A computer hardware and software system designed to collect, manipulate, analyze, and display spatially referenced data for solving complex resource, environmental, and social problems.

Global warming The progressive gradual rise of the earth's surface temperature, thought to be caused by the greenhouse effect and responsible for changes in global climate patterns.

Governance Administration, establishment, brass, organization—the persons (or committees or departments, etc.) who make up a governing body and who administer something.

Government The act or process of governing; specific: authorative direction or control [8].

Greenhouse gases Gases that can absorb heat in the atmosphere.

Hazard assessment An evaluation of the effects of a stressor or determining a margin of safety for an organism by comparing the concentration which causes toxic effects with an estimate of exposure to the organism [11a].

Hazard identification Hazard identification of a given substances is an informed judgment based on verifiable toxicity data from animal models or human studies [11a].

Hazard surveillance A data collecting system that monitors the distribution of specific hazards (e.g., carcinogens).

Hazard (1) Potential for radiation, a chemical or other pollutant to cause human illness or injury. (2) In the pesticide program, the inherent toxicity of a compound [11a].

Hazard A factor or exposure that may adversely affect health [11].

Health assessment An evaluation of available data on existing or potential risks to human health posed by a Superfund site. The Agency for Toxic Substances and Disease Registry (ATSDR) of the Department of Health and Human Services (DHHS) is required to perform such an assessment at every site on the National Priorities List [11a].

Health education A program of activities to promote health and provide information and training about reducing exposure, illness, or disease that result from hazardous substances in the environment.

Health investigation An investigation of a defined population, using epidemiologic methods, that would help determine exposures or possible public health impact by defining health problems, which require further investigation through epidemiologic studies, environmental monitoring or sampling, and surveillance.

Health surveillance The periodic medical screening of a defined population for a specific disease or for biologic markers of disease for which the population is, or is thought to be, at significantly increased risk.

Health Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity [12].

Herbicide A chemical that kills weeds and other plants.

Hydroponics (n) A method of growing plants using mineral nutrient solutions, in water, without soil.

Hypersensitivity A greater than normal bodily response to a foreign agent.

In utero Within the womb; not yet born.

In vitro In an artificial environment, as in a test tube or culture medium.

In vivo In the living body.

Incidence The rate of development of disease in a population that can be expressed as either incidence density or cumulative incidence. Prevalence refers to existing cases of a health condition in a population, and incidence refers to new cases [13].

Ingestion Taking food or drink into the body. Chemicals can get in or on food, drink, utensils, cigarettes, or hands from which they can be ingested.

Inhalation Breathing. Exposure can occur from inhaling contaminants because they can be deposited in the lungs, taken into the blood, or both.

Insecticide An agent that kills insects.

Interaction An outcome that occurs when exposure to two or more chemicals results in a qualitatively or quantitatively altered biologic response than that predicted from the actions of the components administered separately.

Kyoto Protocol An international agreement struck by 159 nations attending the Third Conference of Parties to the United Nations Framework Convention on Climate Change, held in December 1997 in Kyoto, Japan, to reduce worldwide emissions of greenhouse gases.

Leukemia Cancer of the blood-forming tissues.

Media Soil, water, air, plants, animals, or any other parts of the environment that can contain contaminants.

Metabolism The sum of chemical changes occurring in tissue. For example, food is *metabolized* (chemically changed) to supply the body with energy. Chemicals can be *metabolized* and made either more or less harmful by the body.

Metabolite Any product of metabolism.

Microgram (µg) One one-millionth of a gram.

Milligram (mg) One one-thousandth of a gram.

Mixture Any set of two or more chemical substances, regardless of their sources, that may jointly contribute to toxicity in the target population.

Morbidity rate The number of illnesses or cases of disease in a population.

Morbidity Illness or disease.

Mortality The condition of being mortal; death.

National Priorities List (NPL)	EPA's listing of Superfund sites that have undergone preliminary assessment and site inspection to determine which locations pose immediate threat to persons living or working near the release.
Particulate matter	A kind of air pollution that includes soot, dust, dirt, and aerosols.
Peer review	Evaluation of the accuracy or validity of technical data, observations, and interpretation by qualified experts in an organized group process [10].
Percentile	Any of the values in a series dividing the distribution of the individuals in the series into 100 groups of equal frequency.
Picogram (pg)	One one trillionth of a gram.
Plume	An area of chemicals in a particular medium, such as air or groundwater, that moves away from its source in a long band or column. For example, a plume can be a column of smoke from a chimney or chemicals moving with groundwater.
Policy	A definite course or method of action selected from among alternatives and in light of given conditions to guide and determine present and future directions [8].
Politics	The total complex of relations between people living in society [8].
Potentially responsible parties	Persons or organizations liable under CERCLA for the costs of remediating NPL sites.
Precautionary principle	Decisions about the best ways to manage or reduce risks that reflect a preference for avoiding unnecessary health risks instead of unnecessary economic expenditures when information about potential risks is incomplete [10].
Prevalence	The proportion of ill persons in a population at a point in time, expressed as a simple percentage. Prevalence refers to existing cases of a health condition in a population, and incidence refers to new cases [13].
Primary prevention	The prevention of an adverse health effect in an individual or population through marked reduction or elimination of the hazards known to cause the health effects.
Public comment	Invited comment from the general public on agency findings or proposed activities.
Public health assessment	An evaluation by ATSDR of data and information on the release of hazardous substances into the environment to assess any current or future impact on public health, develop health advisories or other recommendations, and identify studies or actions needed to evaluate and mitigate or prevent human health effects; also, the document resulting from that evaluation.
Public health	"Public health is the process of mobilizing local, state, national, and international resources to solve the major health problems affecting communities" [14].
Pulmonary	Pertaining to the lungs.
Quantitative structure activity relationships (QSAR)	The relationship between the properties (physical and/or chemical) of substances and their ability to cause particular effects, enter into particular reactions, etc. The goal of QSAR studies in toxicology is to develop procedures whereby the toxicity of a compound can be predicated from its chemical structure by analogy with the known toxic properties of other toxicants of similar structure (adapted from [6]).
Random samples	Samples selected from a statistical population so that each sample has an equal probability of being selected [1].
Range	The arithmetic difference between the largest and smallest values in a data set.
Record of decision	An EPA document that discusses the various cleanup techniques that were considered for a site and an explanation of why a particular course of action was selected [15].
Reference dose (RfD)	The amount of a chemical that one can ingest every day for a lifetime that is not anticipated to cause harmful noncancer health effects.
Reference concentration (RfC)	The concentration of a chemical that one can breathe every day for a lifetime that is not anticipated to cause harmful noncancer health effects.
Registry	A system for collecting and maintaining, in a structured record, information on specific persons from a defined population.
Residual risk	The health risk remaining after risk-reduction actions are implemented, such as risks associated with sources of air pollution that remain after maximum achievable control technology has been applied [10].
Risk Assessment	Qualitative and quantitative evaluation of the risk posed to human health and/or the environment by the actual or potential presence and/or use of specific pollutants [11a].
Risk assessment	The characterization of the potential adverse health effects of human exposures to environmental hazards" [16].
Risk communication	An interactive process of exchange of information and opinion among individuals, groups, and institutions [17].
Risk estimate	A description of the probability that organisms exposed to a specific dose of a chemical or other pollutant will develop an adverse response, e.g., cancer.
Risk	The probability that an event will occur [11].
Route of exposure	The means by which a person may contact a chemical substance. For example, drinking (ingestion) and bathing (skin contact) are two different *routes of exposure* to contaminants that may be found in water.
Rulemaking	The agency process for formulating, amending, or repealing a rule [18].
Rule	The whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy [18].
Screening program	A program of screening for a health problem, diagnostic evaluation of persons who have positive screening test results, and treatment for persons in whom the health problem is diagnosed.

Screening	A method for identifying asymptomatic individuals as likely, or unlikely, to have a particular health problem.
Secondary prevention	The prevention or slowing of the progression of a health problem attributable to specific hazards through use of education, protective equipment, relocation away from the hazards or other means to avoid contact with the hazard.
Soluble	Dissolves well in liquid.
Solvent	A substance that dissolves another substance.
Stakeholder	An individual or group that has an interest in or will be affected by an action.
Statistical significance	A calculated value that infers the probability whether an observed difference in quantities being measured could be due to variability in the data rather than an actual difference in the quantities themselves.
Stressor	A chemical, material, organism, radiation, noise, temperature change or activity that stresses an organism's health or well-being.
Superfund	Another name for the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLAct). The term is also used to refer to the Hazard Substance Superfund, the trust fund established by CERCLA.
Surveillance	A data collection system that monitors the occurrence of disease (disease surveillance) or the distribution of hazard (hazard surveillance).
Sustainable development	"Development which meets the needs of the present without compromising the ability of future generations to meet their own needs" [19].
Synergism	A response to a mixture of toxic chemicals that is greater than that suggested by the component toxicities.
Toxicant	A substance not produced by a living organism that causes a harmful effect when administered to a living organism. See toxin.
Toxicity	The property of chemicals that causes adverse effects on living organisms.
Toxicokinetics	Toxicodynamics; the study of the quantitative relationship between absorption, distribution, and excretion of toxicants and their metabolites [6].
Toxicology	The science that deals with poisons (toxicants) and their effects [6].
Toxics Release Inventory	A publicly available EPA database that contains information on toxic chemical releases and other waste management activities reported annually by certain covered industry groups as well as federal facilities. This inventory was established under the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) and expanded by the Pollution Prevention Act of 1990.
Toxin	A toxicant produced by a living organism [6].
Tumor	An abnormal mass of tissue.
Volatile organic compounds (VOCs)	Substances containing carbon and different proportions of other elements such as hydrogen, oxygen, fluorine, chlorine, bromine, sulfur, or nitrogen. These substances easily become vapors or gases. Many *VOCs* are commonly used as solvents (paint thinners, lacquer thinner, degreasers, and dry cleaning fluids).
Weather	The short-term changes we see in temperature, clouds, precipitation, humidity, and wind in a region or a city. Weather can vary greatly from one day to the next or even within the same day. In the morning, the weather may be cloudy and cool. But by afternoon, it may be sunny and warm [20].
Weight-of-evidence	A systematic method for applying biomedical judgment to empirical observations and mechanistic considerations to qualitatively assess the potential toxicity of a substance, singly or in a chemical mixture, for a given target organ or system.

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