ENHANCING FOOD SAFETY

THE ROLE OF THE FOOD AND DRUG ADMINISTRATION

Committee on the Review of the Food and Drug Administration's Role in Ensuring Safe Food

Food and Nutrition Board

Board on Agriculture and Natural Resources

Robert B. Wallace and Maria Oria, *Editors*

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

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COMMITTEE ON THE REVIEW OF THE FOOD AND DRUG ADMINISTRATION'S ROLE IN ENSURING SAFE FOOD

ROBERT B. WALLACE (*Chair*), Professor, College of Public Health, University of Iowa, Iowa City
DOUGLAS L. ARCHER, Associate Dean for Research and Professor, Institute of Food and Agricultural Sciences, University of Florida, Gainesville
KEITH C. BEHNKE, Professor, Department of Grain Science and Industry, Kansas State University, Manhattan
ANN BOSTROM, Associate Dean and Professor, Evans School of Public Affairs, University of Washington, Seattle
ROBERT E. BRACKETT, Director and Vice President, National Center for Food Safety and Technology, Illinois Institute of Technology, Chicago
JULIE A. CASWELL, Department Chair and Professor, Department of Resource Economics, University of Massachusetts, Amherst
LEWIS A. GROSSMAN, Associate Dean and Professor, Washington College of Law, American University, Washington, DC
LEE-ANN JAYKUS, Professor, Food Science Department, North Carolina State University, Raleigh
TIMOTHY F. JONES, State Epidemiologist, Tennessee Department of Health, Nashville
BARBARA KOWALCYK, Director, Food Safety, Center for Foodborne Illness Research and Prevention, Grove City, Pennsylvania
J. GLENN MORRIS, JR., Director, Emerging Pathogens Institute, University of Florida, Gainesville
MARTHA RHODES ROBERTS, Special Assistant to the Director, Institute of Food Agricultural Sciences, University of Florida, Gainesville
JOSEPH V. RODRICKS, Principal, ENVIRON, Arlington, Virginia

Consultants

CATHERINE W. CARNEVALE
LOUIS J. CARSON

Study Staff

MARIA ORIA, Study Director
RUTHIE S. ARIETI, Research Associate
ALICE VOROSMARTI, Research Associate
GUI LIU, Senior Program Assistant
STEPHANIE GOODWIN, Fellow
LINDA D. MEYERS, Director, Food and Nutrition Board
ROBIN SCHOEN, Director, Board on Agriculture and Natural Resources

Reviewers

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

HENRY J. AARON, Senior Fellow, The Brookings Institution, Washington, DC
JOHN BAILAR, III, Professor Emeritus, University of Chicago, Washington, DC
KATHRYN J. BOOR, Professor, Food Science Department, Cornell University, Ithaca, New York
BONNIE BUNTAIN, Professor, Ecosystem and Public Health Department, University of Calgary, Alberta, Canada
J. JOSEPH CORBY, Executive Director, Association of Food and Drug Officials, York, Pennsylvania
LESTER M. CRAWFORD, JR., Senior Counsel, Policy Directions, Inc., Georgetown, South Carolina
CAROLINE SMITH DEWAAL, Director, Food Safety Program, Center for Science in the Public Interest, Washington, DC

MICHAEL P. ERIKSEN, Professor, Georgia State University, Atlanta
BOB GELLMAN, Privacy and Information Policy Consultant, Washington, DC
DERRICK JONES, Head, Analytical Services, Survey and Research Policy, United Kingdom Food Standards Agency, London
GULBANU KAPTAN, Researcher, Department of Social and Decision Sciences, Carnegie Mellon University, Pittsburgh, Pennsylvania
ANNA LAMMERDING, Chief, Microbial Food Safety Risk Assessment, Public Health Agency of Canada, Guelph, Ontario
RICHARD A. MERRILL, Professor Emeritus, University of Virginia School of Law, Charlottesville
DALE L. MORSE, Assistant Commissioner, Office of Science, New York State Department of Health, Albany
MARION NESTLE, Professor, Department of Nutrition, Food Studies, and Public Health, New York University, New York
FRANK YIANNAS, Vice President, Food Safety, Walmart, Bentonville, Arkansas

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the report's conclusions or recommendations, nor did they see the final draft of the report before its release. The review of this report was overseen by **Enriqueta C. Bond,** President Emeritus, Burroughs Wellcome Fund, and **Elena O. Nightingale,** Scholar-in-Residence, Institute of Medicine. Appointed by the National Research Council and Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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* Appendixes B–G are not printed in this book. They are available on the CD in the back of this book.

Preface

This Institute of Medicine/National Research Council report was written in response to a congressional request that the U.S. Food and Drug Administration (FDA) contract with the National Academies for a comprehensive study of gaps in public health protection provided by the food safety system in the United States. In particular, the study was to review the role of the FDA in ensuring the safety of the nation's food supply. The committee that conducted this study hopes that the recommendations in this report will help the FDA in achieving the very important goal of protecting the health of the American public.

Important functions of the FDA in regard to food safety are too numerous to be listed here. To name but a few, they range from resolving crises in the most expeditious and efficient manner; to predicting the next intentional food contamination episode, whether here or abroad; to communicating with and educating the public about food safety. The committee found it difficult to make recommendations for enhancing the FDA's role in ensuring food safety without also addressing the rest of the complex system of local, state, and federal government agencies that, together with the FDA, govern food production in the United States. One main tenet of the committee's recommendations is a call for a risk-based approach to allocating food safety resources and efforts. The committee suggests a number of enhancements at the FDA that would improve the efficiency of resource allocation and protection of the public health and could be initiated independently from other agencies. For other enhancements, however, improvement will not come without seamless cooperation with other agencies. For some recommendations, changes in federal law or structural reorganization are

essential. In essence, the committee found that the time has come to modernize the nation's food safety system so it becomes a truly integrated national program.

In addition, although most of the recommendations offered are directed to the FDA, it is imperative to recognize that the FDA cannot guarantee food safety on its own, given the many other private and public parties involved in the nation's food supply chain. Hence, some of the recommendations also assume the responsibility of others, including food producers and distributors and consumers. Although the committee's deliberations were focused on improving the FDA's functions and operations, the success of its food safety enterprise cannot be realized without the involvement of other responsible parties, and the report refers to them when appropriate.

On behalf of the committee, I would like to express my great appreciation to the staff at the FDA's Office of Foods (formerly the Office of Food Protection) for the substantial time and effort they put into supporting our work. They were available to clarify the committee's task and to educate its members about the FDA's operations, challenges, and aspirations. In particular, this study could not have been conducted without the assistance of Dr. David Acheson, Ms. Kari Barret, and Dr. Chad Nelson, who tirelessly assisted the committee with answering numerous questions and requests for information, meetings, and conference calls. I would like to thank Michael Taylor, who served as an unpaid project consultant until June 2009, prior to his appointment as senior advisor to the FDA commissioner. On behalf of the committee, I sincerely thank the participants and speakers who contributed to the two workshops held to inform this study (see Appendix A) for addressing topics critical to the completion of the committee's work. Their presentations served as essential references and resources for the committee.

I would also like to gratefully acknowledge the time, effort, and skill that committee members invested in this process, with a spirit of continuous improvement and with the ultimate goal of assisting the FDA in accomplishing its food safety mission. Their diverse backgrounds and experience ensured that all aspects of this challenging topic were addressed and that all deliberations were carried out with respect and empathy. Finally, I thank the project staff and support staff of the National Academies for their tireless dedication to the production of this report.

Robert B. Wallace, *Chair*
Committee on the Review of the Food and Drug Administration's Role in Ensuring Safe Food

Summary

Providing nutritious, abundant, and safe food requires the efforts of many partners that together make up today's complex and evolving food system.[1] Since 1906, the U.S. Food and Drug Administration (FDA) and its predecessor agencies have regulated foods, among other products. Today the agency has oversight of approximately 80 percent of the U.S. food supply.[2]

Although there have been prior efforts to identify needed improvements in food safety, recent multistate foodborne illness outbreaks have again highlighted a food safety system that is not always effective in protecting the public health. The FDA has been criticized as responding only reactively to food safety problems and neglecting its preventive functions. With these concerns in mind, in 2008 Congress requested that the FDA contract with the National Academies for a comprehensive study of gaps in the FDA's food safety system. While the responsibility for addressing these challenges

[1] Unless otherwise indicated, the term "food" refers to both food and animal feed.

[2] The U.S. Department of Agriculture's Food Safety and Inspection Service is primarily responsible for the safety of meat, poultry, and unshelled egg products. The FDA shares responsibility for the safety of alcoholic beverages with the Alcohol and Tobacco Trade Bureau of the Department of the Treasury. The FDA shares jurisdiction with state and local governments over food in interstate commerce. State and local governments have the main responsibility for food produced or sold within their borders. The major FDA offices with responsibility for food safety are the Office of the Commissioner, the Office of Foods, the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the Office of Regulatory Affairs, and the National Center for Toxicological Research.

does not lie solely with the FDA, the focus of this report is on enhancing that agency's food programs, specifically those devoted to food safety.

STUDY APPROACH

To conduct this study, a 13-member committee with extensive experience in FDA food programs and policies, food law and regulations, risk analysis and communication, economics, epidemiology, monitoring and surveillance, food microbiology and toxicology, feed issues, and state food programs was convened. The committee gathered information through six meetings, statements in response to specific queries to the FDA, and public documents.

As requested (Box S-1), the committee reviewed the FDA's 2007 Food Protection Plan (FPP), a road map aligned with the agency's strategic plan, but it also worked to identify additional tools and capacities to improve food safety. Since the publication of the FPP, organizational and leadership changes in the federal government[3] have altered the U.S. food safety scene. In this new environment, the committee envisioned the FPP as a point of departure but focused its attention on providing the FDA with concrete guidance in various areas of concern, including the need to implement a risk-based food safety management system.

The committee left many of the details of the implementation of its recommendations to the FDA, especially since food safety is just one of the agency's many responsibilities. The committee considered cost and resource issues in a general sense by drawing on the experience of members who formerly held senior leadership positions at the FDA. Because essential information was not always accessible, however, the committee lacked the full evidence base needed to address these issues in detail.

CONCLUSIONS

This section presents the committee's main conclusions. It begins with a brief review of the FPP, which is evaluated throughout the report as appropriate. It then presents conclusions concerning the development and implementation of a stronger, more effective food safety system built on a risk-based approach to food safety management.

[3] For example, these include a change in administration, the formation of the White House Food Safety Working Group, and the FDA's establishment of a new Office of Foods with oversight and authority over the two FDA centers that regulate food—the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine.

BOX S-1
Statement of Task

An ad hoc committee of the Institute of Medicine and the National Research Council will undertake a study to examine gaps in public health protection provided by the farm-to-table food safety system under the purview of the Food and Drug Administration (FDA) and identify opportunities to fill those gaps. The study will address the recommendations of the November 2007 FDA Food Protection Plan by evaluating the plan and identifying gaps and opportunities (recommendations) to fill the gaps. The committee's consensus report will include legislative, regulatory, and administrative recommendations and estimates of costs of such recommendations, as feasible.

Specifically, the committee will:

- Evaluate the FDA Plan in light of past reports directed at strengthening food safety including, but not limited to *Ensuring Safe Food from Production to Consumption* (IOM/NRC, 1998), *Scientific Criteria to Ensure Safe Food* (IOM/NRC, 2003), the 2007 FDA Science Board report, and relevant GAO reports;
- Identify strengths and weaknesses of the FDA Plan, factors that may limit its achievement, and needed revisions or additions; and
- Identify and recommend enhancements in FDA's tools and capacity that are needed to implement a comprehensive plan and assure a risk-based preventive system, including in the areas of new regulatory tools and statutory authority; research mandate; resources required for research, scientific and technical infrastructure, standard setting, inspection, and enforcement; integration of programs with other regulatory and public health agencies involved in food safety surveillance, research and regulation at federal, state and local levels; expansion of FDA's international presence and international regulatory information exchange; and changes in organizational and leadership structures on food safety within the Department of Health and Human Services.

The FPP

Strategic planning is an essential element of a food safety program and should precede the design and implementation of a risk-based approach to food safety management. At a broad level, strategic planning entails identifying public health goals (e.g., reducing the number of infections caused

by specific foods), identifying tools for attaining those goals (e.g., research, education activities), and developing measures with which to evaluate success. The FDA's strategic plan for food safety management should explain its risk-based regulatory philosophy and the factors it will weigh in making decisions about the prioritization of efforts, allocation of resources, and selection of interventions. At a specific level, all of the risk-based activities discussed in the report (e.g., data collection) should be undertaken only after strategic planning.

The FPP (Appendix G) presents the FDA's general philosophy on food safety, focusing on three core elements: (1) prevention, (2) intervention, and (4) response. It also outlines the following four cross-cutting principles: (1) focus on risks over a product's life cycle, (2) target resources to achieve maximum risk reduction, (3) address both unintentional and deliberate contamination, and (4) use science and modern technology systems.

The committee concluded that while the FPP can serve as a platform for initiating a transformation at the FDA, it lacks sufficient detail on which to base policy decisions on prevention and risk. For example, it does not provide specific strategies to achieve the actions proposed. Moreover, terms such as "risk" and "risk-based approaches" are not adequately defined in the FPP; thus they do not clearly elucidate the FDA's philosophy and can be misunderstood. The committee concluded that the FPP needs to evolve and be supported by the type of strategic planning described in this report.

Adopting a Risk-Based Decision-Making Approach to Food Safety

In a food safety system, decisions about resource allocation need to be made consistently in order to maximize benefits and reduce risks while also considering costs. Food safety risk managers must consider a wide variety of concerns in their decision making, including the needs and values of diverse stakeholders, the controllability of various risks, the size and vulnerabilities of the populations affected, and economic factors. Although the balancing of diverse risks, benefits, and costs is challenging, the lack of a systematic, risk-based approach to facilitate decision making can cause problems ranging from a decrease in public trust to the occurrence of unintended consequences to society, the environment, and the marketplace. Moreover, to carry out all its food safety responsibilities and ensure continuity of everyday operations, the FDA needs to have sufficient staff working on food issues to ensure that routine functions continue even when a crisis occurs.

The committee examined concrete examples of the FDA's risk-based activities and identified gaps. Although the FDA is to be commended for embracing classic tools of risk assessment and management, it currently lacks a comprehensive, systematic vision for a risk-based food safety sys-

tem. Many of the attributes necessary for such a system, including strategic planning, transparency, and formalized prioritization processes, are lacking in the agency's approach to food safety management. The FDA also has made only limited progress toward establishing performance metrics for measuring improvements in food safety.

Food safety is a shared responsibility of industry, retailers, consumers, and government agencies, and determining their roles is an important component of strategic planning. Regulators also must establish a systematic means of evaluating, selecting, and designing interventions to address high-priority risks. The FDA lacks a clear regulatory philosophy for assigning responsibility and a comprehensive strategy for choosing the level and intensity of interventions, as well as the extensive resources necessary to design and support a comprehensive risk-based food safety management system.

The risk-based approach recommended by the committee is summarized in Box S-2.

Creating a Data Surveillance and Research Infrastructure

Data form the foundation of a risk-based decision-making approach, and vast amounts of such data are being collected by the government, industry, and academia. However, the FDA has not adequately assessed its data needs and lacks a systematic means by which to collect, analyze, manage, and share data. Barriers to the availability and utilization of data to support a risk-based approach include a lack of data sharing, the absence of a comprehensive data infrastructure, and limited analytical expertise within the FDA.

The FDA's surveillance role is supported by its research capacity, which gives the agency an opportunity to fill data gaps and address uncertainties to help refine its risk-based decision making. The FDA's current food safety research program appears to be fragmented and poorly managed, lacking strategic planning and coordination of research that is conducted intramurally and at the five extramural research centers. Many basic questions, such as the size and scope of the FDA's research program and the appropriate balance between basic and applied research, need to be addressed before the program can be supportive of a risk-based approach. In particular, inadequate attention is given to research aimed at determining the efficacy and value of specific food safety management policies.

Integrating Federal, State, and Local Government Food Safety Programs

Food safety activities of state and local (including territorial and tribal) governments, including inspection, surveillance, and outbreak investigation, have long been important contributors to the U.S. food safety system.

BOX S-2
A Recommended Risk-Based Approach

Step 1: Strategic Planning

1. Identify public health objectives related to food safety in consultation with stakeholders.
2. Establish a risk management plan (general and specific strategic plans for meeting public health objectives and for considering and choosing policy interventions to achieve those objectives).
3. Establish metrics with which to measure performance in consultation with stakeholders.

Step 2: Public Health Risk Ranking (Ranking of Hazards)

1. Develop or select tools (models, measures, or other) for public health risk ranking in consultation with stakeholders.
2. Rank risks based on public health outcomes.
3. Report results to stakeholders and solicit feedback.

Step 3: Targeted Information Gathering on Risks and Consideration of Other Factors That May Influence Decision Making

1. Identify and consider additional criteria upon which risk-based decision making will be based (e.g., public acceptance, cost, controllability, environmental effects, market impacts) in consultation with stakeholders.
2. Conduct targeted information gathering. For each high-priority and/or uncertain risk, determine the need for collection of additional information and implement accordingly:
   a. additional data collection (research, surveillance, survey, baseline data); and
   b. risk assessment (qualitative, quantitative, semiquantitative).
3. Based on that additional information, identify priority risks for which intervention analysis is needed.

However, these activities are not fully integrated so that duplication is minimized. Integration will require harmonization so that all programs and functions related to food safety meet a minimum set of standards. The FDA has standards in place that, if broadened and implemented properly, could serve as the basis for this harmonization. As with the federal system, state and local efforts should be built on a risk-based approach.

Step 4: Analysis and Selection of Intervention(s)

1. Identify an appropriate level of protection for each high-priority risk, based on available data and in consultation with stakeholders.
2. Identify intervention options in consultation with stakeholders.
3. Identify the types of technical analysis, including but not limited to risk assessment, needed to evaluate the options; identify performance measures and the initial design of databases.
4. Gather the information necessary to conduct the technical analysis.
5. Choose intervention strategies for implementation using multicriteria decision analysis.
6. Report results to stakeholders, solicit feedback, and modify intervention strategies if needed.

Step 5: Design of an Intervention Plan

1. Develop a plan for implementing the selected interventions in consultation with stakeholders.
2. Allocate resources and implement interventions.

Step 6: Monitoring and Review

1. Collect and analyze data on evaluation measures selected during strategic planning.
2. Interpret data and evaluate whether interventions result in the desired intermediate outcomes.
3. Determine whether public health objectives are being met by using performance metrics developed in Step 1 (broad strategic planning).
4. Communicate results to stakeholders.
5. Review and refine the entire process in an iterative manner as necessary to accomplish both intermediate outcomes and public health objectives so as to achieve continuous improvement over time.

Enhancing the Efficiency of Inspections

For years, the inspectional capacity and efficiency of the FDA have been criticized as inadequate. Although mindful of potential gains from allocating more resources to the FDA's inspection system, the committee focused on increasing the system's efficiency. One barrier to improved efficiency is that the FDA's food programs lack direct authority over the work of inspectors, resulting in potential substantial delays in policy implementation in the field. Nor have inspection procedures been reviewed for efficiency or consis-

tency with a risk-based approach. The committee concluded that exploring alternative models for the inspection of food facilities (e.g., delegating some inspection activities to state and local governments, accepting third-party auditing of food facilities) could lead to gains in efficiency.

Improving Food Safety and Risk Communication

Risk communication is integral to risk-based food safety management. The FDA should envision risk communication not only as consultation with stakeholders at various steps of the risk-based process, but also as a form of policy intervention to achieve objectives in its strategic plan. The FDA's risk-based food safety management system must incorporate effective risk communication and food safety education for consumers and those who could impact public health through their professions, such as public health officials. The FDA should continue to use the advice of the Risk Communication Advisory Committee; below the committee offers several other recommendations to enhance risk communication.

Modernizing Legislation to Enhance the U.S. Food Safety System

Since 1938, Congress has occasionally amended the Federal Food, Drug, and Cosmetic Act (FDCA) to enhance the FDA's power to fulfill its food safety mission. In some fundamental respects, however, the law under which the FDA must ensure the safety of 80 percent of the nation's food has remained unchanged since 1938—despite the dramatic changes in food production and distribution patterns that have taken place. Those food safety provisions of the FDCA that are broad delegations of power rather than specific grants of authority have led to the FDA's vulnerability to court challenges and, consequently, the agency's reluctance to take action. This deficiency in the food safety system needs to be remedied.

Achieving the Vision of an Efficient Risk-Based Food Safety System

The committee is confident that the risk-based approach recommended in this report would enhance the FDA's ability to ensure food safety now and in the future. Nonetheless, the committee recognizes that this approach will not work optimally under the current organizational structure of the food safety system. The committee is encouraged by the establishment of the Office of Foods in 2009, but it has not been persuaded that this single consolidation step will resolve the important problems related to the separation of responsibilities in the FDA's food programs.

Food safety in the United States is managed by many government agencies. The ability of the FDA, and the government in general, to succeed in

ensuring food safety through the development of a risk-based food safety management system would be greatly enhanced if the recommendations in this report were implemented in the context of organizational changes, such as the integration of activities currently scattered among poorly coordinated agencies. There are many potential avenues of organizational reform and many serious barriers to overcome. Hence, the importance of in-depth analysis and planning of such changes cannot be overemphasized.

RECOMMENDATIONS

The committee's deliberations resulted in suggested directions for improving food safety management (Box S-3) and specific recommendations for overcoming deficiencies in the food safety system (Box S-4).

LOOKING FORWARD

Although food safety is the responsibility of everyone, from producers to consumers, the FDA and other regulatory agencies have an essential role. In many instances, the FDA must carry out this responsibility against a backdrop of multiple stakeholder interests, inadequate resources, and competing priorities. The committee hopes that this report provides the FDA and Congress with a course of action that will enable the agency to become more efficient and effective in carrying out its food safety mission in a rapidly changing world.

BOX S-3
Suggested Directions for Improving the U.S. Food and Drug Administration's (FDA's) Food Safety Management

- Apply the recommended risk-based approach to the management of all food hazards.
- Address the lack of resources (e.g., data infrastructure, human capacity) and organization for the implementation of a risk-based food safety management system.
- Identify metrics with which to measure the effectiveness of intervention strategies and the food safety system as a whole.
- Define the roles of the various parties sharing responsibility for food safety, and develop a roadmap with defined criteria for the level and intensity of policy interventions and plans to evaluate them.
- Develop a strategic plan to identify data needs for a risk-based approach, and establish mechanisms to coordinate, capture, and integrate the data. Remove barriers to the practical utilization of data to support a risk-based system, including problems with data sharing and gaps in analytical expertise within the FDA.
- Conduct strategic planning and coordination of the FDA's food safety research portfolio.
- Integrate food safety programs at the federal, state, and local levels, with the ultimate goal of utilizing all food surveillance, inspectional, and analytical systems as part of the national food safety program.
- Address the existence of barriers to improving the efficiency of inspections, such as the inefficiency of inspection procedures and the fact that the FDA's food programs do not have direct authority over the work of inspectors.
- Continue development of a single source of authoritative government information on food safety, safe food practices, foodborne illnesses and risks, and crisis communications.
- Create a centrally controlled plan for communicating with one voice with all affected parties during food safety crises.
- Modernize the legislative framework to give the FDA the necessary legal authority to perform its role in ensuring the safety of FDA-regulated foods.
- Implement organizational changes that would greatly enhance the ability of the FDA to succeed in ensuring food safety.

BOX S-4
Recommendations

Toward a Risk-Based Approach

Recommendation 3-1: The type of risk-based food safety approach outlined by the committee in Box S-2 should become the operational centerpiece of the U.S. Food and Drug Administration's (FDA's) food safety program. This approach should be embraced by all levels of management and should serve as the basis for food safety decision making, including prioritization of resources dedicated to all agency functions (e.g., inspections, promulgation of regulations, research). This approach should be applied to all domestically produced and imported foods and to all food-related hazards, whether due to unintentional or intentional (i.e., with intent to harm) contamination. The FDA should work with local, state, and national regulatory partners to facilitate the incorporation of these principles into their programs.

Recommendation 3-2: The FDA should develop a comprehensive strategic plan for development and implementation of a risk-based food safety management system. The agency should also develop internal operating guidelines for the conduct of risk ranking, risk assessment, risk prioritization, intervention analysis, and the development of metrics with which to evaluate the performance of the system. The strategic plan and guidelines should include descriptions of data, methodologies, technical analyses, and stakeholder engagement. Further, the strategic plan and all guidelines for the risk-based system should be fully supported by the scientific literature and subjected to peer review. When appropriate, the FDA should adopt guidelines already established by other federal agencies or international organizations.

Recommendation 3-3: The FDA, in collaboration with partners, should identify metrics with which to measure the effectiveness of the food safety system, as well as its interventions. The FDA should include these metrics, and plans for any related data collection, as part of strategic planning. The metrics should have a clearly defined link to public health outcomes.

Recommendation 3-4: The FDA should identify expertise needed to implement a risk-based approach. This includes training current

continued

BOX S-4 Continued

and/or hiring new personnel in the areas of strategic planning; management of data; development of biomathematical models and other tools for risk ranking, prioritization, intervention analysis, and evaluation; and risk communication.

Sharing the Responsibility

Recommendation 4-1: To ensure food safety, the FDA should develop a plan for defining the extent of and form for sharing responsibilities with the states, the private sector, third parties (e.g., independent auditors), and other countries' governments.

Recommendation 4-2: The FDA should develop a comprehensive strategy for choosing the level and intensity of policy interventions needed for different food safety risks. Criteria for choosing the level and intensity of policy interventions and a plan for evaluating the selected interventions should be developed with transparency, stakeholder participation, and clear lines of communication.

Creating a Data Surveillance Infrastructure

Recommendation 5-1: Data collection by the FDA should be driven by the recommended risk-based approach and should support risk-based decision making. It is critical that the FDA evaluate its food safety data needs and develop a strategic plan to meet those needs. The FDA should review existing data collection systems for foods to identify data gaps, eliminate systems of limited utility, and develop the necessary surveillance capabilities to support the risk-based approach. The FDA should formulate and implement a plan for developing, harmonizing, evaluating, and adopting data standards. The FDA should also establish a mechanism for coordinating, capturing, and integrating data, including modernization of its information technology systems. To coordinate, capture, and integrate data, the FDA could lead the implementation of a multiagency food safety epidemiology users group (see Chapter 5). The centralized risk-based analysis and data management center proposed in recommendation 11-3 in Chapter 11could serve the functions of data storage and analysis in support of a risk-based approach. Mechanisms should also be instituted to build trust with industry and, in partnership, collect and analyze industry data.

Recommendation 5-2: The FDA should evaluate its personnel needs to carry out its roles in collecting, analyzing, managing, and communicating food safety data. The agency should establish an analytical unit with the resources and expertise (i.e., statisticians, epidemiologists, behavioral scientists, economists, microbiologists, risk analysts, biomathematical modelers, database managers, information technology personnel, risk managers, and others as needed) to support risk-based decision making.

Recommendation 5-3: The FDA should evaluate statutes and policies governing data sharing and develop plans to improve the collection and sharing of relevant data by all federal, state, and local food safety agencies. For example, in collaboration with other food safety agencies, the FDA should develop and implement technologies and procedures that will ensure confidentiality and facilitate data sharing. Congress should consider amending the law, to the extent that legal changes are needed, to allow sufficient data sharing among government agencies.

Creating a Research Infrastructure

Recommendation 6-1: The FDA should have a food safety research portfolio that supports the recommended risk-based approach. To this end, the agency's current food safety research portfolio should undergo a comprehensive review. Following this review and with consideration of the agency's broad strategic plan, the FDA should examine the relevance and allocation of its research resources by using public health risk ranking and prioritization. Future research should address the most pressing public health issues and directly support further characterization of risk and selection, implementation, and evaluation of interventions. In addition, research should be coordinated to prevent duplication of effort, especially for cases in which research efforts are better suited to the academic or medical sector.

Recommendation 6-2: Implementation of recommendation 6-1 requires reorganization of the FDA's research portfolio, including reallocation of resources from irrelevant or poorly performing initiatives; hiring of new staff in critical areas and, where appropriate, retraining of existing staff; and identification of future resource

continued

BOX S-4 Continued

needs to support risk-based food safety management. Although the committee recognizes the difficulty of transferring scientists from one research focus to another, the FDA should foster an environment of fluidity in which teams of scientists can be formed with ease to address different research initiatives as necessary.

Recommendation 6-3: Keeping in mind that the FDA will not be able to address all important research needs, the agency should continue to utilize alternative funding mechanisms (e.g., cooperative agreements, university-based centers, contracts) based on a competitive, peer-review process. These efforts could be expanded by establishing a competitive extramural research funding program.

Integrating Federal, State, and Local Food Safety Programs

Recommendation 7-1: The FDA should utilize the surveillance, inspection, and analytic systems and resources of state and local governments in a fully integrated food safety program. As a prerequisite to such integration, the FDA should work with the states and localities to harmonize their programs by providing adequate standards and overseeing their implementation, beginning with those states that meet such standards. Standardization and integration of state and local food safety programs should be conducted in an evolutionary fashion, with intermediate goals and associated performance measures. The White House Food Safety Working Group should make integration of federal and state food regulatory programs a priority and provide leadership to the already established Integrated Food Safety System Steering Committee. The agency should provide training, auditing, and oversight of state and local programs and should facilitate nationwide implementation of the recommended risk-based approach.

Enhancing the Efficiency of Inspections

Recommendation 8-1: The FDA should work toward an inspection system in which the frequency and intensity of inspection of each facility are based on risk, with minimum standards for the frequency and intensity of inspection of all facilities. To support the establishment of such a system, an outside panel should review the potential legal and cultural roadblocks to streamlining inspections and revise the *Investigations Operations Manual* so as to enhance efficiency and protection of the public health. As a prerequisite for a risk-based inspection system,

the FDA should update its Good Manufacturing Practices, including those for medicated animal feed, now and hereafter as necessary.

Recommendation 8-2: As alternative regulatory models emerge, the FDA should evolve toward conducting fewer inspections, instead delegating inspections to the states and localities (including territories and tribes). The FDA should maintain a cadre of inspectors for several critical tasks, such as auditing inspections, providing specialty expertise, developing training and instructional materials for inspectors, identifying and evaluating new inspection techniques, and serving as a backup corps in situations of special need. In preparation for this move, the FDA should review and update curricula specific to general food inspections as well as to particular types of inspections (e.g., seafood Hazard Analysis and Critical Control Points). Agency employees with responsibility for auditing inspections by others should also be provided with specific training. An FDA-sponsored food safety certification program should be established whereby inspectors become certified as they meet agency standards. The agency should include in its budget a line item to fund state contracts and partnerships to help the states move toward and maintain full certification. Plans for implementation of the suggested changes should proceed in an evolutionary fashion, with intermediate goals and associated performance measures.

Recommendation 8-3: The FDA should fully consider the implications of accepting inspection data from an auditing program in which third-party auditors would inspect facilities for compliance with food safety regulatory requirements. If this approach is utilized, the FDA should set minimum standards for such auditors and audits, with oversight and implementation being assigned to an accreditation and standards body.

Improving Food Safety and Risk Communication

Recommendation 9-1: In its effort to integrate risk communication into the recommended risk-based food safety management system, the FDA should play a leadership role in coordinating the education of the food industry, the public, clinical health professionals, and public health officials at all government levels. The FDA could carry out its leadership role in educating industry personnel, health pro-

continued

BOX S-4 Continued

fessionals, and public health officials by seeking authority to mandate the setting of training standards, preparing training materials, certifying trainers, and providing technical support for the interpretation of policies and for the implementation of the risk-based approach.

Recommendation 9-2: In collaboration with other federal agencies, the FDA should continue efforts to develop a single source of authoritative information on food safety practices, foodborne illness and risks, and crisis communications. The FDA, with other federal agencies, should develop a coordinated plan for communicating in one voice with all affected parties during crises so that stakeholders receive timely, clear, and accurate information from a single recognizable source.

Recommendation 9-3: The FDA should improve its understanding of the knowledge and behavior of industry, health professions personnel, and consumers with respect to food safety, paying specific attention to knowledge about demographic groups that are particularly susceptible to food risks.

In making critical decisions about risk communication to implement recommendations 9-1, 9-2, and 9-3, the FDA should explore new mechanisms (e.g., tabletop discussions,[a] public forums, consultations) for expanding its use of strategic partnerships and collaborations.

Modernizing Legislation

Recommendation 10-1: Congress should consider amending the Federal Food, Drug, and Cosmetic Act to provide explicitly and in detail the authorities the FDA needs to fulfill its food safety mission. The following are the most critical areas in which Congress should enact amendments: mandatory reregistration of food facilities and FDA authority to suspend registrations for violations that threaten the public health, mandatory preventive controls for all food facilities, FDA authority to issue enforceable performance standards, mandatory adoption by the FDA of a risk-based approach to inspection frequency and intensity, expansion of the FDA's access to records, FDA authority to mandate recalls, and FDA authority to

[a] A tabletop discussion is a focused practice activity that places the participants in a simulated situation requiring them to function in the capacity that would be expected of them in a real event.

identify countries with inadequate food safety systems and to ban all imports from such countries.

Realizing the Vision of an Efficient Food Safety System

Recommendation 11-1: The committee recommends that the FDA's Office of Foods have complete authority over and responsibility for all field activities for FDA-regulated foods, including inspection, sampling, and testing of foods. Implementing this recommendation would resolve issues associated with the separation between the agency's enforcement functions and larger public health roles and responsibilities, and ensure a well-trained field workforce with specialized expertise in food safety and risk-based principles of food safety management.

Recommendation 11-2: There is a compelling need to elevate and unify the nation's food safety enterprise so that the FDA and relevant sister agencies can better ensure a safe food supply. The committee recognizes that organizational change to enhance the effectiveness and efficiency of the nation's food safety system as a whole is an evolutionary process that would require careful analysis, planning, and execution. With this in mind, the committee recommends that the federal government move toward the establishment of a single food safety agency to unify the efforts of all agencies and departments with major responsibility for the safety of the U.S. food supply.

Recommendation 11-3: Regardless of the evolution of the food safety system, an integrated, unimpeded, and centralized approach to risk-based analysis and data management is required to enhance the FDA's and the broader federal government's ability to ensure a safe food supply. To achieve this goal, and as a potential intermediate step toward the creation of a single food safety agency, the committee recommends the establishment of a centralized risk-based analysis and data management center. This center should be provided with the staff and supporting resources necessary to conduct rapid and sophisticated assessments of short- and long-term food safety risks and of policy interventions, and to ensure that the comprehensive data needs of the recommended risk-based food safety management system are met. This center should be as free from external political forces and influence as possible and accountable to the public health needs and mission of the regulatory agencies.

Part I

Setting the Stage for Understanding and Improving the U.S. Food and Drug Administration's Role in the Food Safety System

1

Introduction

The nation's food supply has evolved into a complex system involving more than $450 billion worth of food each year under the jurisdiction of the U.S. Food and Drug Administration (FDA), more than 156,008 FDA-regulated firms (FDA, 2010), and an additional 2,000 FDA-licensed feed mills (Behnke, 2009). Many parties are responsible for providing safe food, including suppliers, farmers, food handlers, processors, wholesalers and retailers, food service companies, consumers, third-party organizations, and government agencies in the United States and abroad. The path from production to consumption can involve only one step—from a farmer directly to a consumer at a farmer's market—or as many as six or even more steps—for example, from a farmer, to various processers, to a warehouse, to a transporter, to a grocer, to a consumer.

Paralleling the evolution of the food system is a similarly complex history of legislative actions that form the foundation for the current governance of the safety of the food supply in the United States. Since 1906, the Federal Food, Drug, and Cosmetic Act (FDCA) and amendments thereto have charged the FDA with oversight of this governance function (with the exception of meat, poultry, and egg products). This means the FDA has regulatory authority over approximately 80 percent of the U.S. food supply, encompassing products from fresh produce, to seafood, to packaged snack foods, to cereal, to pet food, to animal feed for food-producing animals. The major FDA entities with responsibility for food safety are the Office of the Commissioner, the Office of Foods, the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), the Office of Regulatory Affairs, and the National Center for Toxicological

Research. At the same time, the FDA is only one of many federal agencies that administer at least 30 laws related to food safety. The U.S. Department of Agriculture (USDA) is responsible for the safety of meat, poultry, and egg products, while state and local governments have jurisdiction over foods produced or sold within their borders. All of the significant agencies and departments that are responsible for various aspects of food safety are detailed in Chapter 2.

According to a recent public opinion poll, in general, confidence about the safety of the food supply appears to be lower now than it has been since 2001 (Gallup, 2010). The complexity of the system, combined with highly publicized recalls and outbreaks costing millions of dollars, the resulting impacts on the public health, and the piecemeal nature of the current system, has raised concern about the FDA's ability to ensure the safety of the nation's food supply. The purpose of this study is to identify gaps in the FDA's food safety system and recommend actions that can be taken to fill those gaps.

STUDY CONTEXT

Increasing Discussion and Controversies About the FDA's Ability to Ensure Safe Food

Many recent changes in the nation's food system have prompted increasing discussion of the FDA's ability to ensure safe food. The 1998 Institute of Medicine (IOM)/National Research Council (NRC) report *Ensuring Safe Food: From Production to Consumption* identifies some of these changes, such as the food safety implications of emerging pathogens, the trend toward the consumption of more fresh produce, the trend toward eating more meals away from home, and changing demographics, with a greater proportion of the population being immunocompromised or otherwise at increased risk of foodborne illness.[1] These developments must be understood in the context of a wide range of global and societal changes that greatly increase the complexity of the food safety system and the challenges faced by those responsible for implementing the system. These changes, detailed in Chapter 2, include changes in the food production landscape, climate change, evolving consumer perceptions and behaviors (e.g., the growing demand for fresh produce and for its availability year-round[2]), globalization and increased food importation, the role of labor–management

[1] A demographic change receiving particular attention today is the growth of the elderly population, which is at higher risk of foodborne illness. It is estimated that by 2015, 20 percent of the population will be over age 60, and the number at risk will increase accordingly (GAO, 2010).

[2] From 1992 to 2005, there was a 180 percent increase in consumption of leafy greens in the United States (GAO, 2008a).

relations and workplace safety, heightened concern about bioterrorism, increased levels of pollution in the environment, and the increasing role of international trade agreements. Food production is changing as well, with the number of firms involved with food having increased by roughly 28 percent since 2001 (GAO, 2008b).[3] The importation of food is also increasing; roughly $49 billion worth of food was imported to the United States in 2007 (GAO, 2008a).

A number of high-profile food-related outbreaks have occurred in recent years, including *E. coli* O157:H7 in spinach in 2006, melamine in pet food in 2007, *Salmonella* in produce and in peanut butter in 2008, and *E. coli* O157:H7 in cookie dough in 2009. In 1999, Mead and colleagues estimated that foodborne infections caused about 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year in the United States (Mead et al., 1999). It should be emphasized that these data were reported in 1999, and the morbidity, mortality, and hospitalization estimates would likely be different today; new estimates are in preparation but were not available at the time of this writing. Nonetheless, data for 2008 from the U.S. Centers for Disease Control and Prevention (CDC) suggest that there has been no significant change in the incidence of foodborne infections by the major bacterial agents transmitted through food over the last several years (in some cases, disease may be acquired through other nonfood vehicles, such as reptiles). CDC therefore concludes that problems with bacterial contamination through food are not being resolved (CDC, 2009). According to CDC, the lack of recent progress toward national health objectives for food safety and the continual occurrence of large multistate outbreaks point to gaps in the food safety system. The most recent FoodNet surveillance data (CDC, 2010) show reductions in 2009 (compared with 2006–2008) in the incidence of some infections (shiga toxin-producing *E. coli* O157:H7 and *Shigella*) but not others (*Campylobacter*, *Listeria*, *Salmonella*). The data also show an increase in other infections from food-associated pathogens (*Listeria* and *Vibrio*).

During the last two decades, many organizations and individuals, including the IOM, have devoted effort to identifying needed improvements in food safety. Attention has been focused in particular on the FDA's food safety program. According to a number of reports (GAO, 2004a,b, 2005, 2008a,b; FDA Science Board, 2007), although the FDA is working to ensure safer food, problems with its capacities, functions, and processes persist. The IOM, the NRC, and other groups, including consumer organizations, have made recommendations for strengthening food protection, a few of which are listed here (see Appendix B for a detailed listing):

[3] Between 2001 and 2007, the number of domestic firms under the FDA's jurisdiction increased from about 51,000 to more than 65,500 (GAO, 2008b).

- The 1998 IOM/NRC report *Ensuring Safe Food: From Production to Consumption* concludes that the U.S. food system is fragmented and is facing unprecedented challenges from a global marketplace, a greater reliance on imports, shifting demographics, and changing societal practices. The report recommends modifying the federal statutory framework for food safety to eliminate fragmentation and enable the development and enforcement of science-based standards as well as creating a single food safety agency.
- The 2003 IOM/NRC report *Scientific Criteria for Ensuring Safe Food* (IOM/NRC, 2003) examines the scientific basis for criteria that underlie U.S. food safety regulations, presents a blueprint for how agencies responsible for regulating food safety should develop appropriate science-based criteria, and identifies the failure to adopt new technologies and enforce standards as barriers that impede regulatory action.
- The 2009 IOM report *HHS in the 21st Century* (IOM, 2009) highlights food safety regulatory activities as an area of weakness within the U.S. Department of Health and Human Services (HHS). Specifically, the report offers recommendations for uniting the food safety responsibilities of the two salient agencies (the FDA and USDA's Food Safety and Inspection Service) within HHS.
- Both consumer groups and industry have issued reports addressing food safety: the Center for Science in the Public Interest issued a white paper, *Building a Modern Food Safety System for FDA Regulated Foods* (DeWaal and Plunkett, 2007), while the Grocery Manufacturers Association (GMA) issued *Commitment to Consumers: The Four Pillars of Food Safety*, which focuses on prevention of foodborne illness (GMA, 2007).

An important factor influencing the FDA's ability to fulfill its mission is the resources available to the agency given that, in addition to food, it is required to regulate cosmetics, drugs, biologics, medical devices, and tobacco. Although the agency is responsible for the safety of more than 80 percent of the nation's food supply, its budget accounts for only 24 percent of expenditures on food safety (GAO, 2008b) (see Chapter 2). Moreover, after the events of September 11, 2001, the FDA was given additional responsibilities related to bioterrorism (GAO, 2008b), stretching its funds even thinner. For example, even though the number of domestic food establishments was increasing, the numbers of inspectors and inspections (both domestic and abroad) and the amount of funding allocated to food safety both decreased during the period 2003–2006 (FDA/CFSAN, 2008; GAO, 2008b).

In the face of its decreasing resources, the FDA must continue to make decisions about both appropriate short-term responses to a food crisis and

longer-term prevention functions focused on continued improvements in the public health. While the need to respond to a crisis is clear, the agency has been criticized as responding only reactively to food problems, to the neglect of its preventive functions. In addition to the need to increase efficiency and prioritize its efforts, the FDA's success depends greatly on maintaining strong cooperative relationships with other partners in food safety (e.g., other federal departments and agencies; local, state, and foreign governments; industry). Although the division of responsibilities for food safety with respect to research, commodities, and public health surveillance among different agencies has been long criticized, no genuine attempt has been made to consider alternatives for the governance of food safety. Technological, scientific, environmental, and societal shifts have generated discrete actions, such as reorganizations within the food program at the FDA or amendments to the law, and the result has been the current piecemeal approach to food safety. The unprecedented speed and nature of such changes in the 21st century demand a different kind of response at this time—one that is comprehensive and systematic, giving the FDA and its partners a real opportunity to realize the vision of an integrated food safety system.

There have also been significant leadership and organizational changes in the FDA's operations and their context since this study was requested by Congress in 2008. In addition to a new administration, some of the most significant of these have been the establishment of the White House Food Safety Working Group (FSWG) to advise the administration on food safety matters; the establishment of a new Office of Foods within the FDA, with oversight and authority over CVM and CFSAN; the development of plans for a state–federal Integrated Food Safety System; and the hiring of additional high-level leaders and subject matter experts in food safety management.

The FDA's Food Protection Plan

In 2007, the FDA issued its Food Protection Plan (FPP) (FDA, 2007) (Appendix G), setting forth a general strategy for food safety and defense and identifying three core elements—prevention, intervention, and response (Box 1-1). In each of these areas, the plan describes key actions and needed legislative authority (Box 1-2). The approaches laid out in the plan include new regulatory authority for recalls, preventive controls for high-risk foods, and a shift to a risk-based system for inspections.

PURPOSE AND SCOPE OF THIS STUDY

In response to the heightened public health concerns outlined above, the Consolidated Appropriations Act of 2008 tasked the FDA to contract

BOX 1-1
Three Core Elements of Food Safety in the U.S. Food and Drug Administration's Food Protection Plan

1. **Prevent foodborne contamination:**
- Promote increased corporate responsibility to prevent foodborne illnesses.
- Identify food vulnerabilities and assess risks.
- Expand the understanding and use of effective mitigation measures.

2. **Intervene at critical points in the food supply chain:**
- Focus inspections and sampling based on risk.
- Enhance risk-based surveillance.
- Improve the detection of food system "signals" that indicate contamination.

3. **Respond rapidly to minimize harm:**
- Improve immediate response.
- Improve risk communications to the public, industry, and other stakeholders.

with the National Academies for a comprehensive study of gaps in the public health protection offered by the food safety system in the United States.[4] Box 1-3 presents the statement of task for this study.

The FPP's overarching strategy for food protection encompasses and focuses on microbiological and chemical contaminants that can affect public health. The committee was tasked to evaluate the FDA's plan and to identify its strengths and weaknesses, determine whether it can be implemented effectively, and identify what additional resources (e.g., finances, equipment, personnel) the agency may need for this purpose. The committee was also tasked with evaluating the various additional legislative authorities the FDA has requested and determining whether these authorities are adequate to fulfill the agency's public health mission.

Clarification of the committee's task came from extensive dialogue with FDA food program leadership. Accordingly, the committee addressed microbiological contaminants, chemical contaminants, and intentional food contamination, including financially motivated contamination (as in the

[4] *Consolidated Appropriations Act of 2008*, HR2764, Public Law 110-161, Division A, Title VI.

BOX 1-2
Additional Protections That Involve Legislative Changes to the U.S. Food and Drug Administration's (FDA's) Authority

Prevent foodborne contamination:

- Allow the FDA to require preventive controls to prevent intentional adulteration by terrorists or criminals at points of high vulnerability in the food chain.
- Authorize the FDA to institute additional preventive controls for high-risk foods.
- Require food facilities to renew their FDA registrations every 2 years, and allow the FDA to modify the registration categories.

Intervene at critical points in the food supply chain:

- Authorize the FDA to accredit highly qualified third parties for voluntary food inspections.
- Require a new reinspection fee from facilities that fail to meet current Good Manufacturing Practices.
- Authorize the FDA to require electronic import certificates for shipments of designated high-risk products.
- Require a new food and animal feed export certification fee to improve the ability of U.S. firms to export their products.
- Provide parity between domestic and imported foods if FDA inspection access is delayed, limited, or denied.

Respond rapidly to minimize harm:

- Empower the FDA to issue a mandatory recall of food products when voluntary recalls are not effective.
- Give the FDA enhanced access to food records during emergencies.

recent case of melamine in pet foods) and contamination by terrorists. The committee excluded from its deliberations management of the safety of certain products (see Table 1-1). In particular, although the FDA's regulatory authority encompasses dietary supplements and food additives, the committee was asked to exclude them from its deliberations because their safety determination is not usually based on issues of contamination. Dietary supplements fall into a "gray area" of being a special category of food, and the determination of their safety is typically made by the industry. Manufacturers need not obtain FDA approval before producing or selling them. The

BOX 1-3
Statement of Task

An ad hoc committee of the Institute of Medicine and the National Research Council will undertake a study to examine gaps in public health protection provided by the farm-to-table food safety system under the purview of the Food and Drug Administration (FDA) and identify opportunities to fill those gaps. The study will address the recommendations of the November 2007 FDA Food Protection Plan by evaluating the plan and identifying gaps and opportunities (recommendations) to fill the gaps. The committee's consensus report will include legislative, regulatory, and administrative recommendations and estimates of costs of such recommendations, as feasible.

Specifically, the committee will:

- Evaluate the FDA Plan in light of past reports directed at strengthening food safety including, but not limited to *Ensuring Safe Food from Production to Consumption* (IOM/NRC, 1998), *Scientific Criteria to Ensure Safe Food* (IOM/NRC, 2003), the 2007 FDA Science Board report, and relevant GAO reports;
- Identify strengths and weaknesses of the FDA Plan, factors that may limit its achievement, and needed revisions or additions; and
- Identify and recommend enhancements in FDA's tools and capacity that are needed to implement a comprehensive plan and assure a risk-based preventive system, including in the areas of new regulatory tools and statutory authority; research mandate; resources required for research, scientific and technical infrastructure, standard setting, inspection, and enforcement; integration of programs with other regulatory and public health agencies involved in food safety surveillance, research and regulation at federal, state and local levels; expansion of FDA's international presence and international regulatory information exchange; and changes in organizational and leadership structures on food safety within the Department of Health and Human Services.

safety of dietary supplements is regulated under the Dietary Supplement Health and Education Act of 1994 (DSHEA). The committee excluded from the study a review of the process for notification or self-determination of generally recognized-as-safe ingredients. Food and color additives for both human food and animal feed are subject, respectively, to the 1958 Food

TABLE 1-1 Scope of This Study

Outside the Scope	Within the Scope
• Dietary supplements • Food and color additives • Issues specifically pertinent to genetically modified foods • Issues specifically pertinent to organic foods	• Microbiological contaminants in foods and feed • Chemical contaminants in foods and feed

Additives Amendment[5] and the 1960 Color Additives Amendments[6] to the 1938 FDCA, and they must be preapproved for safety before being added to food or feed. In the case of such additives, the burden of proof is on the manufacturer, who must provide evidence that the additive is safe for consumption. In 1992, the FDA concluded that, with regard to genetically modified foods, "The agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way, and that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding."[7] Therefore, these foods were not considered separately in this study. Likewise, the safety of organic foods was not considered separately.

In defining the scope of the study described in its statement of task, the committee was also guided by the FDA's jurisdiction in food safety. The FDCA, section 201, defines "food" as (1) articles used for food or drink by man or other animals, (2) chewing gum, and (3) articles used for components of any such article.[8] In accordance with this definition, the FPP includes food for both humans and animals. The latter encompasses both pet food and feed for "food-producing animals," a category that includes animals whose products will end up in the human food supply (including, for example, dairy cattle, beef cattle, swine, and chickens [FDA, 2007]). The committee consulted with the FDA on the precise scope of the study with respect to pet food and animal feed. This dialogue resulted in a decision to include in the study issues related to pet food and animal feed only as they might directly affect human health (e.g., because of drug or contaminant residues in pet food consumed or handled by humans or in human foods of

[5] *Food Additives Amendment of 1958*, Public Law 85-929, 72 Stat. 1784 (1958).
[6] *Color Additive Amendments of 1960*, Public Law 86-618, 74 Stat. 397 (1960).
[7] "Statement of policy—foods derived from new plant varieties" (FDA, 1992).
[8] *Federal Food, Drug, and Cosmetic Act*, Sec. 201, 21 U.S.C. §§ 321.

animal origin). In this report, the term "food" encompasses pet food and animal feed unless explicitly indicated otherwise.

METHODS

Committee Composition and Membership

The committee was assembled to include individuals with extensive knowledge of FDA programs, policies, and operations, as well as those with expertise in health policy, food law and regulations, risk analysis and communication, economics, epidemiology, monitoring and surveillance, food microbiology, and toxicology. Representation of state officials with food safety responsibilities was crucial because of the key role of state governments in keeping food safe. In addition, perspectives of the food industry and consumer interest groups were necessary as these sectors are responsible partners in food safety and would be affected by the implementation of the recommendations in this report. Expertise in animal feed was also sought because, as noted above, the safety of these products has the potential to affect human health, and feed safety is within the purview of the FDA.

Information Gathering, Meetings, and Workshops

The committee gathered information for this study from previous NRC and IOM reports, reports from authoritative groups, plans and initiatives from industry, FDA leadership and staff, numerous public sessions at committee meetings, teleconferences and written statements in response to specific queries, expert testimony before congressional committees, and the FDA website. The committee held three workshops to hear expert perspectives and obtain answers to its questions (see Appendix A for the workshop agendas). Participants from all relevant sectors attended the workshops, and the committee found their experience and insights invaluable to this study. They spoke on such topics as the FDA's organization and responsibilities; approaches to food safety prevention, inspection, and research; and perspectives on the FDA from industry and consumer stakeholders. Additionally, the committee held six closed meetings and numerous conference calls.

Study Approach

As noted above, the FPP is a road map founded in basic principles of prevention, intervention, and response. Since its publication and the congressional request for this study, leadership and organizational changes in the government have altered the U.S. food safety scene and affected

the FDA's food programs. As discussed above, these include a change in administration, the formation of the White House FSWG, and the FDA's establishment of the new Office of Foods.

Although the FPP is widely regarded as a positive development, it is only a first step. Since its release, questions have been raised, for example, by the Government Accountability Office (GAO), about the specifics of its implementation—including a lack of clarity on its execution, efficient targeting of resources, budgetary constraints, and the timeline for implementation—as well as about the agency's statutory authority (GAO, 2008a,b). Without sufficient attention to these matters, there is concern that the plan cannot be appropriately implemented, and the likelihood of its success cannot be determined. Additional concern has been raised because of the failure to implement many past recommendations to the FDA.

In this new food safety environment and based on nature of the FPP, the committee concluded that to be useful, the FPP needs to evolve and be supported by more detailed strategic planning. Therefore, in its deliberations, the committee envisioned the FPP as a point of departure but focused its efforts on identifying additional tools and capacities that the FDA needs to improve food safety today and in the future.

In adhering to its statement of task, the committee reviewed the Food Protection Plan and formulated its recommendations in the context of an evaluation of the FDA's functions and operations. Thus, elements of the Food Protection Plan are considered in all chapters of this report, and they are also discussed in the context of the committee's recommendations. As an example, the FPP states that the FDA needs to "strengthen the establishment of a risk-based process to continuously evaluate which FDA-regulated products cause the greatest burden of foodborne disease." The committee recommends a stepwise process for achieving that objective. A synthesis of the committee's evaluation is presented in Chapter 4, which focuses on governing philosophy. The committee took this approach to its task to provide the FDA with a report that would be useful today and reflect all organizational and leadership changes within the agency since the FPP was written in 2007.

In identifying tools and capacities for an effective food safety system, the committee focused on investigating the FDA's food safety programs and operations as well as its progress toward the committee's view of such a system. The committee took great pains to provide recommendations that would maintain a balance between being too general and too prescriptive, and it formulated a number of concrete recommendations to guide the FDA in its food safety management mission, emphasizing the need for the agency to move toward a risk-based approach. Some of these concrete recommendations, for example, are aimed at overcoming current limitations in the acquisition and sharing of data (Chapters 5 and 11), in the FDA's research

capacity and portfolio (Chapter 6), in risk communication and education (Chapter 9), and in legal authorities (Chapter 10). The committee believes that many details of the implementation of its recommendations (e.g., the factors to consider when assessing interventions) are within the purview of the FDA, especially since the agency's food safety program functions in the context of its overall responsibilities for food, which, for example, also include a nutrition program.

Recognizing that many enhancements can be realized without structural changes (through, for example, leadership commitment, staff retention, strategic planning), the committee initially deliberated its recommendations in the context of the current food safety management structure. As the study progressed and the committee's ideas matured, it became clear that there were many reasons to call for a single food agency, including the fact that a risk-based approach should encompass all foods and hazards. This is not a new idea, but it is one that is fraught with challenges that the committee recognizes. To overcome these challenges and to maintain public health as the ultimate goal, the committee formulated a stepwise process for achieving a single food safety system and ensuring maintenance of the day-to-day operations necessary to protect the public health. In formulating its own recommendations, the committee also took into account many recommendations made by other groups and individuals to enhance food safety, some of which the committee explicitly supports. (Appendix B presents a sampling of past recommendations from other sources.) The committee also specified what legislative changes would be required to implement its recommendations.

Finally, the committee was asked, if feasible, to provide cost estimates for implementing its recommendations. However, because essential supporting information was not always accessible and the committee faced time constraints, the evidence needed to address this question in detail was lacking. The committee did consider cost and resource issues in a general sense in all of its deliberations by drawing on the experience of members who formerly held senior leadership positions at the FDA.

ORGANIZATION OF THE REPORT

This report is divided into three parts. Part I sets the stage for understanding and improving the FDA's role in the food safety system. Chapter 2 assesses the current system with respect to how well it has fulfilled its public health mission in the face of the significant changes in the food enterprise discussed briefly above; it also contains a summary of organizational and functional challenges at the FDA. The committee used previous NRC and IOM reports, as well as reports by the agency itself, GAO, industry, and consumer organizations, to document these challenges.

Each chapter in Parts II and III is dedicated to explaining the com-

mittee's understanding of the essential functions of a food safety regulatory agency; these chapters also include the committee's recommendations. Part II presents the committee's vision of a food safety system defined by a risk-based decision-making approach. Chapter 3 details the attributes of such an approach and identifies the infrastructure needed for its implementation, such as personnel and analytical capacity. It also presents an account of the science needed to build a risk-based system, including data analysis and laboratory research. Chapter 4 outlines the types of governance models that might be appropriate for managing food safety and explains the importance of defining the responsibilities of the various parties involved in food safety (e.g., industry, state and local governments).

Part III describes what is necessary to implement the food safety system proposed in Part II. Chapters 5 and 6, respectively, address the creation of the necessary data surveillance and research infrastructures. Chapter 7 describes state and local food safety programs nationwide and calls for their harmonization and integration with the programs of the federal government to achieve a seamless food safety program. Chapter 8 addresses the issue of how to enhance the efficiency of food inspections. Chapter 9 examines the critical issue of communicating about food safety and risks with those who can impact public health through their food safety–related conduct at home (consumers) or at work (e.g., personnel in industry and the health professions). Chapter 10 is dedicated to legislative needs for an enhanced food safety system. Finally, Chapter 11 sets forth the organizational changes needed to achieve the committee's vision of an efficient risk-based food safety system.

Appendixes B–G can be found on the inserted CD. They include the agendas of all public meetings (Appendix A), recommendations of selected past reports (Appendix B), a brief description of food safety systems in the United States and other countries (Appendix C), two commissioned papers on food defense and food importation (Appendixes D and E, respectively, prepared at the committee's request by outside experts and used as background for the committee's deliberations), a sampling of selected FDA research (Appendix F), the FPP (Appendix G), a glossary and a list of acronyms and abbreviations (Appendixes H and I, respectively), and biographical sketches of the committee members (Appendix J).

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2

The Food Safety System: Context and Current Status

Since humans began farming, agriculture has evolved rapidly, with pervasive effects on society. An example is the industrialization of food production in the twentieth century, which, among other things, dramatically changed perceptions and behaviors related to food (Hennessy et al., 2003). While this revolution in food production resulted in great benefits to today's consumers and the ability to feed a growing population, it also resulted in unanticipated foodborne risks. Regulatory agencies responsible for food safety thus are challenged not only to respond to current issues, but also to articulate a vision of food safety that anticipates future risks. This chapter sets the stage for the more detailed assessments, findings, and recommendations that follow by reviewing some of the developments that have contributed to the context for food safety in the United States and by providing an overview of the current U.S. food safety system.

A CHANGING WORLD

The Institute of Medicine (IOM)/National Research Council (NRC) report *Ensuring Safe Food: From Production to Consumption* (IOM/NRC, 1998) identifies a number of developments with implications for food safety, including (1) emerging pathogens, (2) the trend toward the consumption of more fresh produce, (3) the trend toward eating more meals away from home, and (4) changing demographics, with a greater proportion of the population being immunocompromised or otherwise at increase risk of foodborne illness. These developments continue to be important today, but many others affecting food safety have occurred in the decade since that

report was published. Together, these developments contribute to the current context for food safety in the United States, which is characterized by a number of features that must inform any assessment of the food safety system. These include changes in the food production landscape, climate change, changing consumer perceptions and behaviors, globalization and increased food importation, the role of labor–management relations and workplace safety, heightened concern about bioterrorism, increased levels of pollution in the environment, and the signing of international trade agreements.

Changes in the Food Production Landscape

In addition to constant changes in food production and substantial growth in the number of food facilities (the number regulated by the U.S. Food and Drug Administration [FDA] grew by 10 percent between 2003 and 2007 [GAO, 2008a]), the food and agriculture sector has experienced widespread integration and consolidation in recent years. For example, the consolidation of supermarkets has changed the retail grocery landscape in the United States, leading to the dominance of the industry by a small number of large companies. Apart from consequences for the market share of small retailers, the greater dependence of manufacturers on this limited number of retailers for sales volume gives these companies significant leverage to bargain for lower prices and demand safety standards. The result has been an increased tendency to establish private standards, which has changed the enterprise of food safety (Henson and Humphrey, 2009).

For example, large retailers and customers established the Food Safety Leadership Council on Farm Produce Standards to develop standards for the growing and harvesting of fresh produce (FSLC, 2007). Another private effort was the Global Food Safety Initiative, created in 2000 to set common benchmarks for different national and industry food safety programs. Its standards, now used widely around the world, require that the food protection practices of manufacturers of food, including produce, meat, fish, poultry, and ready-to-eat products such as frozen pizza and microwave meals, be audited at regular intervals (GFSI, 2007). Farmers, shippers, and processors in the business of producing leafy greens may participate in the California Leafy Greens Marketing Agreement, a private mechanism operating with oversight from the California Department of Food and Agriculture that verifies whether growers are following certain food safety practices (LGMA, 2010). Adoption of these private standards could be seen as an enhancement of food safety; however, private standards can also impose unnecessary burdens if they are not scientifically justified. For example, private standards may result in unnecessarily higher food prices (DeWaal and Plunkett, 2007). Therefore, a close look at such standards is warranted. As an alternative, public standards can be instituted. For example, Tomato

Good Agricultural Practices for tomato farms and Tomato Best Management Practices for tomato packinghouses are the first mandatory produce safety programs in the United States (Florida Department of Agriculture and Consumer Services, 2007).

Climate Change

Climate change is doubly relevant to the food enterprise: not only may climate change affect food yields, but food production may contribute to climate change by releasing a substantial amount of greenhouse gases, such as carbon monoxide and nitrogen monoxide (Stern, 2007). Stern (2007), among others, has highlighted serious concerns regarding the effects of climate change on future food security, especially for populations in low-income countries that are already at risk of food insecurity.

Climate change can affect food systems directly, by affecting crop production (e.g., because of changes in rainfall or warmer or cooler temperatures), or indirectly, by changing markets, food prices, and the supply chain infrastructure—although the relative importance of climate change for food security and safety is expected to differ among regions (Gregory et al., 2005). A recent Food and Agriculture Organization paper, *Climate Change: Implications for Food Safety* (FAO, 2008), identifies the potential impacts of anticipated changes in climate on food safety and its control at all stages of the food chain. The specific food safety issues cited are increased range and incidence of common bacterial foodborne diseases, zoonotic diseases, mycotoxin contamination, biotoxins in fishery products, and environmental contaminants with significance for the food chain. To raise awareness and facilitate international cooperation, the paper also highlights the substantial uncertainty on the effects of climate change and the need for adequate attention to food safety to ensure effective management of the problem.

Changing Consumer Perceptions and Behaviors

With an increasingly global food market, consumer expectations and behaviors with regard to food have changed dramatically over the past hundred years. Consumers have grown to expect a wide variety of foods, including exotic and out-of-season foods. As a result, the consumption of fresh fruits and vegetables has increased (IOM/NRC, 1998) and is expected to continue to do so: per capita fruit consumption is predicted to grow in the United States by 5–8 percent by 2020, with a smaller increase predicted for vegetables (Lin, 2004). Additionally, consumers are spending more money on food away from home, which accounted for 48.5 percent of total food dollars, or approximately $565 billion, in 2008 (ERS, 2010).

At the same time, consumer perceptions and behaviors with respect to food safety have also changed significantly. Consumer knowledge about foodborne pathogens, high-risk foods, vulnerable populations, and safe food-handling practices has increased in recent years, although this knowledge is sometimes wrong or incomplete (FSIS, 2002). Recent foodborne illness outbreaks have further increased consumer awareness about food safety; in fact, a majority of consumers believe foodborne illnesses are a serious or very serious worry (FSIS, 2002; Hart Research Associates/Public Opinion Strategies, 2009). Further, recent polls indicate a lack of confidence in the ability of the FDA to protect consumers against food-related threats (Hart Research Associates/Public Opinion Strategies, 2009).

While food producers, processors, and retailers have the primary responsibility for the safety of the food they produce, food preparers also play an important role in preventing foodborne illness. Accordingly, several groups have developed educational messages aimed at teaching safe food-handling behaviors to consumers and other food preparers. The Clean, Separate, Cook, Chill approach, for example, is focused primarily on consumers in the home. However, this initiative has proven to be largely ineffective (Anderson et al., 2004). Several studies have found that, although self-reported use of safe food-handling practices has increased, consumers and other food preparers do not always follow these practices (Redmond and Griffith, 2003; Howells et al., 2008; Abbot et al., 2009). Further, the International Food Information Council Foundation found that many consumers fail to use some important food safety practices; for example, just 50 and 25 percent of consumers, respectively, use a different or freshly cleaned cutting board for each type of food and check the doneness of meat and poultry items with a food thermometer (IFICF, 2009). Several factors have been identified as affecting the adoption of safe food-handling practices, including attitudes, lack of motivation, sociodemographic factors, and cultural beliefs (Medeiros et al., 2004; Patil et al., 2005; Pilling et al., 2008). In addition, the media often promote poor food-handling practices during on-air cooking demonstrations and frequently give misinformation on the subject (Mathiasen et al., 2004). The decline of home economics classes in schools, coupled with the increasing trend to eat out, further contributes to the lack of food safety knowledge. In addition, few medical providers diagnose and report foodborne illness, and fewer yet discuss safe food-handling practices with their patients (Wong et al., 2004; Henao et al., 2005).

Globalization and Increased Food Importation

The expansion and liberalization of international trade in recent decades have resulted in an increase in food imports. By 2005, the volume of imported medical supplies and food had increased seven-fold over that in 1994, and

this trend is expected to continue (Nucci et al., 2008). Among foods, the increase has been especially dramatic in the seafood sector, which the FDA oversees. From 1996 to 2006, the volume of FDA-regulated food imports increased almost four-fold, from 2.8 billion to 10 billion pounds (Nucci et al., 2008). About 230,730 facilities that deal with imported foods are registered with the FDA, including foreign manufacturers, packers, holders, and warehouses (FDA, 2010a). Consequently, there is a growing need for a robust regulatory system that can ensure the safety of food imports. This concern over the safety of imported foods is reflected in the number of congressional hearings on the subject in 2007 and 2008 (GPO, 2010).

Various countries are experimenting with models for regulating food imports (e.g., third-party certification, inspections at the border, country certifications; see Appendix E), but there is no consensus on the best regulatory models. In this environment, the United States is attempting to determine the best model to implement given available resources and the vast amount of imported foods to oversee. For example, in 2007, at the request of the White House, the Interagency Working Group on Import Safety was established. It included, among others, representatives of the Department of Health and Human Services (HHS), the parent agency of the FDA, and the Department of Agriculture (USDA). The working group developed a road map recommending both broad and specific actions that would enhance the safety of all food imports (Interagency Working Group on Import Safety, 2007).

The Role of Labor–Management Relations and Workplace Safety

The crucial role of food employees and employers in food safety cannot be overstated, particularly since food workers have been implicated in the spread of foodborne illness (Todd et al., 2007). When addressing food safety, therefore, it is important to consider the potential role of labor–management relations and workplace conditions. For example, if the labor force responsible for producing food on farms and in factories is inadequately trained or paid, is forced to work under unsafe or unsavory conditions, or is ignored by management when it attempts to express concerns, workers may respond by applying less care in the production, processing, or preparation of food, leading to increased risk for consumers. Some elements of this association may be direct since many human pathogens are easily transmitted to foods via contact with human vehicles, and worker sanitation and hygiene are critical factors in this process. Specifically, ensuring that workers have access to appropriate sanitary facilities, providing adequate sick leave, and making hand washing a critical control point are vital to controlling many hazards in the food supply. For example, if farm laborers in the field are not provided with adequate sanitary facilities, there will be increased opportunity for crop exposure to

infectious agents. And if workers are not given sufficient training for their basic work activities, they are also less likely to be trained in minimizing risks for food products.

Regulation and oversight of all phases of the food supply chain by all levels of government can help enhance food safety by identifying situations in which work procedures need improvement or workers need training. Cooperation between the FDA and labor regulatory agencies such as the National Institute for Occupational Safety and Health and the Occupational Safety and Health Administration would appear to warrant exploration.

Heightened Concern About Bioterrorism

Although public health agencies have been concerned about the potential for intentional contamination of food in the past, this concern increased greatly after the events of September 11, 2001. The volume of food animals and commodities, the lack of physical security and robust surveillance systems for food products, and the rapid movement of food products over a broad geographic range and through many hands make the U.S. food supply highly vulnerable to intentional contamination (Kosal and Anderson, 2004). A major activity in response to this threat was the FDA's establishment, with USDA and the U.S. Department of Homeland Security (DHS), of a food defense partnership (i.e., sector organization) with all relevant federal, state, local, and industry counterparts (see Appendix D). Various other efforts followed the establishment of this partnership, increasing the responsibilities of all involved and of the FDA in particular. The FDA is engaged in food defense activities to implement new presidential directives and congressional legislation, as well as to educate and communicate with industry, its own staff, and state, local, and foreign counterparts about matters related to food defense. The issue of terrorism-related prioritization of efforts is highly problematic, however, because of the uncertainty concerning the likelihood and nature of an attack (information about which is generally classified). This uncertainty makes comparisons with other risks and justifications for resource allocation and prioritization difficult.

Increased Levels of Pollution in the Environment

An undesirable consequence of the industrialization of agriculture and manufacturing is the release of chemicals to the environment. Not all food pollutants come from industrial processes, however. For example, dioxins and furans are contaminants released unintentionally into the environment as a result of both preindustrial combustion processes (e.g., the combustion of forests or brush) and modern combustion processes (e.g., industrial burn-

ing, landfill fires, structural fires) (IOM/NRC, 2003). Whether exposure to these pollutants has increased over the years depends on the pollutant, and the data needed to assess trends are often lacking (IOM, 2007).

The bioaccumulation of pollutants in the food chain (e.g., methylmercury in seafood) has received a great deal of attention. The pollutants of concern may change over time as manufacturing processes evolve, but those that are persistent in the environment can be a chronic issue for public health and environmental agencies. The growing attention to the problem is due to both increased understanding of bioaccumulation and greater public concern about environmental pollutants in general, both domestically and internationally. The potential long-term effects of these pollutants, coupled with the difficulty of measuring multiple exposures and potential interactions, present a complex problem.

Although the U.S. Environmental Protection Agency (EPA), not the FDA, is the agency that regulates levels of pollutants in the environment, food commodities are subject to contamination via the environment. Much of the work on collecting and analyzing environmental and toxicological data on food pollutants has already been done by EPA, and EPA's risk assessments can often be used as the basis for food policy. A recent report, however, found that the national residue program is not accomplishing its mission of monitoring the food supply for harmful residues (USDA, 2010a).

The Signing of International Trade Agreements

In the wake of the establishment of the World Trade Organization (WTO) in 1995 and the signing of the Agreement on the Application of Sanitary and Phytosanitary Measures, countries are obliged to follow some basic rules in the application of food safety measures and plant and animal regulations. Countries can set their own standards for safety, but those standards must be based on science. The intent is to avoid protectionism on behalf of domestic producers of food and allow for free trade based on competitive principles. Although the obligations of this agreement were not fully understood at first by governments, it is increasingly viewed as a legal document with the same force as domestic law (Carnevale, 2009). In practical terms, this means that unscientific regulations that affect trade could be successfully challenged at WTO.

As an example, the United States and Canada brought to WTO the European Union's (EU's) ban on the importation of meat and meat products that had been treated with any of six hormones, which favored EU meat producers and blocked exports from the United States and Canada. The WTO Panel and Appellate Body concluded that the prohibition was not based on scientific evidence, and a settlement was reached (Lugard and

Smart, 2006). Policies of the United States have also been under scrutiny. A recent analysis suggests that foreign food producers may be at a disadvantage when they want to export to the United States because they need to comply with costly requirements under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, such as providing prior notice of shipment (GAO, 2004a; Boisen, 2007).[1] As the volume of imported foods continues to rise, such international agreements are becoming more important and must be considered in any discussion of enhancing food safety in the United States. (International trade agreements and their influence on food safety oversight and regulations are discussed in detail in Appendix E.)

LIMITS ON FOOD SAFETY

In examining how to improve a food safety system, one must acknowledge that foodborne illness cannot be completely eliminated. Many factors affect the degree of safety that is achievable, some related to the state of science and others to human factors, such as economic considerations and people's desire to enjoy certain foods whose safety cannot be ensured (e.g., raw milk). The degree of food safety that is attainable also depends on management and oversight practices, on costs versus benefits, and on such factors as regulatory limits, public perceptions, consumer education and responsibility, and public communication.

It is important to stress that responsibility for food safety falls on everyone, from farmers to consumers. However, the FDA is often held responsible for negative events related to food safety, given that ensuring food safety is part of the agency's core mission. This focus on the FDA's responsibilities has grown as such events have become more widespread, garnering increased media attention. Moreover, in recent years, reductions in the incidence of foodborne illness seen in the late 1990s appear to have leveled off (CDC, 2009), and for some pathogens the incidence has recently increased (CDC, 2010). Because many government agencies are responsible for food safety, it is not possible to attribute changes in the rate of foodborne illness to any particular agency. Still, the FDA's responses to these events have sometimes been less than optimal (Produce Safety Project, 2008).

One limit on the degree of food safety attainable is the fact that to achieve a complete absence of pathogens and other contaminants in food is an unrealistic goal (IOM/NRC, 2003). Although the concept of zero tolerance for a particular pathogen may appear justifiable, it is merely a

[1] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)*, Public Law 107-188, 107th Cong., 2nd sess. (January 23, 2002), 306.

regulatory term with little scientific basis. As the IOM/NRC report *Scientific Criteria to Ensure Safe Food* states: "Scientists are often dismayed by the use of the term [zero tolerance] because they recognize the inability to ensure, in most situations, the complete absence of pathogens and contaminants and the limitations of any feasible sampling plan to check for their total absence" (IOM/NRC, 2003, p. 25). Moreover, most interventions to minimize food hazards have only limited effects in decreasing the prevalence of pathogens, and for some foods, such as those sold raw, few interventions are possible. Recognizing these realities, zero tolerances are viewed as an enforcement tool applied to the most problematic hazards with the goal of communicating that the highest level of public health protection is needed (DeWaal, 2009).

The creativity of those seeking to compromise food safety for profit, the evolution of bacteria to increased virulence, and the inevitability of human errors will continue to challenge regulators, producers, and consumers. As demonstrated by the recent incident in which several brands of pet food were contaminated with melamine, researchers struggle with the question of how to predict, mitigate, and prevent such relatively rare events. The predictability of such events must be taken into account when decisions are made about allocating resources to prevention versus rapid response.

OVERVIEW OF THE CURRENT FOOD SAFETY SYSTEM

Although the FDA's role in ensuring safe food needs to be reviewed in the context of the U.S. national food safety system, for brevity the discussion in this section is limited to information that pertains to the FDA and is needed as context for the reminder of this report. Previous reports have reviewed the food safety system in the United States (IOM/NRC, 1998; GAO, 2004a,b,c, 2008b; Becker and Porter, 2007), and the reader is referred to those reports for a more detailed description and historical context of the U.S. food safety system as a whole.

Organization

Table 2-1 lists the main federal agencies that have responsibility for food safety under at least 30 laws. Of these agencies, eight have primary responsibility for ensuring food safety: two under HHS—the FDA and the U.S. Centers for Disease Control and Prevention (CDC); four under USDA—the Food Safety and Inspection Service (FSIS), the Agricultural Marketing Service, the Agricultural Research Service, and the National Institute of Food and Agriculture; DHS; and EPA (GAO, 2004b,c, 2005, 2008a, 2009a).

State and local governments also have food and feed safety responsi-

TABLE 2-1 Food Safety Responsibilities by Federal Agency

Abbreviation	Name	Food Safety Responsibilities
CDC	U.S. Centers for Disease Control and Prevention	Prevents disease, disability, and death caused by a wide range of infectious diseases and does the following: • Investigates with local, state, and other federal officials sources of foodborne disease outbreaks. • Maintains a nationwide system of foodborne disease surveillance (designs and puts in place rapid electronic systems for reporting foodborne infections, works with other federal and state agencies to monitor rates of and trends in foodborne disease outbreaks, develops state-of-the-art techniques for rapid identification of foodborne pathogens at the state and local levels). • Develops and advocates for public health policies to prevent foodborne diseases. • Conducts research to help prevent foodborne disease. • Trains local and state food safety personnel.
DHS	U.S. Department of Homeland Security	Leverages resources within federal, state, and local governments, coordinating the transition of multiple agencies and programs into a single, integrated agency focused on protecting the American people and their homeland.
DHS/CBP	Customs and Border Protection	Works with federal regulatory agencies to ensure that all goods entering and exiting the United States do so according to U.S. laws and regulations.
DHS/OHA	Office of Health Affairs	• Serves as DHS's principal agent for all medical and health matters. • Leads veterinary and agro-defense activities, addressing animal and zoonotic diseases, as well as livestock, food, and water security issues.
DOJ	U.S. Department of Justice	• Prosecutes companies and individuals suspected of violating food safety laws. • Through the U.S. Marshals Service, seizes unsafe food products not yet in the marketplace, as ordered by courts.

TABLE 2-1 Continued

Abbreviation	Name	Food Safety Responsibilities
EPA	U.S. Environmental Protection Agency	Oversees drinking water and certain aspects of foods made from plants, seafood, meat, and poultry; establishes safe drinking water standards; regulates toxic substances and wastes to prevent their entry into the environment and food chain; assists states in monitoring the quality of drinking water and finding ways to prevent contamination of drinking water; and determines the safety of new pesticides, sets tolerance levels for pesticide residues in foods, and publishes directions on the safe use of pesticides.
EPA/OECA	Office of Enforcement and Compliance Assistance	Responsible for inspection/enforcement of pesticide regulations, including the misuse of pesticides.
EPA/OPPTS	Office of Prevention, Pesticides, and Toxic Substances	Responsible for risk assessment of pesticide residues in food, pesticide registration.
EPA/ORD	Office of Research and Development	Provides scientific support for pesticide-related public health issues.

continued

TABLE 2-1 Continued

Abbreviation	Name	Food Safety Responsibilities
FDA	U.S. Food and Drug Administration	Oversees all domestic and imported food sold in interstate commerce, including shell eggs, but not meat and poultry, bottled water, and wine beverages with less than 7 percent alcohol. Also enforces food safety laws governing domestic and imported food, except meat and poultry, by inspecting food production establishments and food warehouses and collecting and analyzing samples for physical, chemical, and microbial contamination; reviewing the safety of food and color additives before marketing; reviewing animal drugs for the safety of animals that receive them and humans who eat food produced from the animals; monitoring the safety of animal feed used for food-producing animals; developing model codes and ordinances, guidelines, and interpretations and working with states to implement them in regulating milk and shellfish and retail food establishments, such as restaurants and grocery stores (e.g., the model Food Code, a reference for retail outlets and nursing homes and other institutions on how to prepare food to prevent foodborne illness); establishing good food manufacturing practices and other production standards, such as plant sanitation and packaging requirements and Hazard Analysis and Critical Control Points (HACCP) programs; working with foreign governments to ensure the safety of certain imported food products; requesting manufacturers to recall unsafe food products and monitoring those recalls; taking appropriate enforcement actions; conducting research on food safety; and educating industry and consumers on safe food-handling practices. See Table 2-2 for detail on the responsibilities of the FDA centers and offices involved in food safety.
FTC/BCP	Federal Trade Commission/ Bureau of Consumer Protection	Protects consumers against unfair, deceptive, or fraudulent practices, including advertising claims for foods, drugs, dietary supplements, and other products promising health benefits.

TABLE 2-1 Continued

Abbreviation	Name	Food Safety Responsibilities
NOAA/NMFS	National Oceanic and Atmospheric Administration/ National Marine Fisheries Service (under the U.S. Department of Commerce [DoC])	Through its voluntary fee-for-service Seafood Inspection Program, inspects and certifies fishing vessels, seafood processing plants, and retail facilities for federal sanitation standards. Provides scientific oversight and system surveillance of the DoC inspection program and seafood HACCP training.
USDA	U.S. Department of Agriculture	Primarily responsible for meat, poultry, and egg products; see also below.
USDA/AMS	Agricultural Marketing Service	Provides standardization, grading, and market news services for five commodities: (1) dairy, (2) fruits and vegetables, (3) livestock and seed, (4) poultry, and (5) cotton and tobacco. Enforces such federal laws as the Perishable Agricultural Commodities Act and Country-of-Origin Labeling. AMS's National Organic Program develops, implements, and administers national production, handling, and labeling standards for organic agricultural products.
USDA/APHIS	Animal and Plant Health Inspection Service	Responsible for monitoring/surveillance of egg products, risk assessment and data collection for pesticides, and inspections, enforcement for the pesticide record-keeping program, including border quarantine activities to detect and eliminate animal health problems and exotic organisms that might harm U.S. agriculture, many of which also pose potential food safety threats.
USDA/ARS	Agricultural Research Service	Provides data for food products and contaminants (fruits and vegetables, dairy products, eggs/egg products, meat/poultry, seafood, grain/rice/related products, imported foods, animal drugs/feeds, and pesticide residues) to support risk assessment by the Food Safety and Inspection Service (FSIS), the Economic Research Service (ERS), the Office of Risk Assessment and Cost-Benefit Analysis (ORACBA), the FDA, and EPA; broad support of Land Grant Universities for research and education across all product areas; and education in the form of information to the National Agricultural Library (NAL) and educational workshops.

continued

TABLE 2-1 Continued

Abbreviation	Name	Food Safety Responsibilities
USDA/ERS	Economic Research Service	Provides risk assessment for meat and poultry and data collection to support the pesticide risk assessment process as well as technical assistance to identify education needs and to analyze the effectiveness of food safety education programs.
USDA/FSIS	Food Safety and Inspection Service	Oversees domestic and imported meat and poultry and related products, such as meat- or poultry-containing stews, pizzas, and frozen foods, as well as processed egg products (generally liquid, frozen, and dried pasteurized egg products). Also enforces food safety laws governing domestic and imported meat and poultry products by • inspecting food animals for diseases before and after slaughter; • inspecting meat and poultry slaughter and processing plants; • with USDA's Agricultural Marketing Service, monitoring and inspecting processed egg products; • collecting and analyzing samples of food products for microbial and chemical contaminants and infectious and toxic agents; • establishing production standards for the use of food additives and other ingredients in preparing and packaging meat and poultry products, plant sanitation, thermal processing, and other processes; • making sure all foreign meat and poultry processing plants exporting to the United States meet U.S. standards; • seeking voluntary recalls of unsafe products by meat and poultry processors; • sponsoring research on meat and poultry safety; and • educating industry and consumers on safe food-handling practices. As of April 2010, FSIS is responsible for mandatory inspection of catfish and catfish products.[a]

TABLE 2-1 Continued

Abbreviation	Name	Food Safety Responsibilities
USDA/GIPSA	Grain Inspection, Packers, and Stockyards Administration	Through its oversight activities, including monitoring programs, reviews, and investigations, fosters fair competition, provides payment protection, and guards against deceptive and fraudulent trade practices that affect the movement and price of meat animals and their products. Protects consumers and members of the livestock, meat, and poultry industries. Its Federal Grain Inspection Service facilitates the marketing of U.S. grain and related agricultural products by establishing standards for quality assessments, regulating handling practices, and managing a network of federal, state, and private laboratories that provide impartial, user fee–funded official inspection and weighing services.
USDA/NAL	National Agricultural Library/USDA/ FDA Foodborne Illness Education Information Center	Collects information on human nutrition and food to support USDA programs. These programs encompass areas as diverse as human nutritional needs, food production, safety and inspection, distribution, economics, and consumer education. Because of USDA's responsibility for food safety and inspection, NAL comprehensively collects works addressing foodborne illness, food toxicology, and food inspection. In addition, in support of USDA's close relationship and regulatory role with the food industry, NAL collects information on the food industry and technology, including food irradiation and biotechnology.
USDA/NASS	National Agricultural Statistics Service	Performs data collection for risk assessment of pesticides.
USDA/NIFA[b]	National Institute of Food and Agriculture	Advances knowledge for agriculture, the environment, human health and well-being, and communities by supporting research, education, and extension programs in the Land Grant University System and other partner organizations. Does not perform actual research, education, and extension but helps fund them at the state and local levels and provides program leadership in these areas.
USDA/ ORACBA	Office of Risk Assessment and Cost-Benefit Analysis	Provides technical assistance to identify education needs and to analyze the effectiveness of food safety education programs.

continued

TABLE 2-1 Continued

Abbreviation	Name	Food Safety Responsibilities
US DOT/BATF	U.S. Department of the Treasury/ Bureau of Alcohol, Tobacco, and Firearms	Oversees alcoholic beverages except wine containing less than 7 percent alcohol, enforces food safety laws governing the production and distribution of alcoholic beverages, and investigates cases of adulterated alcoholic products, sometimes with help from the FDA.

[a] *The Food, Conservation, and Energy Act of 2008*, 21 U.S.C. §§ 601 et seq., 2008 (also known as the 2008 Farm Bill).

[b] The Cooperative State Research, Education, and Extension Service became the National Institute of Food and Agriculture on October 1, 2009.

SOURCE: IOM/NRC, 1998; DHS, 2004; GAO, 2005; Becker and Porter, 2007; AMS/USDA, 2009; FDA, 2009a; APHIS/USDA, 2010; FoodSafety.gov, 2010; USDA, 2010b.

bilities (see also Chapter 7). Forty-four states conduct inspections of food-manufacturing firms under contract to the FDA, and all 50 states have food safety and labeling programs. Additional responsibilities of state and local governments include the following:

- implementing food safety standards, such as Good Manufacturing Practices and Hazard Analysis and Critical Control Points (HACCP), for fish, seafood, milk, and other foods manufactured within state borders with the assistance of the FDA and other federal agencies;
- inspecting restaurants, grocery stores, and other retail food establishments, as well as dairy farms, milk-processing plants, grain mills, and food-manufacturing plants, within the state (the states collect and analyze many food product samples);
- using advisory and enforcement actions to protect the health of their citizens, including placing embargoes on (i.e., stopping the sale of) unsafe food products manufactured, transported, or distributed within state borders;
- providing safety training and education to food establishment personnel and industry as requested;
- preparing for and participating in food recall events and foodborne outbreak investigations independently or with the FDA and other federal agencies (this may include ordering recalls of contaminated foods within state borders and taking enforcement actions against firms within state borders);
- collecting representative samples according to established procedures and with a documented chain of custody (These samples are

then tested at state regulatory laboratories so they can be evaluated for compliance with food regulatory laws.);
- receiving, evaluating, and responding to consumer complaints relating to products manufactured, purchased, or consumed in their state;
- conducting epidemiological investigations of people who have become ill or injured (State, county, and local health officials serve the primary on-site epidemiological role in the United States and coordinate among one another and with CDC in situations of multistate outbreaks.);
- responding to natural disasters—earthquakes, floods, hurricanes—to assess the impact on food safety and take immediate action to prevent problems in affected areas; and
- issuing consumer health advisories or warnings through typical media and outreach channels.

The FDA's Responsibilities for Food Safety

The FDA's responsibilities for food safety are only part of its wide range of responsibilities. The agency has regulatory authority over more than $1 trillion in products sold annually—about 25 cents of every dollar spent by consumers (Fraser, 2009). The FDA is required to oversee the safety of all food products with the exception of meat, poultry, and some egg products. Additionally, the agency's food safety charge includes the safety of animal feed for both pets and food-producing animals (e.g., swine, dairy cattle). In addition to food, moreover, the FDA's jurisdiction extends to drugs, biologics, medical devices, and tobacco.[2] According to the agency's mission statement,

> 1) FDA is responsible for protecting public health by ensuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supplies, cosmetics and products that produce radiation. 2) The FDA is also responsible for advancing the public health by helping to speed innovations that make medicine and foods more effective, safer, and more affordable; and helping the public get the accurate science-based information they need to use medicines and foods to improve their health. (FDA, 2009a)

The FDA has six program centers: (1) the Center for Biologics Evaluation and Research, (2) the Center for Drug Evaluation and Research, (3) the Center for Devices and Radiological Health, (4) the Center for Food Safety

[2] The FDA acquired jurisdiction over tobacco products in 2009.

and Applied Nutrition (CFSAN), (5) the Center for Tobacco Products, and (6) the Center for Veterinary Medicine (CVM). The FDA also has a number of cross-cutting offices that report directly to the FDA Commissioner, including the Office of Operations, the Office of Scientific and Medical Programs, the Office of Regulatory Affairs (ORA), the Office of International Programs, and the Office of Planning, Policy, and Preparedness. A recent addition has been the Office of Foods, which reports directly to the Commissioner (see Figure 2-1) (FDA, 2010b).

In response to the increasing volume of imported products, including foods, the agency recently embarked on the Beyond Our Borders initiative, establishing offices in foreign countries under the Office of International Programs. As of 2009, countries with one or more U.S. offices included Belgium, China, Costa Rica, India, and Mexico. Although the long-term roles of these offices are still in the planning stages, the Beyond Our Borders initiative is designed to build or further strengthen relationships, help in learning more about the industries in these countries, facilitate and leverage inspection resources, increase interactions with foreign manufacturers, and verify that products meet U.S. standards (FDA, 2009b).

The main FDA offices with responsibility for food safety are the Office of the Commissioner, the Office of Foods, CFSAN, CVM, ORA, and the National Center for Toxicological Research (NCTR) (see Table 2-2) (FDA, 2010c).

The regulatory authority for foods is derived primarily from the Federal Food, Drug, and Cosmetic Act (FDCA)[3] and its amendments. Recent amendments include the Infant Formula Act of 1980, the Nutrition Labeling and Education Act of 1990, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and, more recently, the Food and Drug Administration Amendments Act of 2007 (Fraser, 2009). In some fundamental respects, the law under which the FDA must ensure the safety of 80 percent of the nation's food supply[4] remains unchanged since 1938, despite the dramatic changes in food production, processing, and distribution that have taken place since (as discussed earlier in this chapter). Bills currently under consideration in Congress would give the FDA new authorities and, if enacted, would result in significant changes in the way food safety is managed.[5]

[3] *Federal Food, Drug, and Cosmetic Act (FDCA)*, 21 U.S.C. §§ 301 et seq., 1938.

[4] The term "food," as defined in the FDCA, includes "all articles used for food or drink for man or other animals," and thus encompasses what is commonly known as animal feed. Throughout this chapter, therefore, as throughout the report generally (see Chapter 1), the word "food" includes animal feed unless otherwise noted.

[5] HR 2749, *Food Safety Enhancement Act of 2009*; S510 IS § 206: *FDA Food Safety Modernization Act 2009*.

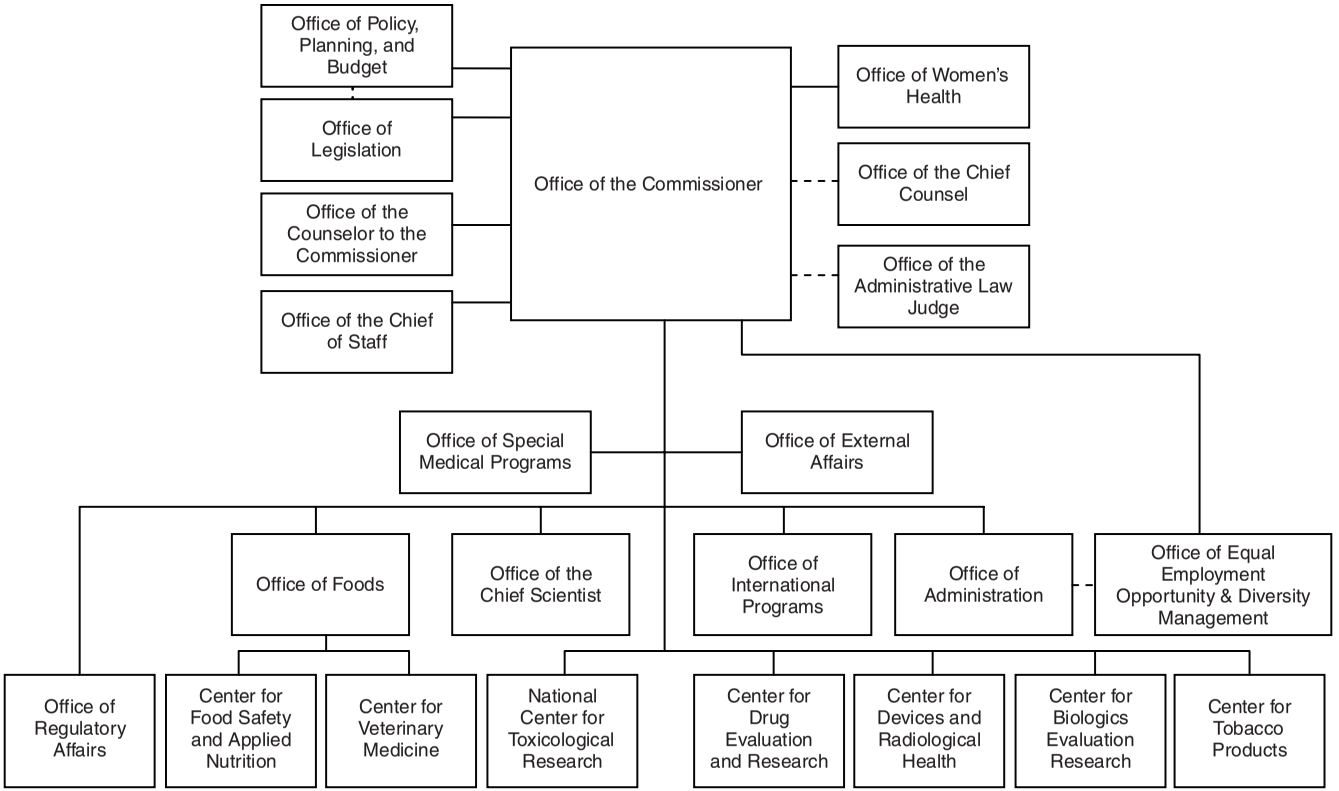

FIGURE 2-1 Organization of the U.S. Food and Drug Administration.
SOURCE: FDA, 2010b.

TABLE 2-2 U.S. Food and Drug Administration (FDA) Offices and Centers with Responsibility for Food Safety

Office	Responsibilities
Office of Foods	• Devises strategic and substantive agencywide domestic and imported food-related policies. • Develops and implements an agencywide visionary strategy for food protection and an approach to promoting and protecting public health with respect to foods (FDA, 2009c; Fraser, 2009).
Center for Food Safety and Applied Nutrition (CFSAN)	Focuses on foods and applied nutrition, but also has responsibility for regulating the safety of cosmetic products. Except for food and color additives, generally it does not have premarket approval authority (in contrast with the centers that deal with drugs and devices, which generally must preapprove products before they can be put on the market). The prevailing regulatory philosophy is that the manufacturer has the primary responsibility for putting a safe product on the market. According to CFSAN's mission statement, "CFSAN, in conjunction with the agency's field staff is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, honestly labeled, and cosmetic products are safe and properly labeled." Specific responsibilities include • safeguarding the nation's food supply by making sure products are safe, • conducting activities in conjunction with ORA and other groups within the agency, and • ensuring that food is free of contaminants (FDA, 2009c; Fraser, 2009).
Center for Veterinary Medicine (CVM)	Regulates foods used to feed animals, including pet food, as well as devices and drugs for animals, which must gain FDA premarket approval (except animal devices). According to CVM's mission statement, "It's a consumer-protection organization that fosters public and animal health by approving safe and effective products for animals and by enforcing other applicable provisions of the FDCA [Federal Food, Drug, and Cosmetic Act] and other authorities" (FDA, 2009c; Fraser, 2009).
Office of Regulatory Affairs (ORA)	With a headquarters location and field offices across the country, serves as the FDA's broad compliance and enforcement arm. ORA has responsibility to "protect consumers and enhance public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products." In a presentation to the committee, the FDA clarified that within ORA, work to foster compliance is often done in partnership not only with the FDA centers but also with industry. During an outbreak, ORA field investigators work closely with the center that is impacted, conduct investigations, and decide on courses of action (FDA, 2009c; Fraser, 2009).
National Center for Toxicological Research (NCTR)	• Focuses on peer-reviewed research and provides expert advice and training to enable the FDA to make science-based decisions. • Focuses on critical biological events and toxicity (Fraser, 2009; NCTR, 2009).

Budget, Strategic Planning, and Performance Measures

Budget

Annual funding for the FDA is provided in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill and is handled by the corresponding appropriations subcommittees in the House and Senate. The total amount the agency can spend is composed of direct appropriations (budget authority) and other funds, mainly user fees. Occasionally, funds are earmarked for various activities or offices by Congress. Implementation of the budget for food programs involves a great deal of collaboration among the centers, ORA, and leadership of the FDA food programs.

Table 2-3 shows the FDA budgets for fiscal years (FYs) 2008, 2009, and 2010 and the President's FY 2011 budget as presented in February 2010. After many years of declining funds and personnel, resources for the agency's food programs have recently increased from 2007 levels (note that the food programs include food safety and nutrition funding).

Appropriations for the FDA's food safety program increased in FY 2009 by $141.5 million to a total of about $644 million, or a little less than 25 percent of the agency's overall budget. The distribution of FY 2009 $141.5M food safety budget increase was as follows: CFSAN received $32 million, ORA $90 million, and CVM $6.4 million.

The FDA's budget for food safety comes not only from its budget for food programs, but also from the budgets for the animal drug and feeds program and NCTR, as well as other budgets. In 2009, the FDA proposed an initiative called Protecting America's Food Supply[6] for which a budget increase of $259.3 million was requested for FY 2010, bringing the total budget for food safety to more than $1 billion (HHS, 2009). This increase was the highest among FDA programs for that year. The administration justified the budget request with reference to investments that would strengthen the safety and security of the food supply chain, including enhancements to the system needed as a result of recent food safety events, the dramatic growth in food imports, and changes in food processing and distribution practices. Among the priorities mentioned in the budget justification were the creation of a food safety system that would integrate federal and state programs, the development of preventive controls, increased frequency of domestic and foreign inspections, improved laboratory capacity and food surveillance, and enhanced information technology (IT) to support all food safety programs. The proposed 2011 budget increases the agency's

[6] See http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm152276.htm (accessed October 8, 2010).

TABLE 2-3 U.S. Food and Drug Administration (FDA) Budgets for Fiscal Years (FYs) 2008, 2009, 2010, and 2011 (in millions)

	FY 2008 (Enacted)	FY 2009 (Enacted)	FY 2010 (Appropriation)	2011 President's Budget
Total FDA	2,420	2,691	3,284	4,023
$	1,870	2,055	2,362	2,508
User fees	549	636	922	1,233
FTEs[a]	NA	11,413	12,335	13,677
Total Food Programs	577	644	784	1,042
Center	NA	210	237	337
Field	NA	434	547	705
User fees[b]	0.00	0.00	0.00	194
FTEs (center)	NA	854	981	1,186
FTEs (field)	NA	2,165	2,505	2,902
Total Animal Drugs and Feeds	115	133	156	175
Center	NA	90	102	113
Field	NA	43	53	62
User fees	14	20	23	24
FTEs (center)	NA	424	447	472
FTEs (field)	NA	238	278	319

NOTE: FTE = full-time equivalent; NA = not available.

[a] In general, the numbers of FTEs decreased from 1992 to 2007 and increased thereafter, in parallel with increases in the FDA's budget for food programs. (The FDA could not provide the number of food-dedicated FTEs at the Center for Veterinary Medicine because its staff is also responsible for products other than foods [e.g., approval of animal drugs]).

[b] Current law includes user fees for animal drug approval and export color certification (certification ensures that products meet regulatory requirements for exportation). Incorporated in the FY 2011 budget for the FDA's food programs is approximately $194 million in user fees, which has been proposed by Congress for registration of food facilities, reinspection, and food and feed export certification.

SOURCES: HHS, 2008, 2009, 2010.

funding for food safety by $318 million. Major activities mentioned to justify this increase include setting standards to integrate state and federal programs and enhancing analytical tools and laboratory capacity. Increased inspection is also proposed.

Strategic Planning and Performance Measures

Strategic planning involves fundamental decisions about the nature, mission, and goals of an organization. When a strategic plan is linked to performance measures, an approach that has been adopted by the federal government, it is also a tool to enhance accountability, which is especially

important as the FDA uses public money to implement its plan. The Government Performance and Results Act of 1993 requires that all cabinet-level departments and independent agencies develop a strategic plan covering 6 years, with updates every 3 years.[7] Under this act, HHS is required to have a strategic plan, but not the FDA, which is a sub-cabinet-level department within HHS; however, all the operating divisions of HHS do in fact develop such a plan. As discussed further below, the FDA last developed a strategic plan in 2007.

An additional requirement of the 1993 act is an annual performance plan and a report on how well that plan was implemented during the previous year. During the Bush Administration, the performance plan and report for HHS were integrated with the annual budget submission to Congress. This year, the integrated FY 2010 performance plan and report for HHS were provided as an appendix to the budget request to Congress in compliance with HHS performance planning and reporting requirements (HHS, 2009). The Program Assessment Rating Tool was also introduced during the Bush Administration as a governmentwide evaluation tool, with strategic planning being one of the areas assessed (OMB, 2008). Chapter 3 of this report includes a list of performance measures that have been used by the FDA and are linked to long- and short-term objectives. The President's FY 2011 budget as presented in February 2010 introduces a significant number of new performance measures in the area of food. For example, a reduction in the number of days spent on subtyping priority pathogens in food is linked to the strategic objective of detecting safety problems earlier (HHS, 2010).

Reorganization at the FDA

CFSAN has undergone various reorganizations in an attempt to become more efficient and to adopt new ways of accomplishing its mission under new circumstances. For example, in 1992, as a result of concern expressed by FDA leadership about the ability of the agency's food programs to address emerging food safety issues, the FDA (1) conducted a management study of CFSAN'S programs and activities, (2) reorganized CFSAN and created organizational units to respond directly to certain new food technologies, and (3) established an advisory committee on issues related to food safety. The intent was to make the center more efficient in performing its scientific and regulatory activities and to enhance its ability to meet new challenges. The reorganization was aimed at integrating policy, regulatory, and scientific specialists into offices according to their areas of expertise.

[7] *Government Performance and Results Act of 1993 (GPRA)*, Public Law 103-62, 107 Stat. 285.

The FDA believed this new structure would increase managers' accountability for program results and streamline approvals (Suydam, 1996; Johnson et al., 2008). This reorganization was a major change for a center that had been organized by scientific discipline (i.e., toxicology, physical sciences, and nutrition) for the previous 20 years. According to the U.S. Government Accountability Office (GAO, 1992), concern arose at the time that the reorganization's dispersion of scientists could threaten the agency's science base and impede consistency.

Since 1992, other reorganizations have occurred at the FDA. Most notably, the agency was reorganized in 2007 in an effort to consolidate its structure, realign programs with similar or overlapping functions and operational activities, and improve communication and coordination.[8] To reduce the number of management layers, most research activities were merged into two primary offices and the compliance and enforcement functions into one office. The ultimate goal was to maintain a strong and flexible food safety system as new public health challenges continued to emerge. In 2007, the Office of Food Protection was established under the commissioner's oversight to develop an agencywide, visionary strategy for food protection and serve as a liaison to HHS on food protection issues. This office has now merged into the new Office of Foods, headed by a new deputy commissioner of foods and having responsibility and authority for all aspects of food policy under agency jurisdiction (see Box 2-1). Figure 2-1 (presented earlier) reflects these latest changes, plus the addition of the Office of Foods, in 2009 (FDA, 2009d).

Since the Obama Administration took office, the FDA has undergone further changes, which continue even as this report is being written. With a greater emphasis on food safety and public health and an increase in resources for 2010 (see above) (Hamburg and Sharfstein, 2009), the new administration is making substantive attempts to effect strategic changes, for example, through the creation of the White House Food Safety Working Group (FSWG).

RECENT ANALYSES OF FOOD SAFETY MANAGEMENT AT THE FDA[9]

Over the years, the U.S. government has changed its food safety management approach to meet new challenges and adapt to changes in cir-

[8] Personal communication, Robert Brackett, Director and Vice President, National Center for Food Safety and Technology, Illinois Institute of Technology, Chicago, July 14, 2009.

[9] This section does not reflect the conclusions of the committee but instead summarizes the findings of various other reviews of the U.S. food safety system focusing on the FDA. (To complement this section, Appendix B contains numerous recommendations made over the last two decades for enhancing the FDA's management of food safety.)

BOX 2-1
Responsibilities of the Office of Foods

- Provides executive leadership and management to all U.S. Food and Drug Administration (FDA) food-related programs.
- Exercises, on behalf of the Commissioner, direct line authority over the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM).
- Exercises, on behalf of the commissioner, all food-related legal authorities that the Commissioner is empowered to exercise under the Federal Food, Drug, and Cosmetic Act, as amended; the Public Health Service Act; and other applicable laws.
- Directs efforts to integrate the programs of CFSAN, CVM, and the Office of Regulatory Affairs and thereby ensure the optimal use of all available FDA resources and tools to improve the safety, nutritional quality, and proper labeling of the food supply.
- Directs the development of integrated strategies, plans, policies, and budgets to build the FDA's food-related scientific and regulatory capacities and programs, including recruitment and training of key personnel and development of information systems.
- Represents the FDA on food-related matters in dealings with the Office of the Secretary of the U.S. Department of Health and Human Services, the Centers for Disease Control and Prevention, the U.S. Department of Agriculture, the White House, and other elements of the executive branch.
- Represents the FDA on food-related matters in dealings with Congress.
- Represents the FDA on food-related matters in dealings with foreign governments and international organizations.
- Directs FDA efforts to build an integrated national food safety system in collaboration with other federal agencies and state and local governments.
- Directs a program of public outreach and communication on food safety, nutrition, and other food-related issues to advance the FDA's public health and consumer protection goals.

SOURCE: FDA, 2009d.

cumstances and expectations, scientific advances, and new evidence-based understanding of effective management practices. For example, since the mid-1990s, greater emphasis has been placed on preventive programs, such as HACCP, and on industry responsibility. In 1997, after a series of serious foodborne outbreaks, President Clinton announced a request for $43.2 million to fund a nationwide early-warning system for foodborne illness, increase seafood safety inspections, and to expand food safety research, training, and education. In addition, the Secretary of Agriculture, the Secretary of HHS, and the Administrator of the EPA were directed to identify specific steps to improve the safety of the nation's food supply (FDA/USDA/EPA/CDC, 1997).

Several initiatives, including science-based HACCP regulatory programs for seafood (FDA/HHS, 1995), meat and poultry (FSIS, 1996), and juice (FDA/HHS, 2001), reflected an effort not only to place greater emphasis on prevention, but also to be more flexible in the governance of food safety by allowing manufacturers to identify their own preventive controls. (For a more detailed description of the progression of food safety philosophies over the years, see Chapter 1 of the IOM/NRC report *Scientific Criteria to Ensure Safe Food* [IOM/NRC, 2003]).

Reported Funding Discrepancies Based on Volume of Foods

According to GAO, the FDA is responsible for approximately 80 percent of the nation's food supply, yet the federal funds the agency receives do not reflect this level of responsibility (GAO, 2004c).[10] Whereas more than 75 percent of consumer expenditures on food are for FDA-regulated products, roughly 60 percent of food safety funding is allocated to USDA (GAO, 2004c). The reason for this disparity lies partly in the federal laws governing food safety, which require USDA/FSIS (the agency with responsibility for meat, poultry, and egg products) to conduct daily inspections of meat and poultry processing plants and carcass-by-carcass inspections of slaughtered animals (GAO, 2004c).

Fragmented Nature of the Food Safety System

The 30 laws that govern food safety activities were enacted over time between 1906 (the 1906 Pure Food and Drugs Act) and today (e.g., HR3580, the Food and Drug Administration Amendments Act of 2007), and they are based on the issues that were faced in each time period—there has been no overall strategic design to the food safety system. For example,

[10] In 2009, the budgets for food safety were $649 million for the FDA and $1,092 million for USDA's Food Safety and Inspection Service (www.fda.gov; www.usda.gov).

the FDA was created (in its first incarnation as the Bureau of Chemistry under USDA) to prohibit adulterated and misbranded food and drugs in interstate commerce. The FDCA of 1938, which established the current FDA, was passed in response to the 1937 Elixir Sulfanilamide disaster.[11]

According to a recent GAO report, this situation results in "fragmentation and overlap," as well as the lack of a strategic design to protect the public health. According to GAO, "What authorities agencies have to enforce food safety regulations, which agency has jurisdiction to regulate what food products, and how frequently they inspect food facilities is determined by the legislation that governs each agency, or by administrative agreement between the two agencies, without strategic design as to how to best protect public health" (GAO, 2004c, p. 4).

Gaps in the System

Although there is overlap in the U.S. food safety system in some areas (e.g., inspection of certain establishments), past reviews have identified some gaps that could result in threats to food safety. These gaps are most obvious in two areas—imported foods and on-farm food safety—and relate to both intentional and unintentional threats. For example, GAO has expressed concern about the food safety system because both the FDA and USDA lack statutory authority to "regulate all aspects of security at food-processing facilities" (GAO, 2004c, p. 16).

Imported Foods

As discussed earlier, a significant portion of the nation's food supply—and more than 75 percent of its seafood—comes from abroad; however, the FDA inspects less than 2 percent of imported foods (GAO, 2004c; FDA Science Board, 2007). GAO also found that while USDA saves money and time by mandating U.S.-equivalent food safety standards for countries supplying imports, the ability of the FDA to do the same needs strengthening (GAO, 2004c). The Interagency Working Group on Import Safety's 2007 *Action Plan for Import Safety* requests additional, expanded, or strengthened authorities for the FDA to require preventive controls for certain foods, measures to prevent the intentional contamination of foods, and certification or other assurance that a product under its jurisdiction complies with agency requirements (Interagency Working Group on Import Safety, 2007). The report specifically cites the FDA as the lead for its recommendations or requests for new authorities more frequently—28 times—than is the case

[11] See http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SulfanilamideDisaster/default.htm (accessed October 8, 2010).

for any other agency (Interagency Working Group on Import Safety, 2007). A 2009 GAO report recognizes that some steps have been taken to ensure the safety of imported foods but also highlights gaps in enforcement and collaboration among U.S. Customs and Border Protection, the FDA, and FSIS (GAO, 2009b). Appendix E contains a detailed discussion of the FDA's imported food program.

On-Farm Food Safety Policies

On-farm regulation has received increased attention recently as a result of outbreaks involving pathogen-contaminated fresh produce. The FDA relies almost completely on voluntary guidance documents and initiatives (for example, the Produce Safety Initiative) for on-farm regulation (Becker, 2009). Occasionally it will inspect farms, but almost exclusively during periods of crisis (FDA Science Board, 2007). Although the FDA had requested authority to regulate shell eggs, such measures were postponed because of industry concerns (Becker, 2009); the Egg Safety Rule, which regulates the production of shell eggs on the farm, was published only recently (FDA/HHS, 2009). A further barrier to the FDA's on-farm efforts lies in the FDCA, in which farms are specifically exempted from requirements for record keeping (Consumers Union, 2008) and registration. Both exemptions hinder traceability, and ending these exemptions is a recurrent recommendation of GAO and other groups to help protect the public health (DeWaal, 2003; Consumers Union, 2008).

Lack of Mandatory Recall Authority

Also lacking is authority for the FDA to order mandatory food recalls—aside from infant formulas (USDA also lacks this authority [Brougher and Becker, 2008; GAO, 2008b]). The need for this authority is controversial because some argue that in the majority of cases, food companies voluntarily recall products suspected of being contaminated (Degnan, 2006), and that the FDA already has legal authority to seize adulterated and misbranded products and to administratively detain articles of food for which it "has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death."[12] In addition, the FDA routinely uses the embargo authority of the states to remove and hold products off market until federal seizure actions can be implemented. In support of mandatory authority, however, others observe that detention procedures must be carried out through the courts and therefore are not expeditious; meanwhile, the food supply and public health are endangered

[12] FDCA 304(h)(1).

(GAO, 2004b, 2008b). Moreover, when manufacturers or producers issue a recall, neither the FDA nor USDA has mechanisms for tracking the recall's effectiveness or accounting for the recalled products. Nor does either agency mandate timelines for recalls (GAO, 2004b). A 2004 GAO report found that, in some cases, the time it took for the agency to verify a recall was longer than the shelf life of the recalled products (GAO, 2004b). Accordingly, both consumer groups and GAO have recommended that the FDA and USDA be given mandatory recall authority (GAO, 2004b, 2008b; Consumers Union, 2008), and in the FDA's Food Protection Plan (FPP), the agency itself requests this authority (FDA, 2007; GAO, 2008b).

The FDA's Use of Resources

Groups such as the Alliance for a Stronger FDA,[13] Consumers Union, and the IOM have for years called for increased funding for the FDA (IOM/NRC, 1998; Consumers Union, 2008). Yet while the FDA's funding and staffing levels have not kept pace with its increased workload, the agency has opportunities to improve the management of its resources (GAO, 2008a). For example, GAO has identified some overlap in the activities of USDA and the FDA, including inspection and enforcement, training, research, and rulemaking. By simply enforcing interagency agreements, the FDA could "leverage inspection resources and possibly avoid duplication of effort" (GAO, 2005, p. 33). The same report suggests that the FDA and USDA consider a joint inspection training program. These examples illustrate the potential for savings and better use of limited resources (GAO, 2005, 2008a).

Inspection

In 2004 and 2005, GAO identified the three main deficiencies in the FDA's inspection program as (1) duplication of effort, (2) insufficient inspection, and (3) a poor basis for determining which facilities to inspect (GAO, 2004c, 2005). According to GAO, in 2003 USDA and FDA inspection and enforcement activities included overlapping inspections of 1,451 domestic food-processing facilities that produce multi-ingredient foods. This overlap occurs because of the differences in the statutory responsibilities of the two agencies.

Insufficient inspection takes many forms. Facilities can go as long as 10 years without an inspection, and the rate of inspection has declined by 78 percent in the past 35 years (FDA Science Board, 2007). GAO reported in 2004 that the FDA had roughly 1,900 full-time equivalents (FTEs) who

[13] See http://www.strengthenfda.org/members.htm (accessed October 8, 2010).

inspected an estimated 57,000 facilities. In comparison, USDA had 9,170 inspectors for "daily oversight of approximately 6,464 meat, poultry, and egg product plants" (GAO, 2004c, p. 10). Further, these 1,900 FTEs were also responsible for inspecting other FDA-regulated products. In fact, the FDA was unable to tell the committee specifically how many FTEs were dedicated to food inspections (Givens, 2009). Without a sufficient number of inspectors and inspections, the agency cannot ensure the safety of the food supply (FDA Science Board, 2007). To illustrate the problem, the Peanut Corporation of America facility, at the root of a 2009 salmonella outbreak that sickened 700 people and contributed to 9 deaths, had last been inspected by the FDA in 2001, 8 years before the outbreak. Intermittent inspections had been conducted by the state of Georgia, but significant problems had not been detected, leading the recently appointed Advisor to the FDA Commissioner on Food to say during the outbreak that it was an example of "a basic breakdown" and to call for the agency to raise its standards (Schmidt, 2009).

Prior reports have expressed concern about insufficient inspection with respect to certain kinds of commodities—fresh produce and imported products—and certain kinds of facilities, such as farms (see On-Farm Food Safety Policies). When the FDA conducts fresh produce inspections—which declined in number to just 478 in FY 2007—it tests primarily for pesticide rather than microbial contamination (GAO, 2008c).

The 1998 IOM/NRC report *Ensuring Safe Food* notes that, although there is a computer system to track FDA- and USDA-regulated imported products and their inspection, "there is no way to determine whether the agencies are focusing their attention on the most important health risks" (IOM/NRC, 1998, p. 89). The FDA lacks control over detained imported shipments and does not punish those who violate the rules. Seafood is inspected minimally, although, as noted earlier, 75 percent of seafood consumed in the United States is imported, and shellfish alone is reported to have caused 21 percent of all foodborne illness from 1978 to 1992 (IOM/NRC, 1998; GAO, 2004c). This situation reflects an inherent flaw in FDA inspections: they are not risk-based in frequency or in facilities targeted (GAO, 2004c). Federal regulation, not risk, determines which facilities are inspected by which agency. For example, according to GAO, the frequency of inspection of a facility that produces ham and cheese sandwiches depends on the percentage of meat used rather than on risk (GAO, 2004c). The law, in this case, inhibits science-based decisions in food safety programs (IOM/NRC, 1998).

Research

Without an adequate research program, there is insufficient information with which to make science-based decisions (IOM/NRC, 1998). Indeed, a thorough scientific understanding of threats to the food supply would likely be more cost-effective for the FDA in the long term than simply adding more inspectors.

In 2007, the FDA Science Board completed a general review of the agency's research programs. The review concluded that these programs were in urgent need of enhancement. The Science Board's report stated that basic research programs and risk assessments would determine pressing risks to the food supply so that the agency's limited funds could be used for targeted research to address those risks (FDA Science Board, 2007). The agency maintains several research centers at academic institutions, but these, too, are poorly funded. When the Science Board examined CFSAN's critical research priorities, such as detection of foodborne viruses, many were found to be on target, but the agency does not always maintain staff with scientific expertise in those areas. It was suggested that some of these priorities could be shared with USDA (FDA Science Board, 2007). The FDA also lacks plans for critical research in other areas, such as produce safety (GAO, 2008c).

In 2007, a new center was formed to conduct research and serve as a source of scientific information to enhance food safety and defense. The Western Institute for Food Safety and Security is a program at the University of California, Davis, partnering with the California Department of Food and Agriculture, the California Department of Public Health, the FDA, and USDA. See Chapter 6 for further discussion of the FDA's research centers and their funding.

With limited funds and inadequate staff, the FDA relies on USDA to meet some of its research needs (FDA Science Board, 2007). Much of the data the FDA needs is expensive to acquire, however, and other agencies are not willing to make the investment (FDA Science Board, 2007). Data the FDA itself collects are not available to every researcher within the agency, and data obtained by other agencies often are not made available to the FDA (FDA Science Board, 2007; GAO, 2009a).

A review of CFSAN and CVM research programs was recently initiated by subcommittees of the FDA Science Board. As of this writing, only the CVM review had been completed. The report from that review highlights that since the 2007 review (FDA Science Board, 2009), CVM has made much progress in the research function, but the report also points to areas of weakness, such as regulatory science and the external consultative process for research planning.

Information Technology Infrastructure

Related to the above problems is the lack of an adequate IT infrastructure both within the FDA and between the FDA and related agencies responsible for food safety (see Chapter 5) (FDA Science Board, 2007). Although the FDA has made progress in addressing this deficiency by hiring new staff, forming internal IT governance boards, developing strong partnerships with other agencies, and updating management systems, in 2007 the Science Board found that the FDA's IT infrastructure could not support the agency's public health mission (FDA Science Board, 2007). Specific problems mentioned include (1) the quality of data, which are not standardized; (2) the integration of IT systems within centers; (3) inconsistent data collection across different centers and even within discrete agency program areas (GAO, 2009a); (4) antiquated hardware lacking security measures (FDA Science Board, 2007; GAO, 2009a); and (5) delays in sharing data (FDA Science Board, 2007). A 2008 report describing the FDA's plan to revitalize ORA proposes ways to deal with many of these IT issues. GAO supports such efforts but concludes that without initiating a strategic plan as is required by federal law, the agency may not be effective in carrying them out (Glavin, 2008; GAO, 2009a).

An example of how IT problems contribute to inefficiency is the significant duplication of effort among the agencies responsible for ensuring safe food discussed above. GAO has found that one reason this duplication occurs is that the agencies "do not have adequate mechanisms to track interagency food safety agreements" (GAO, 2005). An IT system should facilitate the FDA's public health mission by allowing data flow and being responsive to scientific innovation, but the agency's system does not meet these requirements (GAO, 2009a).

Lack of a Research and IT Strategic Plan

One key problem at the FDA has been the lack of an overarching strategic plan for research addressing the agency's food safety mission. Development of a new strategic plan is said to be under way (Musser, 2009). The FDA's efforts to enhance and modernize its programs are uncoordinated and inefficient and may lead to little or ineffectual improvement (GAO, 2009a). Without a clearly delineated mission statement, goals, and performance metrics, the agency cannot align itself with a direction, measure how well it fulfills its responsibilities, or determine the effectiveness of its programs (FDA Science Board, 2007; GAO, 2009a). The FDA needs to define its mission to meet its regulatory obligations and build its research, inspection, IT, and other programs to fulfill that mission. The Science Board report acknowledges both the lack of resources available to the FDA and the current initiatives to improve its programs, but it finds that without

clear goals, the agency cannot know, for example, what expertise is needed as it recruits new staff, what laboratory capabilities are needed, or how to organize data in an efficient and productive way (FDA Science Board, 2007).

LOOKING FORWARD

The nation is undergoing many changes related not only to technology advances, but also to changes in the way business is conducted and the way its citizens interact with the rest of the world. Although ensuring food safety is the responsibility of everyone, the public will continue to view regulatory agencies as the ultimate repository of salient scientific knowledge, reliable advisors, and overseers of food safety activities in the private sector. The flaws in the existing food safety system have been well investigated, and recent changes in the approach to food safety offer cause for hope that the nation is ready to take the steps necessary to create an efficient and effective food safety system. The first signs of progress at the FDA were seen in the development and early stages of implementation of the FPP, a document that outlines basic principles of prevention, intervention, and response for food safety and defense of domestic and imported products (FDA, 2007). However, a 2008 GAO report states that, while the FPP proposes some positive first steps to enhance oversight of food safety, the plan lacks specific information about strategies and resources needed for its implementation (GAO, 2008b).

With a new FDA commissioner in place and the creation of the White House FSWG and the Office of Foods, many further positive changes are anticipated, and some of them are already well under way. In the following chapters, the committee encourages the FDA to continue with its recent initiatives and plans and to delineate a course of action that will enable it to become more efficient at carrying out its food safety responsibilities.

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Part II

Toward a Stronger and More Effective Food Safety System

3

Adopting a Risk-Based Decision-Making Approach to Food Safety

As described in Chapter 2, the responsibilities of the U.S. Food and Drug Administration's (FDA's) new Office of Foods include providing executive leadership and management to all FDA food-related programs; directing the development of integrated strategies, plans, policies, and budgets to build the FDA's food-related scientific and regulatory capacities and programs, including the recruitment and training of key personnel and the development of information systems (FDA, 2009); and exercising direct line authority over the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM). Its responsibilities include both short-term decision making in direct response to a food crisis and longer-term initiatives focused on sustained, continued improvement in food safety and public health. The former responsibility requires rapid decision making in cooperation with multiple regulatory partners, while the latter requires long-term strategic planning aimed at proactive activities that are based on data and risk-based prediction and prioritization. For example, the FDA's responsibility during a foodborne illness outbreak would focus on identification of the source of contamination (product trace-back), initiation of regulatory action, and product recall. More proactive activities might involve conducting research to address crucial unknowns, undertaking formalized quantitative risk assessment, identifying candidate mitigation strategies to prevent repeat incidents, and ensuring the implementation of those strategies. Critical to both long- and short-term initiatives are improvements in cooperation with partners (see Chapters 4 and 7); efficient data collection, sharing, and analysis (Chapter 5); and communication with the public (Chapter 9).

Clearly, short- and long-term responsibilities coexist as the FDA seeks to both manage and prevent foodborne illness. As noted earlier, the FDA has often been criticized as responding reactively to food problems. Sometimes, this type of action is necessary; the FDA has no choice but to react when a problem manifests itself. However, greater proactive efforts by the FDA would enhance food safety. This chapter presents a conceptual approach for the prioritization of activities and allocation of resources to support both short- and long-term FDA responsibilities for food safety. Accordingly, the chapter lays out the foundation for a proactive, risk-based food safety system. Succeeding chapters describe elements of such a system that are dependent on the success of the approach presented here. For instance, application of a risk-based approach at all levels of regulation is a prerequisite for harmonization of federal, state, and local food safety programs (Chapter 7). Similarly, effective cooperation and communication with diverse stakeholders will require that all levels of the FDA embrace a proactive, risk-based approach to food safety management and facilitate its implementation (Chapter 9).

The committee did not conduct a comprehensive review of the details of all the risk-based activities of the FDA, such as the models utilized or factors considered in making individual decisions. The committee was provided with general information with regard to the FDA's risk-based activities and describes its understanding of those activities in this chapter. In this discussion, the committee uses concrete examples of those activities and identifies gaps with respect to the extent to which they adhere to the attributes and steps of the recommended approach. Although the committee concluded that those activities would have been enhanced by the use of a more extensive risk-based approach, in this and subsequent chapters the committee also recognizes that the FDA will face challenges in this regard. The committee identified challenges and courses of action to overcome them, for example, in hiring the appropriate personnel and coordinating data collection and sharing (Chapter 5), reorganizing the agency's food safety research portfolio (Chapter 6), integrating FDA programs with those of state and local governments (Chapter 7), carrying out risk communication and education (Chapter 9), and addressing organizational problems (Chapter 11).

There is consensus that food safety programs and any approach to food safety reform must be both science- and risk-based. This view was first articulated in the 1998 Institute of Medicine (IOM)/National Research Council (NRC) report *Ensuring Safe Food: From Production to Consumption* (IOM/NRC, 1998) and is also addressed by other reports of the IOM/NRC (IOM/NRC, 2003), the U.S. Government Accountability Office (GAO) (GAO, 2004a,b,c, 2005, 2007, 2008, 2009a,b), consumer groups (Consumers Union, 2008; Tucker-Foreman, 2009), and Congress (Becker,

2008, 2009; Brougher and Becker, 2008). These reports have emphasized the importance of using the best available science to understand foodborne illness, including the identification of causative agents (chemicals, toxins, and microbes) and transmission pathways and the development of appropriate surveillance systems. As the science base has developed, attention over the last decade has increasingly turned to its application within a risk-based framework, with the ultimate goal of improving public health. The term "risk-based" implies the existence of an underlying science base; however, it goes a step beyond to encompass use of the tools of risk and decision analysis to create systems that optimize the ability to prevent and control foodborne illness and improve public health. This chapter focuses on how this type of risk-based system might be constructed and implemented to enable the FDA to deal more effectively with food safety problems.

Ensuring Safe Food provides a rough description of the components necessary for the implementation of a risk-based system:

> . . . [It] require[s] identification of the greatest public health needs through surveillance and risk analysis. The state of knowledge and technology defines what is achievable through the application of current science. Public resources can have the greatest favorable effect on public health if they are allocated in accordance with the combined analysis of risk assessment and technical feasibility. . . . Thus, both the relative risks and benefits must be considered in allocating resources. (IOM/NRC, 1998, p. 93)

Other documents have furthered the concept of risk-based food safety management. For example, a 2002 discussion paper issued by Resources for the Future[1] states:

> If the primary objective of the food safety system is to reduce the burden of disease, success requires risk-based resource allocation. The food safety system must make the best possible use of its resources to reduce the disease burden. This means focusing government effort on the greatest risks and the greatest opportunities to reduce risk, wherever they may arise. It means adopting the interventions—presumably some combination of research, regulation, and education—that will yield the greatest reduction in illness. (Taylor, 2002, p. 7)

These previous documents go beyond the scope of traditional technical risk assessment by introducing such terms as "risk-based resource allocation" and "relative risk and benefit." In its deliberations, the committee recognized the need to address risk analysis in the broader context of regu-

[1] See http://www.rff.org/rff/Documents/RFF-IB-02-02.pdf (accessed January 25, 2010).

latory decision-making processes and risk governance (see, for example, IRGC, 2005, 2009) to manage food safety.

The challenges and best practices for integrating science to support effective risk management decisions are widely recognized, as summarized by a recent NRC study (NRC, 2009a):

> The most effective decision support efforts are organized around six principles: begin with users' needs; give priority to processes over products; link information producers and users; build connections across disciplines and organizations; seek institutional stability; and design processes for learning. Following these principles improves the likelihood of achieving the three main objectives of decision support: increased usefulness of information, improved relationships between knowledge producers and users, and better decisions. (NRC, 2009a, p. 67)

In short, in a society with limited resources, decisions about allocation need to be made in a consistent manner and with the goal of maximizing benefits and reducing risks while considering associated costs. In the area of food safety, a process is needed for allocating resources based on public health data and information. Risk managers must consider a wide variety of factors in their decision-making process, including the needs and values of a diverse set of stakeholders, which may diverge even with respect to public health. These factors might include economic considerations, the controllability of risk, and the population affected. The committee recognizes that such multidimensional comparisons are a highly challenging endeavor. However, the lack of such a systematic approach to risk-based decision making causes problems, from a decrease in public trust to unintended consequences in the marketplace, the environment, and society. In addition, the lack of such an approach may make a regulatory agency more vulnerable to political influences. The need to formally acknowledge the complexity of such decision making and then establish a transparent and systematic way to carry out the decision-making process is the subject of the next section. In addition, in Chapter 4, the committee elaborates further on the issue of how to select interventions. It should be noted that, while the committee concluded that providing the FDA with a stepwise process as a tool for making decisions is appropriate, the development of the FDA's philosophy, including specific criteria and their weight, is a management decision beyond scope of this study. Thus in Chapter 4 (recommendation 4-2), the committees recommends that the FDA develop its philosophical approach by defining a strategy that delineates factors to consider (e.g., economic factors, public perception, environmental factors) and their weight.

A RISK-BASED APPROACH TO FOOD SAFETY MANAGEMENT

Definitions

Many groups have defined risk and risk characterization. For example, the World Health Organization's (WHO's) International Program on Chemical Safety defines risk as "the probability of an adverse effect in an organism, system, or (sub)population caused under specified circumstances by exposure to an agent" (IPCS, 2004). Others have expanded this definition to include the fact that this probability can be expressed quantitatively or qualitatively and that risk characterization includes a discussion of the significant scientific uncertainties in this information. Further, the committee agreed upon the following working definition for a risk-based approach: "a systematic means by which to facilitate decision making to reduce public health risk in light of limited resources and additional factors that may be considered." The committee identified the following as key attributes of a risk-based food safety system: (1) is proactive based on a strategic management plan; (2) is data driven; (3) is grounded in the principles of risk analysis; (4) employs analytical methods to rank risks based on public health impact; (5) incorporates deliberation with key food safety stakeholders; (6) considers factors such as consumer perception, public acceptance, market impacts, and environmental impacts in decision making when appropriate; (7) employs analytical methods to prioritize the allocation of limited resources to manage risk most effectively; (8) employs measures to evaluate the efficacy of the risk management program on a continuous basis; and (9) performs all of these functions in a systematic and transparent manner with the involvement of stakeholders. These attributes are further described in Box 3-1.

A Conceptual Approach to Risk-Based Food Safety Management

The risk-based system envisioned by the committee will entail analysis and prioritization at several distinct levels:

- the formulation of a strategic plan that identifies outcomes/goals of the risk-based system,
- broad-based risk ranking to identify the most important risks based exclusively on public health considerations,
- the identification of additional data/information needs upon which prioritization of resources may be based,
- the choice of intervention strategies and allocation of regulatory resources, and
- the evaluation of outcomes.

BOX 3-1
Attributes of a Risk-Based Food Safety System

A risk-based system is proactive and based on a strategic management plan. Notwithstanding the need to respond to unforeseeable crises, risk activities should be planned in advance, an exercise that should include various stakeholders and be based on the knowledge gained from past experience with a vision of predicting food contamination problems. Managing a crisis in the short term and implementing a well-developed strategic plan for managing food safety in the long term are equally important; attention to unanticipated outbreaks should not detract from implementation of the strategic plan.

A risk-based system is data driven. Although expert opinion is a valuable asset when there are uncertainties or data must be interpreted, a risk-based system should be grounded in science. That is, the collection, analysis, and interpretation of quality data, as well as data management, are essential tasks for the implementation of a risk-based system.

A risk-based system is grounded in the principles of risk analysis. A risk-based system should be grounded in risk analysis, with risk assessment, risk communication, and risk management as the essential basis for establishing a sound public health protection capability. If implemented appropriately, the system ideally provides a transparent, data-driven means by which to determine the extent of public health protection achieved as a result of different risk management actions, and therefore it provides a decision-making tool. This concept has worldwide support and has been applied for several decades by regulatory and public health agencies.

A risk-based system employs analytical methods to rank risks based on public health impact. A risk-based system systematically ranks risks even if those risks differ in complexity and uncertainty. The development of analytical methods (models) that can assign numerical values to the various risks based on public health impact is the foundation of this activity.

A risk-based system employs analytical methods to prioritize the allocation of limited resources to manage risk most effectively. The evaluation of intervention strategies is an essential element of risk management. Risk managers must consider multiple characteristics or

attributes of different risks and integrate these data for the purpose of prioritizing and making effective use of resources. In this manner, decisions are made by considering the food system as a whole, that is, with a systems-based approach. Important decision analysis tools that may be used in this process are feasibility, cost-effectiveness, and cost–benefit analyses. A major element of this activity is a clear statement of regulatory philosophy and the use of a road map showing how decisions will be made regarding the mix of private responsibility, government incentives, and government regulation that will be used to manage different risks.

A risk-based system considers other factors, such as consumer perception, cost, controllability, public acceptance, environmental effects, and market impacts, in decision making when appropriate. Risk mitigation strategies and public policy decision making are influenced by factors other than public health risk. These considerations should be formally communicated to stakeholders.

A risk-based system employs measures to evaluate the efficacy of the risk management program on a continuous basis. An essential step in a risk-based system is evaluation of the efficacy of the system itself with respect to public health and other factors selected by decision makers. Evaluation of programs, always a daunting process, requires the identification of indicators by which to link interventions to public health outcomes. To collect and integrate food safety data so that attribution models can be built is a critical first step in this process.

A risk-based system performs all of these functions in a systematic and transparent manner with the involvement of stakeholders. Risk managers should develop a process for implementing a two-way communication approach whereby stakeholders have an opportunity to engage in the risk-based decision-making process. This approach should include input and access to discussions regarding the basis for decision making, as well as information about the uncertainties and variability of the underlying data. Likewise, a risk-based approach requires disclosure of all sources of information, comprehensive analysis, and transparency regarding the considerations taken into account in the decision-making process. In addition, independent peer review is fundamental to all scientific undertakings and critical for risk-based decision-making processes.

Figure 3-1 depicts the cycle of risk prioritization and regulatory (intervention) activities that constitutes the basis of a risk-based food safety system. As the figure shows, the system encompasses six basic steps. These steps are outlined below and then discussed in detail, recognizing that they could be ordered differently and are likely to be taken iteratively.

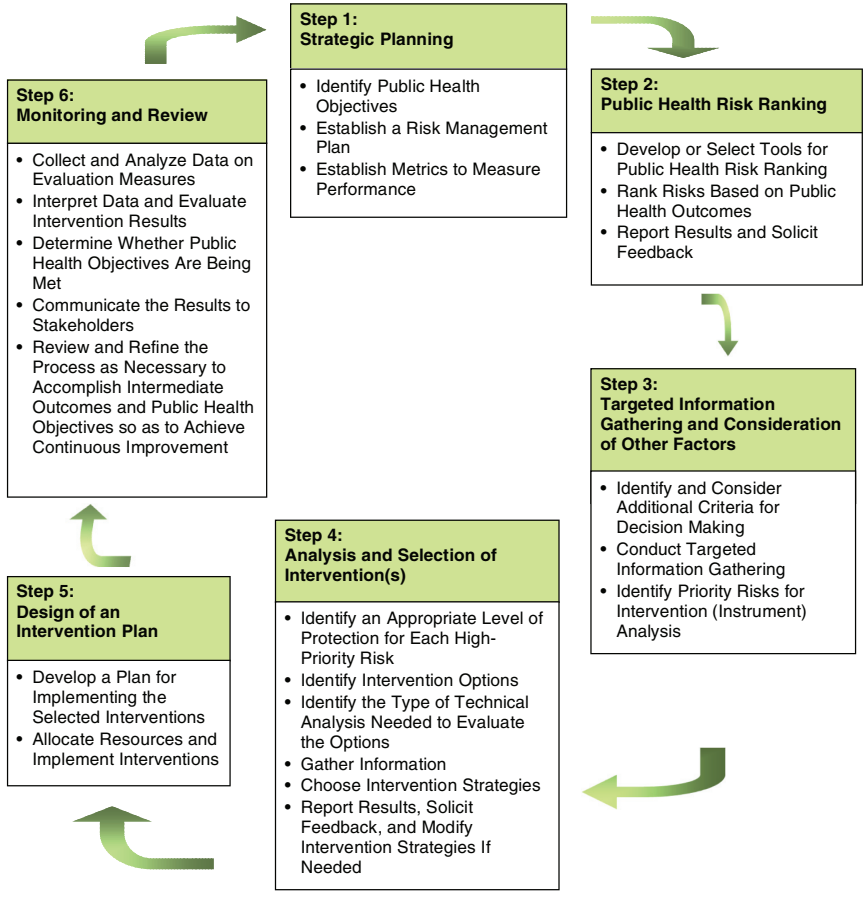

FIGURE 3-1 Steps in a risk-based food safety system (iterative between and within boxes).

Step 1: Strategic Planning

1. Identify public health objectives related to food safety in consultation[2] with stakeholders.
2. Establish a risk management plan (general and specific strategic plans for meeting public health objectives and for considering and choosing policy interventions to achieve those objectives).
3. Establish metrics with which to measure performance in consultation with stakeholders.

Step 2: Public Health Risk Ranking (Ranking of Hazards)

1. Develop or select tools (models, measures, or other) for public health risk ranking in consultation with stakeholders.
2. Rank risks based on public health outcomes.
3. Report results to stakeholders and solicit feedback.

Step 3: Targeted Information Gathering on Risks and Consideration of Other Factors That May Influence Decision Making

1. Identify and consider additional criteria upon which risk-based decision making will be based (e.g., public acceptance, cost, controllability, environmental effects, market impacts) in consultation with stakeholders.
2. Conduct targeted information gathering. For each high-priority and/or uncertain risk, determine the need for collection of additional information and implement accordingly:
   a. additional data collection (research, surveillance, survey, baseline data), and
   b. risk assessment (qualitative, quantitative, semiquantitative).
3. Based on that additional information, identify priority risks for which intervention analysis is needed.

Step 4: Analysis and Selection of Intervention(s)

1. Identify an appropriate level of protection for each high-priority risk, based on available data and in consultation with stakeholders.
2. Identify intervention options in consultation with stakeholders.
3. Identify the types of technical analysis, including but not limited

[2] In this context, the term "consultation" means "discussions with other interested individuals or groups to obtain advice."

to risk assessment, needed to evaluate the options; identify performance measures and the initial design of databases.
4. Gather the information necessary to conduct the technical analysis.
5. Choose intervention strategies for implementation using multicriteria decision analysis.
6. Report results to stakeholders, solicit feedback, and modify intervention strategies if needed.

Step 5: Design of an Intervention Plan

1. Develop a plan for implementing the selected interventions in consultation with stakeholders.
2. Allocate resources and implement interventions.

Step 6: Monitoring and Review

1. Collect and analyze data on evaluation measures selected during strategic planning.
2. Interpret data and evaluate whether the interventions result in the desired intermediate outcomes.
3. Determine whether public health objectives are being met by using performance metrics developed in Step 1 (broad strategic planning).
4. Communicate the results to stakeholders.
5. Review and refine the entire process in an iterative manner as necessary to accomplish both intermediate outcomes and public health objectives so as to achieve continuous improvement over time.

Further Description of the Proposed Approach to Risk-Based Food Safety Management

Step 1: Strategic Planning

Strategic planning, conducted at several different levels, is an essential element of a successful food safety program. The highest level of strategic planning involves the identification of long-term and broadly stated goals for protecting public health from the threats associated with food contaminants, sometimes referred to as public health objectives. Perhaps the best example of such goals is those proposed for Healthy People (Box 3-2). These goals are considered national in scope and concern the entire food safety system, including components of the system not under FDA jurisdiction. In strategic planning, however, the FDA would also likely include agency-specific intermediate objectives, which might lead only indirectly to

BOX 3-2
Food Safety Goals Proposed for Healthy People 2020

Objectives Retained as Is from Healthy People 2010

FS HP2020–1: Reduce severe allergic reactions to food among adults with a food allergy diagnosis.

FS HP2020–2: (Developmental) Improve food-employee food preparation practices that directly relate to foodborne illnesses in retail food establishments.

Objectives Retained but Modified from Healthy People 2010

FS HP2020–3: Reduce infections caused by key pathogens commonly transmitted through food.

FS HP2020–4: Reduce infections associated with foodborne outbreaks due to pathogens commonly transmitted through food.

FS HP2020–5: Prevent an increase in the proportion of nontyphoidal *Salmonella* and *Campylobacter jejuni* isolates from humans that are resistant to antimicrobial drugs.

FS HP2020–6: Increase the proportion of consumers who follow key food safety practices.

Objectives New to Healthy People 2020

FS HP2020–7: Reduce the number of outbreak-associated infections caused by food commodity group.

FS HP2020–8: Reduce contamination of meat and poultry products by foodborne pathogens.

FS HP2020–9: (Developmental) Increase the number of States that have prohibited sale or distribution of unpasteurized dairy products (as defined by FDA, unpasteurized liquid milk and cheeses aged <60 days).

SOURCE: http://www.healthypeople.gov/hp2020/Objectives/TopicArea.aspx?id=22&TopicArea=Food+Safety (accessed October 8, 2010).

improvements in public health. Examples of these sorts of objectives might be improved efficiency of inspections or reorganization of the FDA research function. While accomplishing these objectives might not lead directly to improvements in public health, achieving efficiencies that would ultimately enable improvements in public health would represent measurable movement toward increased safety of the U.S. food supply.

Identification of the specific means by which the goals are to be achieved—for instance, defining the regulatory structures and the nature

and size of the human and technical resources required—is another important component of strategic planning. The strategic planning phase is also when the agency further delineates how scientific research, inspection, and enforcement activities are to be prioritized and deployed. Budgetary issues are central to long-term strategic planning as well. Another important component of strategic planning is describing the metrics that will be used to measure the success of the strategic plan's implementation, that is, how the program will be evaluated with respect to its success in achieving the stated public health objectives. The issue of measuring success is an important and potentially troublesome one, as will be discussed later in this chapter.

In addition to broadly stated public health objectives, each specific agency function, such as research, inspection, and policy, needs its own strategic plan. Other more narrowly focused strategic planning requirements also arise frequently in conjunction with specific food safety issues. Sometimes these issues can be anticipated, but often they cannot. Therefore, an important aspect of a risk-based food safety management strategy is having the necessary structure and resources in place so the agency can respond rapidly to such emergent situations. Planning for emergencies must therefore be part of the strategic planning process.

The committee believes that all of the risk-based activities discussed in this chapter (e.g., risk assessment, collection of data, research, intervention analysis) should be undertaken only after sufficient strategic planning has been completed. Further, the results of strategic planning should be shared with all constituents involved in each path to decisions. Therefore, risk communication must be carried out during the earliest planning stage. In fact, provisions for the stakeholder contributions expected at all levels of food safety management should be outlined as part of the strategic planning process, to include defining the various stakeholders, the nature of the consultations that will take place with them, the methods to be employed to obtain their feedback and with what frequency, and the process by which the agency will respond to that feedback.

The committee is aware that a balance must be achieved between the time spent in planning and that spent on other, more narrowly focused risk management efforts, but it is convinced that inadequate attention to planning (and an ill-planned initiation of technical analysis) is fatal to an effective risk-based food safety program. Strategic planning is necessary to identify the most efficient path to achieve food safety objectives.

Step 2: Public Health Risk Ranking (Ranking of Hazards)

The first step in support of the strategic plan is to identify which risks constitute the greatest threat to public health and hence should be a priority

for future analysis. This step is accomplished using tools of public health risk ranking, which itself is a type of risk assessment. Public health risk ranking is a formalized process that involves comparing the relative risk of multiple hazards, including foods, with the purpose of aiding in the establishment of risk management priorities, the allocation of resources, and the identification of critical data and research needs (CAST, 2006; Havelaar et al., 2006; Mangen et al., 2009). At this initial phase of the risk-ranking process, the emphasis is on identifying and comparing hazards and foods with the greatest impact on public health, without consideration of other factors that might also play a role in decision making.

A number of public health risk-ranking models have been produced over the last decade. They differ in their degree of complexity, level of quantification, and approach to model construction. The simplest approach to risk ranking involves the use of personal judgment to create a "risk versus severity" table or matrix to assign rankings. At the other extreme of the spectrum is the joint FDA (CFSAN)–U.S. Department of Agriculture (USDA, Food Safety and Inspection Service [FSIS]) *Listeria monocytogenes* in Ready-to-Eat Foods Risk Ranking (CFSAN/FSIS, 2003), which ranks foods based on their listeriosis risk and encompasses all the components of a full quantitative risk assessment. Somewhere in the middle are many simpler, semiquantitative public health risk-ranking tools, some of which are summarized in Table 3-1.

Each public health risk-ranking model has been designed with a specific purpose in mind, which then informs its design, scope, and degree of rigor. The general approach involves consideration of the body of scientific evidence on attributes (e.g., potential for amplification of the hazard in the food) that define the risk(s) posed by the various agent–food combinations. These attributes (or criteria) are described qualitatively or semiquantitatively and together are the basis for the risk ranking. Each criterion or attribute is defined by one or more input variables that are described using relevant data sources, usually a combination of personal judgment and scientific evidence. Some of the commonly used criteria are (1) burden of illness (epidemiological attribution), (2) illness severity, (3) population susceptibility, (4) likelihood of contamination, (5) potential for agent amplification, and (6) breadth of exposure. The inputs are combined using a mathematical algorithm that assigns a "rank" based on the values or weights given to each input variable. Although risk ranking can be done at a macro level (such as the entirety of risk associated with a specific food or hazard), it is most often applied to specific hazard–commodity pairs.

A useful way to differentiate risk-ranking approaches is by the features of the data sources used in model construction. In the surveillance-based or "top-down" approach, the level of risk associated with specific foods, hazards, or their combinations is based on information gathered

TABLE 3-1 Semiquantitative Food Safety Risk-Ranking Methods

Method	Brief Description	Metrics and Design	Originator(s)
Foodborne Illness Risk-Ranking Model[a]	A science-based tool for prioritization of resources in food safety. Consists of three modules: (1) disease incidence, (2) valuation of health outcomes, and (3) attribution.	Ranks on five measures of social burden. Analytical design with user-friendly interface.	Food Safety Research Consortium (U.S.).
iRISK	Semiquantitatively compares risks of hazard–commodity pairs. Allows for comparison of microbial and chemical hazards. Closest to the standard risk assessment paradigm. Considers (1) exposure assessment (populations, consumption), (2) hazard characterization (dose–response), (3) process information (effect on prevalence and level of contaminant through stages in continuum), and (4) public health metric pseudo-disability adjusted life years (pDALY).	pDALY calculation for comparative ranking purposes. Analytical platform with web-based user interface.	Institute of Food Technologists, Risk Sciences International, and the Food and Drug Administration (U.S.).
Risk Ranger[b]	Determines relative risks from different product–pathogen–processing combinations. Based on 11 questions posed to the user, which deal with (1) susceptibility and severity, (2) probability of exposure, and (3) probability of the food containing an infectious dose.	Excel-based mathematical model converts answers to numerical values; values combined to produce a risk-ranking score scaled logarithmically between 0 and 100.	Australian Food Safety Center of Excellence.
Food Safety Universe Database	Systematic ranking of food safety risks in three dimensions: food, hazard, and location in chain. Establishes two "axes" upon which are determined (1) probability (consumption, contamination, exposure) and (2) impact (P[illness], severity, difficulty of limiting impact).	Risk score calculated multiplicatively as a product of six subscores.	Ontario Ministry of Agriculture and Food.

[a] See http://www.thefsrc.org/firrm.htm (accessed October 8, 2010).
[b] See http://www.foodsafetycentre.com.au/riskranger.php (accessed October 8, 2010).

from epidemiological systems such as disease reporting and outbreak databases. It can be argued that these are the best sources of information for public health–based risk ranking because they reflect illness at the point of consumption (NRC, 2009b). However, good epidemiologically based foodborne illness attribution data are not available at this time for the vast majority of hazard–food combinations under FDA jurisdiction, and in most instances do not exist for chronic chemical exposures associated with foods. Another concern with this approach is that it represents disease risk only at the "point of consumption," which is the net sum of contamination occurring at the preharvest, processing, and final preparation stages (NRC, 2009b). This does not necessarily translate directly to an understanding of the possible source of contamination in the supply chain, including a source at the point of processing, which is the location of the large majority of the FDA's current activity. The overall role of foodborne illness attribution in a risk-based food safety management system is discussed further at the end of this chapter.

The alternative or "bottom-up" approach to public health risk ranking adheres roughly to the standard microbial risk assessment paradigm and follows the agent through the food chain to produce a prediction of risk to human health relative to other agents and/or foods. This approach is based on research data supplemented by expert judgment, and therefore can be resource-intensive and subjective. It frequently presupposes an understanding of the behavior of microorganisms in complex and changing environments, complexities that may be very difficult to model. It could be argued that some combination of both approaches (bottom-up and top-down) would be better than either one alone.

Many considerations arise in designing a public health risk-ranking model, including model structure, degree of resolution (categorization of foods and agents broadly or narrowly), choice of key risk attributes and their defining criteria, data sources, and weighting approach. Nonetheless, a good risk-ranking model should be fit-for-purpose and be scientifically credible, balanced, transparent, easy to use, and flexible. As such it must provide both the information and the framework necessary to facilitate public health risk ranking in a systematic manner.

As is the case for strategic planning, public health risk ranking can be applied to decision making at various levels. At the uppermost level, identification of the highest-priority risks can be used to support decisions about the balance of resources dedicated to different agency functions. For example, for risk X, what proportion of the agency's resources should go to research relative to inspection versus risk communication? Or within the inspection function, what proportion of resources should be dedicated to commodity A versus commodity B based on their relative risk ranking? At a lower level, predictive (bottom-up) risk-ranking models with a high

degree of resolution can even function as preliminary risk assessments to determine the need for additional data collection or to predict the efficacy of competing mitigation approaches. In short, public health risk ranking supports the other functions of a risk-based food safety management system in the spirit of the iterative nature of the system.

Step 3: Targeted Information Gathering on Risks and Consideration of Other Factors That May Influence Decision Making

The committee recognizes that even a risk-ranking process based exclusively on public health aspects and grounded in scientific knowledge requires weighing competing values and objectives. Risk decision making takes place in a broader social context. In its mission to protect the safety of the public food supply, the FDA must usually consider such additional factors as (1) the feasibility of mitigation; (2) economic constraints (both costs and economic consequences); (3) additional public health and welfare concerns of consumers, farmers, the food processing industry, and other stakeholders; and (4) the environmental impacts of proposed mitigation measures. Therefore, it is critical during the information-gathering stage to identify which factors will be considered in the decision-making process.

Risk prioritization, an emerging approach in the food safety arena, uses the combined tools of risk assessment and decision analysis to determine the importance of one risk relative to another. Unlike risk ranking, which the committee has defined as a type of risk assessment exercise, risk prioritization is inherently a risk management tool. In particular, multiple criteria decision analysis (MCDA) shows promise for supporting complex decision making. MCDA allows for the systematic structuring of a decision problem from the perspective of multiple dimensions (not just public health). Implemented as an element of structured decision support (NRC, 2009a), it can assist in decision making by integrating value judgments as well as objective, quantitative measurements within a transparent and systematic framework.

Structured decision making incorporating MCDA consists of three basic phases (compare NRC, 2009a, p. 57). In the first phase, called problem structuring, the agency defines the decision problem with input from key stakeholders. This activity includes (1) bounding the problem and identifying the question to be addressed and the factors to be included or excluded from consideration, (2) identifying the values and objectives of the decision-making process, (3) identifying the specific criteria with which potential actions are to be compared, (4) identifying the attributes with which the performance of a given alternative will be measured, and (5) identifying the potential actions to be compared in the analysis. Examples of criteria that may be used are public health improvements, health risk reductions, eco-

nomic impact, consumer perception, social sensitivity, and environmental effects. In the next phase, called preference modeling, analysts work with all parties to evaluate and represent agency and stakeholder preferences relative to each criterion and to develop an aggregated model that combines preferences across criteria for the purposes of comparing alternative actions (interventions) and assessing trade-offs among the alternatives. Finally, after the ranking of alternatives, sensitivity analysis is performed to identify the most influential criteria and attributes and to evaluate the influence of different preference judgments, an activity that may lead to a change in the ranking of the alternatives (Belton and Stewart, 2002). Recent examples of MCDA approaches applied to food safety include those of Ruzante and colleagues (Henson et al., 2007; Fazil et al., 2008; Ruzante et al., 2009). Ultimately, the outcome of Step 3 is to rerank or reprioritize competing risks.

In some cases, risk prioritization will result in the identification of substantial uncertainties that could well impact the decision-making process. For example, what are the major stakeholder concerns, and how important are they? Are candidate mitigation strategies available, and if so, what is known about their effectiveness? Is the degree of contamination in a product actually known? Is the infectivity/toxicity of a candidate hazard in a population of interest understood? In instances where unknowns are critical to informed decision making, Step 3 helps inform resource allocation with respect to surveillance, research, or further risk assessment efforts. This is not to say that decision making should be placed on hold until every piece of missing information is gathered. When there are sufficient uncertainties that might well impact the choice of a control strategy, however, it is prudent to invest in the collection of information that will improve the ability to make an informed, science-based decision. Alternatively, a risk-ranking/prioritization model (Steps 2 and 3 of the risk-based system) could be designed that would take into account the degree of certainty about public health impact or the need to prioritize based on the potential to cause a particularly serious disease (e.g., bovine spongiform encephalopathy).

Step 4: Analysis and Selection of Intervention(s)

The next step in a risk-based approach is to identify and select interventions (or instruments) for the highest-priority risks. In economic and policy analysis, the term "instrument" is used to describe the means a government has at its disposal to achieve public policy outcomes—to govern. Instrument types that are often used include laws, economic incentives, self-regulation, standards, contracts, and information and education, all of which establish relationships between the state and its citizens (Treasury Board of Canada Secretariat, 2007). However, the term "instrument" can be interpreted in

many different contexts (e.g., the medical discipline), so to avoid potential misinterpretations, the committee chose to use the term "intervention" instead. For the purposes of this report, the term "intervention" should not be equated exclusively with legislation, but with any means by which policy objectives are pursued. This broad definition includes forms of government action in addition to legislation and encompasses a spectrum from no intervention through reliance on industry self-regulation, use of information and education strategies, coregulation, establishment of incentive-based structures, direct regulation, or a combination of actions (see Chapter 4).

Choosing interventions based on decision analysis is a process that involves multiple tasks. The first is to establish an acceptable level of risk (appropriate level of protection) for each high-priority risk, consistent with the broad goals for protecting public health identified in Step 1 (strategic planning). This task should, of course, be carried out in consultation with stakeholders. Next, it is necessary to identify interventions that could be used—alone or together with other interventions—to address each risk. Candidate interventions can be identified or designed through consultation with stakeholders and based on the scientific analyses performed in Step 3. In point of fact, many candidate interventions will already have been identified in Steps 1, 2, and 3 of the risk-based system during the gathering of information about the risks and the discussion of potential mitigation strategies. Because the objective of the risk-based approach is to allocate limited resources to maximize benefits and minimize risks, decisions about interventions should include an analysis of the value of public health outcomes and uncertainties as well as of the costs and risks of the intervention. This analysis should be undertaken with the understanding that for some interventions (e.g., a new regulatory approach to food inspections), the impact on public health and the cost will be realized only in the long term, and therefore the timing of the analysis is an important consideration. It is important at this stage to consider systematically the full spectrum of interventions (Treasury Board of Canada Secretariat, 2007) to ensure that the alternatives are not prejudged (see also Hammond et al., 1999).

Candidate interventions should then be evaluated by using analytical tools (e.g., risk assessment) that can help identify the types of additional information that might be needed to evaluate the alternatives and the data required. Based on this information and analysis, intervention strategies should be selected and assessed using formal MCDA approaches as described under Step 3. The MCDA approach does not need to be highly sophisticated, but it does need to provide a road map to ensure that the same factors and trade-offs are considered across intervention alternatives for different risk situations. A template (Treasury Board of Canada Secretariat, 2007) can help ensure that more salient aspects of a particular alternative do not dominate the overall choice among interventions (see

Chapter 4). Documenting intervention choices is essential to achieving transparent decision processes.

Step 5: Design of an Intervention Plan

The fifth step in a risk-based system is to design and implement the selected intervention(s) in consultation with stakeholders. Each intervention will have unique implementation needs, so the details of this step will vary based on the selected intervention and the risk being addressed. For example, this step may involve writing regulations, setting standards, overseeing self-regulation, or designing educational programs and tools, as might be the case for labeling. This step also requires the definition of interim measures (intermediate outcomes) with which to monitor the progress of the intervention's implementation; these measures, however, should not be a substitute for the ultimate performance measures identified in Step 1 (strategic planning), that is, the measurement of progress in meeting public health objectives. This step also involves systematically choosing the types of resources to be used in carrying out different intervention plans, for example, the mix of federal and state resources. The role of each partner (e.g., federal, state, and local governments; industry) in implementing the intervention needs to be discussed with partners and delineated in the plan.

Step 6: Monitoring and Review

Integral to any management system is continued monitoring of the system outcomes. In addition to common goals of greater accountability and improvements in performance-based decision making (Cavalluzzo and Ittner, 2004), performance measurement and monitoring can be used for evaluation, control, budgeting, learning, motivation or promotion, and recognition of achievement (Behn, 2003). The committee cautions that, while there is evidence that performance measurement can improve government performance (Bevan and Hood, 2006), it can also be ineffective or even harmful, producing gaming and other unintended consequences (Bird et al., 2005; Johnsen, 2005). For example, the Government Performance and Results Act (GPRA) has been criticized for focusing public managers more on procedural compliance than on performance (Lynn, 1998).

As each intervention is undertaken, it is essential to map appropriate predetermined goals (set during Step 1), such as public health objectives and intermediate objectives, to the actual outcomes of an intervention. Direct metrics of public health might include cases of illness, hospitalizations, deaths, measurements of disease burden (e.g., disability-adjusted life years), or economic costs (e.g., cost of illness). Intermediate metrics are those that,

for example, measure contamination at a point between farm and table. As part of the strategic planning in Step 1, the agency should define one or more agencywide goals, ideally linked with national public health objectives and relating to national reductions in the incidence of key pathogens and their associated diseases or the presence of chemical contaminants. This should be seen as a means of measuring the overall outcome of the risk-based system, providing the agency with a way of assessing whether the selected approach to risk management is effective.

Needless to say, the identification and design of appropriate metrics must be consistent with the data collection system and the means by which the data are interpreted (see also Chapter 5). Foodborne illness attribution data can be particularly relevant in this regard. A prime example of an effort to link human health outcomes with regulatory controls is the creation of the Foodborne Diseases Active Surveillance Network (FoodNet) program in the late 1990s. FoodNet was initiated by the U.S. Centers for Disease Control and Prevention in collaboration with USDA and the FDA, and was intended to assess the effectiveness of the 1996 Hazard Analysis and Critical Control Points (HACCP)/Pathogen Reduction regulations (Scallan, 2007). While FoodNet has produced valuable information (e.g., improved foodborne illness estimates, standardization of methods, identification of risk factors for pathogen-specific illnesses), it does not meet the need for information for effective monitoring of the success of the HACCP/Pathogen Reduction regulations. The overall role of foodborne illness attribution in a risk-based food safety management system is discussed further at the end of this chapter.

The committee discussed and recognized the challenges associated with measuring the success of policy interventions, which have also been cited by others (Havelaar et al., 2006; Charlebois and Yost, 2008). For example, whereas intermediate variables (e.g., pathogen testing in food at the time of processing) may be relatively easier to correlate with the adoption of an intervention, such correlation is, in general, much more difficult for a public health outcome (e.g., measured by FoodNet or national public health trends), even in cases where a link has high face validity (e.g., an intervention that decreases food contamination would be expected to improve public health). In many instances, other factors that are not necessarily controllable confound the identification of such correlations. Although intermediate measures are useful, direct measures of public health impact are essential for truly evaluating the effectiveness of food safety interventions in the long term. Hence, again, the need for accurate and comprehensive foodborne illness attribution data is clear.

Ideally, the monitoring and review step should be performed not by the group planning the intervention but by a different group with expertise in designing the collection, analysis, interpretation, and communication

of appropriate data and results to stakeholders (Chapter 5). As discussed in Chapter 11, this monitoring role could be assumed by an independent, centralized risk-based analysis and data management center. As with other aspects of a risk-based system, this process must be transparent and involve stakeholders meaningfully.

Finally, the entirety of the risk-based approach (Steps 1 through 6) should be seen as an iterative process, with a strong focus on continuous public health improvement. The monitoring and review process should be subject to rigorous quality assurance standards, with periodic quality reviews not only when goals are not being met, but also when goals are being consistently met, which may suggest the need for new standards or new measurement tools.

MOVING TOWARD THE DEVELOPMENT OF A COMPREHENSIVE RISK-BASED APPROACH TO FOOD SAFETY MANAGEMENT

The risk-based system described above is consistent with the principle of evidence-based public health, which has been defined as "the development, implementation, and evaluation of effective programs and policies in public health through application of principles of scientific reasoning, including systematic uses of data and information systems" (Brownson et al., 2003, p. 4). The evidence-based approach includes key characteristics of (1) interventions being based on the best possible science, (2) reliance on multidisciplinary problem solving, (3) systematic program planning, (4) sound evaluation of program efficacy, and (5) information dissemination. The committee advocates application of the evidence-based approach to food safety management.

The risk- and evidence-based food safety management approach described above is meant to be comprehensive in that the general steps are applicable to virtually all FDA food-related decision making. Certainly, the approach is relevant to broad-based prioritization, as might be the case for strategic planning of how best to use agency resources associated with specific functions (e.g., research, inspection, communication, surveillance). However, it is also applicable to decision making within any one unit of the agency, as might be the case for prioritization of the use of resources dedicated to the risk assessment function (e.g., which risk assessments to perform). It is fully applicable as well to specific decision making, such as deciding which of several competing risk reduction strategies to choose for implementation. The committee therefore sees the risk-based approach as providing the underlying structure for all of the FDA's food safety decisions.

The steps outlined above are not meant to be conducted in a fixed order; rather, the system as a whole should be envisioned as fluid. Further-

more, as noted above, the overall approach, like risk analysis, is intended to be iterative. For example, broad-based public health risk ranking (Step 2) might be applied at the general commodity level (produce versus fish) and considering all agents to identify those of greatest public health concern. This activity would be followed by prioritization and reranking (Step 3) on the basis of additional factors that might affect the decision to intervene. Once high-priority hazards and/or commodities had been identified, the agency might return to Step 2 to place the riskiest specific products and their hazards in a high-risk general commodity category, followed by prioritization (Step 3). Following prioritization would be analysis and selection of intervention(s) (Step 4), during which frequent iteration would occur between Steps 4 and 6 in an effort to establish appropriate levels of protection, identify and evaluate candidate intervention strategies, and collect the information necessary to support the choice of intervention(s), which might or might not include the need for a full quantitative risk assessment. Once the intervention plan had been implemented and monitored (Steps 5 and 6), there would be a need for periodic reevaluation using risk ranking and prioritization (back to Steps 2 and 3) to ensure that resources would continue to be allocated appropriately.

Indeed, given the diversity and inherent dynamics of food safety issues, it is impossible to account for all potential eventualities in advance. As noted earlier, therefore, the risk-based system must be sufficiently flexible to respond to rapidly emerging food safety issues, and it must be reactive enough to facilitate its use in emergency situations, such as the management of foodborne illness outbreaks. Activities within each step, such as data collection, analysis, and modeling, will depend on the type of hazard. During an outbreak, for example, decisions must be made quickly and possibly with an incomplete collection of data. For this reason, it is essential that strategic planning performed in emergency situations be largely standardized so that immediate decisions are based on lessons learned and the likely availability of needed data. As another example, government tools for overseeing the safety of imported foods necessarily differ from those available to ensure the safety of domestically produced food. (Appendix E contains background information on various tools that are used to oversee imported foods here and in other countries.) As discussed in Chapter 4, the lack of jurisdiction over the production of food in other countries is an important differentiating factor for governance purposes. In fact, for imported foods, the data available to make decisions based on risk may be very different from those available for domestic foods, and the analysis will need to take into consideration such factors as the FDA's knowledge of the foreign country's food safety system. Still, decision making about prioritizing inspections, allowing importation of a product into the United States, or responding to an emergency situation should be based on the same

attributes listed in Box 3-1 and should follow the same basic risk-based approach. At a different level, flexibility needs to be integrated to allow for the "human element"; for example, an inspector should not be prevented from pursuing a hunch that something might be wrong.

RELATIONSHIP BETWEEN RISK ANALYSIS AND THE RISK-BASED FOOD SAFETY SYSTEM

To date, the term "risk-based" has been interpreted largely in the context of the basic elements of risk analysis. However, there has been some discussion for about a decade regarding the need to expand the meaning of the term. For example, a 2001 discussion paper issued by Resources for the Future[3] (Taylor and Hoffman, 2001) suggests that the role of risk analysis be broadened:

> There are, however, much broader roles for risk analysis at the level of system design and management. . . . They include: (1) guiding the allocation of inspection and enforcement resources, and (2) setting priorities for risk reduction initiatives. These are roles for risk analysis that can significantly enhance the effectiveness of the food safety system in reducing risk. (Taylor and Hoffman, 2001, p. 5)

The risk-based food safety management system presented here takes the concepts of risk analysis to an operational level by creating a process that uses analytical methodology to evaluate risk, and then facilitates decision making in light of the myriad factors that need to be considered in the risk management process. This sort of approach is not unlike that of HACCP, which provides the foundation for food safety control at the processing level of the food chain. Like HACCP, this conceptual approach to a risk-based food safety management program provides a road map that clearly defines the course of the process and the types of inputs that need to be considered along the way. This road map is a key component of the transparency of the system, with a focus not just on what has been done, but also on how the system will operate in the future. As envisioned by the committee, such a framework is comprehensive (providing a uniform means of assessing and comparing risk across the food safety system) and transparent (incorporating a clear understanding of how one goes from data to decisions); these and other key attributes of the risk-based system were noted earlier in Box 3-1.

[3] See http://www.rff.org/documents/RFF-DP-01-24.pdf (accessed January 26, 2010).

THE ROLE OF RISK ANALYSIS IN THE FDA'S CURRENT FOOD SAFETY MANAGEMENT PROGRAM

The FDA has been engaged in risk-based efforts in food safety management for more than a decade now. This section provides a brief synopsis of the committee's understanding of those efforts, based on a public workshop held March 24, 2009, in Washington, DC, and on follow-up questions and interviews with CFSAN and CVM staff as well as background analysis by the committee. Although the committee has not attempted an in-depth evaluation of the FDA efforts, it has identified some gaps in these efforts. The committee notes that creation of the Office of Foods in 2009 with direct line of authority over CFSAN and CVM will likely impact both the functioning of these units and the ultimate implementation of a risk-based food safety approach.

Risk-Based Activities of CFSAN

Although CFSAN has a long history of conducting safety assessments for food additives and risk assessments for chemicals, it was not until 1999 that the center conducted more complex quantitative risk assessments for pathogens. In 2002, a CFSAN risk analysis working group produced an internal report *Initiation and Conduct of All Major Risk Assessments Within a Risk Analysis Framework,* which is based on the principles of risk analysis and describes how to prioritize and conduct risk assessments.[4] Several offices within CFSAN have a role in developing and coordinating risk-based initiatives[5]:

- The Risk Assessment Coordination Team (RACT) in the Office of Food Defense, Communication, and Emergency Response coordinates and manages risk profiles and assessments that require representation from different offices within CFSAN, and sometimes outside of CFSAN or even outside of the FDA. The RACT oversees "virtual" teams that are formed to conduct a project. It also serves as a liaison to appropriate entities—federal, state, and local government; industry; consumer groups; and academia—in the planning of food safety risk analysis activities and related research, and it provides direction for the conduct and coordination of risk analysis activities related to food.
- In the Office of Food Safety, the Chemical Hazards Assessment Team conducts safety/risk assessments of industrial chemicals, both

[4] Personal communication, Chad Nelson, Office of Foods, FDA, September 3, 2009.

[5] Personal communication, Marianne Miliotis, Deputy Director, Office of Applied Research and Safety Assessment, CFSAN, FDA, April 21, 2009.

elemental and organic, including naturally occurring contaminants and allergens.
- The Economics Team in the Office of Regulations, Policy, and Social Sciences conducts analyses that are integrated with risk assessments, including economic impact analyses of decisions and cost–benefit analyses.
- The Division of Field Programs and Guidance in the Office of Compliance coordinates and provides oversight for risk-related initiatives that impact field work planning.
- Other offices at CFSAN that perform food safety assessments are the Office of Food Additive Safety and the Office of Nutrition, Labeling, and Dietary Supplements.

Risk-Based Activities of CVM

CVM also uses tools of risk ranking and risk assessment in its regulatory process (Hartogensis, 2009). CVM representatives stated that their risk management strategy is to prioritize activities aimed at reducing or mitigating risks according to the ranking of the risks and the limits of their authority and resources. However, CVM has not produced a document that delineates a standardized process for conducting risk assessments (or rankings) for potential contaminants in feed or specific guidelines for risk ranking or prioritization (Hartogensis, 2009). Only a few specific examples of CVM's risk-based activities were provided to the committee. Specifically, the Office of New Drug Evaluation, which reviews information on approvals to manufacture and market animal drugs, is also responsible for evaluating human health impacts that might result from the consumption of drug residues present in the tissues of food animals. To date, the committee is uncertain about the mechanism by which this evaluation is performed. In 2003, a group consisting of CVM officials, along with representatives from the Office of the Commissioner and state regulatory officials, announced the implementation of the Animal Feed Safety System (AFSS). This system represented the first step toward making the agency's animal feed safety program more comprehensive and risk based. To date, five public meetings to gather stakeholder input have been conducted, and this group is apparently developing a framework document describing the major processes, guidance, regulations, and policy issues entailed in addressing feed safety. As of this writing, however, the significance of the AFSS as applied to risk-based food safety management is unclear (Hartogensis, 2009).

Risk Analysis Products

Over the years, CFSAN and CVM have produced a variety of products related to risk analysis, including safety assessments, risk profiles, qualitative and quantitative risk assessments, and risk–benefit analyses. Perhaps the most comprehensive effort in this regard is the joint FDA (CFSAN)–USDA (FSIS) *L. monocytogenes* risk-ranking (assessment) model development mentioned earlier. Although the second iteration of this model was completed in 2003 (CFSAN/FSIS, 2003), action plan items are still being developed and implemented (CFSAN, 2008). Another notable risk assessment activity included evaluation of *Vibrio parahaemolyticus* risks associated with oyster consumption (FDA, 2005). In addition, the agency provides a high level of support to international organizations, such as the Food and Agriculture Organization/WHO and the Codex Alimentarius Commission, which have produced their own risk assessments. The FDA has also used others' risk assessments in formulating regulations, such as the Shell Egg Rule, for which USDA's "Risk Assessments for *Salmonella Enteritidis* in Shell Eggs and *Salmonella* spp. in Egg Products" was used. Similarly, the U.S. Environmental Protection Agency's risk assessments have been applied by the FDA for management of chemical contaminants in the food supply.

A complete review of all food safety risk analysis activities with which the FDA has been involved is beyond the scope of this report. However, three new approaches described by FDA representatives during the public workshop held March 24, 2009, are worth discussing.

Public Health Risk Ranking

Under an FDA cooperative agreement, the Institute of Food Technologists convened a panel of experts to develop a risk-ranking prototype designed to analyze data on hazards (both chemical and biological) in food and return an estimate of the resulting health burden at a population level. Termed the iRisk model, this is a bottom-up or predictive modeling approach to risk ranking that requires the application of data and expert judgment to assemble sufficient information with which to predict the ecology of the hazards in the food supply. These results are combined with food intake data and information on hazard virulence or toxicity to produce a prediction of the relative level of risk to human health of the particular hazard–food pair. The model produces a semiquantitative characterization of the disease burden, which can be used for comparison (ranking) purposes and can facilitate evaluation of the impacts of hazard control measures. The model was further developed by Risk Sciences International, a consulting company, into a web-accessible tool. RTI International is currently populat-

ing the iRisk model with data for proof-of-concept testing; Risk Sciences International is revising the model to improve its performance with respect to a variety of features (Wagner, 2009).

Risk-Based Inspection

Much like FSIS, the FDA has been developing models to assist in the allocation of inspectional resources, sometimes referred to as "risk-based inspection" (Engeljohn, 2009; Maczka, 2009). For example, CFSAN's Division of Field Programs and Guidance, which is responsible for developing tools to assist the Office of Regulatory Affairs (ORA) in resource management, has been working on the identification of high-risk food categories to support the targeting of field inspections and sample collection resources as applied to domestic food products and manufacturers. This effort began in 2002 as a simple document based on expert opinion from CFSAN technical experts. By 2008, a risk-based domestic priorities list had been developed for ranking particular product–hazard combinations and facilities (Wagner, 2009). The model appears to utilize such information as the occurrence of multiple hazards, the potential for fatal illness outbreaks, consumption by all segments of the population, and conditions under which the hazard is likely to occur. For ranking purposes, risk is considered a function of the likelihood of a hazard in a product and the severity of the health effect.

CFSAN also performed a risk-ranking exercise on food manufacturers based on their association with Class I recalls,[6] outbreaks, or serious adverse events during 2004, 2005, and 2006. The statistical analysis resulted in a scoring algorithm that was applied to each of the individual food firms. For fiscal year (FY) 2010, the FDA intends to design an updated version of the 2009 algorithm that will be overlaid with compliance history information for specific facilities. In the future, criteria such as the financial viability of the firms and their legal status may also be included as ranking criteria (Givens, 2009; Wagner, 2009).

ORA has reported prioritizing its inspectional resources for FY 2009 based on three categories: category 1, high-risk firm inspections; category 2, inspected plants with compliance issues; and category 3, low-risk industry blitzes. Likewise, CVM is in the process of changing its allocation of inspectional resources so that the resources are allocated in alignment with more objective ranking criteria for the various areas of each program (Hartogensis, 2009). The CVM efforts, which appear to be focused on medicated feeds, are still being developed in conjunction with AFSS; the committee was provided with only limited details.

[6] A Class I recall denotes a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

Risk-Based Management of Imported Foods

The FDA recently embarked on the development of a risk-based approach to managing the safety of food imports, which culminated in the release of the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) model (see also Appendix E). PREDICT is an import screening tool that is intended to automate decisions currently made by import entry reviewers by utilizing intelligence information from numerous sources so as to direct resources to products presenting the greatest risks to public health in a streamlined manner. Criteria such as information about recalls, registration of low-acid canned food processes, agreements with other countries, monitoring of products, and information on certification of facilities and from import certificates are used to calculate a risk score upon which decisions about a food import shipment are based. After a pilot study in June 2007 that the FDA judged to be successful, the agency estimated that PREDICT would be widely implemented by September 2009 (Solomon, 2009).

Food Safety Performance Measures

The Healthy People food safety goals could theoretically serve as the basis for the identification of specific performance measures. However, these goals now use such words as "reduce" and "improve," which cannot serve as metrics per se. Other targets and indicators for measuring the performance of the federal food safety system have been recently described. For example, the U.S. Department of Health and Human Services (HHS) has identified some food safety–related outcome indicators in its strategic plan (see Box 3-3). Elements of the 2004 FDA Program Assessment Rating Tool (PART) report and progress on implementation of the Food Protection Plan also can be used to identify some performance measures. PART was introduced in 2002 to standardize the measurement of performance in federal agencies, with the intent of linking performance to budgets (Gueorguieva et al., 2009) (see also Chapter 2). Presented by the Office of Management and Budget as a tool for implementing the GPRA, PART assesses GPRA performance strategies and goals, albeit to a limited extent. The GPRA requires that agencies demonstrate accountability and the effectiveness of programs to Congress and the public by establishing performance measures. PART has been described as applying a different level of analysis than the GPRA, conflicting with the GPRA regarding what to measure and how to measure it (GAO, 2005) and having serious limitations and questionable reliability (Radin, 2006; Gueorguieva et al., 2009). More specific to the FDA's food protection efforts, the agency's 2010 budget justification for implementation of the Food Protection Plan (FPP) includes several long-term objec-

BOX 3-3
Food Safety–Related Outcome Indicators Listed Under "Other Outcome Indicators," U.S. Department of Health and Human Services' Strategic Plan (2009)

1. Reduce the incidence of infection with key foodborne pathogens: *Campylobacter* species. 2010 12.3 cases/100,000 by December 2011.
2. Reduce the incidence of infection with key foodborne pathogens: *Escherichia coli* O157:H7. 2010 1.0 cases/100,000 by December 2011.
3. Reduce the incidence of infection with key foodborne pathogens: *Listeria monocytogenes*. 2010 0.24 cases/100,000 by December 2011.
4. Reduce the incidence of infection with key foodborne pathogens: *Salmonella* species. 2010 6.8 cases/100,000 by December 2011.

tives and associated measures (see Box 3-4). Overall, these objectives and measures focus on numbers of outputs, voluntary outcomes, and indirect measures of capacity to achieve public health, and hence they might be considered potentially useful metrics of performance. Recent progress reports on the implementation of the FPP also describe a wide variety of outputs (e.g., numbers of public meetings and workshops, technical guidance and rules issued, foreign offices established, memorandums of understanding, cooperative and interagency agreements).

COMPARISON OF THE CURRENT FDA APPROACH TO RISK MANAGEMENT AGAINST THE VISION AND ATTRIBUTES OF A TRUE RISK-BASED DECISION-MAKING APPROACH TO FOOD SAFETY MANAGEMENT

Based on the information presented in public meetings and conversations with FDA staff and other publicly available information, the committee concluded that the agency currently is not practicing some aspects of a systematic risk-based food safety management approach with the attributes identified in Box 3-1. The agency has embraced the tool of risk assessment, and it should be commended for doing so. The development of the risk-ranking/assessment model for *L. monocytogenes* mentioned above is a notable example of a comprehensive risk assessment produced in cooperation with another food safety agency and with stakeholder involvement.

BOX 3-4
Objectives Listed in the U.S. Food and Drug Administration's (FDA's) 2010 Congressional Budget Justification for Food

Long-Term Objective: Increase access to safe and nutritious new food products.

Measure 213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, including petitions for food contact substances, within 360 days of receipt. (Output)

Long-Term Objective: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.

Measure 214101: Number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards. (Outcome)

Measure 214102: Percentage of the enrolled jurisdictions which meet 2 or more of the Standards. (Outcome)

Long-Term Objective: Provide consumers with clear and timely information to protect them from foodborne illness and promote better nutrition.

Measure 212401: Increase by 40 percent the percentage of American consumers who correctly identify that trans fat increases the risk of heart disease. (Outcome)

Measure 212402: Increase by 10 percent the percentage of American consumers who correctly identify that saturated fat increases the risk of heart disease. (Outcome)

It appears that in general, the agency's microbial risk assessments have been performed in accordance with well-recognized standards (FAO/WHO, 2006; NRC/IOM, 2009).

However, the production of risk assessments and profiles alone does not constitute a risk-based food safety management system. The FDA does not employ the stepwise process outlined above, and it does not appear to have any strategic vision for a risk-based system. The fact that risk-based ranking and inspection models are under development and in various stages of implementation is commendable, but the use of these tools does not imply that a comprehensive risk-based approach is being pursued.

Measure 212403: Improve by 10 percent the percentage of American consumers who correctly identify that omega-3 fat is a possible factor in reducing the risk of heart disease. (Outcome)

Long-Term Objective: Detect safety problems earlier and better target interventions to prevent harm to consumers.

Measure 214201: Number of prior notice import security reviews. (Output)
Measure 214202: Number of import food field exams. (Output)
Measure 214203: Number of Filer Evaluations. (Output)
Measure 214204: Number of examinations of FDA refused entries. (Output)
Measure 214205: Number of high-risk food inspections. (Output)
Measure 214206: Maintain accreditation for Office of Regulatory Affairs labs. (Outcome)
Measure 214303: Convert data from new Electronic Laboratory Exchange Network (eLEXNET) participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange. (Outcome)
Measure 214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply (radiological and chemical samples/week). (Outcome)

NOTE: "Output" and "Outcome" designations appear in the Budget Justification.

The absence of a strategic vision to embrace and implement a risk-based food safety management system is apparent at almost every level. Despite many counterexamples, the relative lack of strategic planning and incorporation of appropriate metrics for evaluating the efficacy of food safety control strategies illustrates the point well. For example, although the latest PART report[7] for the FDA, produced in 2003, resulted in a performance rating of "moderately effective," the report does not mention any direct public health

[7] See http://www.whitehouse.gov/omb/expectmore/detail/10001057.2003.htm (accessed October 8, 2010)

measures for food safety. Of the ten long-term performance goals[8] adopted by the FDA in 2003, the report includes only one that pertains directly to food safety: "increase laboratory surge capacity in the event of a terrorist attack on the food supply." In this case, it is unclear from the report how the specific targets (i.e., radiation and chemical contamination) for surge capacity were identified. In a similar manner, the recent FPP reports do not appear to map progress to metrics, and the 2010 FDA Congressional Budget Justification for the FPP does not appear to map directly to the plan's eight goals. Perhaps most notable, the FDA's 2010 Congressional Budget Justification for Food (Box 3-4) identifies objectives that are not necessarily consistent with the food safety goals proposed for Healthy People 2020 (Box 3-2), and specific metrics for the agency to use in measuring performance in food safety are not identified, with the exception of the few food safety outcome measures stated in the 2009 HHS Strategic Plan (Box 3-3). Briefly, it is not clear that efforts to identify performance measures for food safety or public health are linked to strategic goals as recommended by this committee.

Also, the measures identified in the FPP, the HHS Strategic Plan, and Healthy People 2020 fall short of suggested standards for performance indicators and systems (see, for example, the recommendations in Bird et al., 2005). GAO reports and other assessments suggest that performance indicators have been underutilized to improve agencies' decision making in the last decade (Cavalluzzo and Ittner, 2004; GAO, 2009a; Taylor, 2009). Among the obstacles to effective use of performance measurement are ambiguous goals and objectives, a lack of commitment to performance measurement on the part of top management, and inadequate measurement and analysis systems (Cavalluzzo and Ittner, 2004; Johnsen, 2005; Taylor, 2009). Overall, the committee found that the FDA and HHS have made limited progress toward establishing and applying performance measures, particularly those related to public health outcomes, as part of a risk-based food safety system.

Most of the other attributes of a risk-based food safety management system (e.g., public health risk ranking, prioritization for resource allocation, transparency in risk management, effective and frequent communication with stakeholders) are all but absent from the FDA's current approach to food safety. For example, well-articulated management objectives were not delineated when the iRisk model was presented to the committee. Likewise, the committee was not provided with additional details on the PREDICT model, which should undergo extensive peer review before being deployed

[8] Examples of such nonfood safety–related long-term goals laid out in PART include that the FDA shall "[i]ncrease by 40 percent the percentage of American consumers who correctly identify that trans fat increases the risk of heart disease" and "[r]educe the average time for marketing approval for safe and effective new devices."

in the field. Of interest, it was apparent during the workshop held on March 24, 2009, that stakeholders were unaware of many of the FDA's more recent risk-ranking/prioritization efforts, including its plans for a risk-based inspection system or the development of PREDICT as a risk-based tool to manage food imports (Bell, 2009; Gombas, 2009; Scott, 2009). Consistent with a recent report (USDA, 2010), the committee concluded that improvement of the agency's risk-based approach is also needed in the area of preventing risk from chemical contaminants.

The area of risk communication also remains a challenge. In general, the committee found a lack of transparency in the FDA's food safety activities and insufficient communication with stakeholders. Examples include insufficient description of risk-based initiatives and use of peer-review. Although the FDA's Risk Communication Advisory Committee (RCAC) was recently created to advise the agency on communication strategies and programs, and the FDA has created an internal Communication Committee to coordinate its communication activities, prioritizing and evaluating risk communication efforts remain a challenge (Chapter 9). During its August 2009 meeting, the RCAC discussed the FDA's research on consumer knowledge of food recalls and plans for monitoring the effectiveness of communication during recalls. An integrated risk-based management system should enable the FDA to target, design, and evaluate its risk communication more effectively (Morgan et al., 1992).

IMPLEMENTATION OF A RISK-BASED FOOD SAFETY MANAGEMENT SYSTEM

Implementation of a risk-based food safety management system will be successful only if the necessary resources are dedicated to the effort. It should be clear from the preceding discussion that this will be a substantial undertaking. Virtually all of the recommendations in this report can and perhaps should be adopted with the stated purpose of supporting a risk-based approach to food safety management. Nonetheless, the committee has identified a few areas that it considers particularly critical to the successful implementation of a risk-based system, which are discussed below.

Personnel and Analytical Tools

There is a tendency on the part of government agencies, including the FDA, to assume that scientists are interchangeable: that individuals trained to conduct bench experiments in microbiology, for example, can easily be shifted to performing risk assessment or crisis management. It is essential that new scientific staff be acquired to provide the core competencies necessary to create a new, risk-based approach for the agency. The committee

recognizes the difficulty of finding individuals trained in the breadth and depth of food safety problems who are also proficient in epidemiology, mathematical modeling, economics, or other disciplines necessary to support a risk-based approach. Academic institutions do not typically configure their programs with the necessary training to prepare students to be a part of a risk management team. Accordingly, it may be necessary to initiate agencywide recruitment and training efforts to train professionals in the skills necessary to support a risk-based approach. A good example of this sort of initiative is the new FDA Commissioner's Fellowship Program.

Further, the body of FDA scientists must be able to support both management of crises at the time they occur and prevention of future crises. To ensure that all of the FDA's responsibilities are met, resources need to be allocated for both routine operations and prevention of long-term food safety problems. While, as recommended here, a risk-based approach is institutionalized over time, the FDA should continue to attend to more immediate issues. The committee found disturbing various testimony confirming that during an emergency, work is redirected, and the FDA's focus on prevention and long-term efforts receives lower priority. To alleviate this situation and to advance the FDA toward a risk-based regulatory approach, experts will need to be hired in the areas recommended by the committee.

To carry out all its food safety responsibilities and specifically to ensure continuation of everyday operations, then, the FDA's food programs must include sufficient staff working on food issues to ensure that routine functions will continue even when a crisis emerges. A logical way to address this need is to form functional teams that would work in defined areas identified during the strategic planning process. Many of these teams could support efforts to manage the identified risk-based priorities with a focus on prevention. For example, there could be a Research Team, whose major function would be to support the high-priority research necessary to support the risk-based mission. Likewise, a Surveillance Team would be responsible for interacting with other federal agencies and state and local jurisdictions and for managing centralized epidemiological databases supporting modeling efforts. Similarly, there might be a Risk Assessment Team, a Risk Communication Team, and a Risk Management Team. Recognizing the need for continuous support of the crisis management function, it could be appropriate to have a separate team dedicated to this function. However, crises must not be allowed to preempt a substantial part of the effort allocated to essential noncrisis activities.

Alternatives to the development of agency competency to build and operate a risk-based food safety system are discussed in Chapter 11. One option is to create a centralized risk-based analysis and data management center, which would provide a multiagency and multidisciplinary core of expertise in risk analysis for all agencies with responsibilities for food safety.

This center would mirror the European model, in which such expertise is often housed in quasigovernmental research institutes (such as the National Institute for Public Health and the Environment in the Netherlands) that assist in data collection and provide independent analyses of incoming data for policy makers. Such a center would not subsume an agency's prerogative to develop food safety policy, and there would remain a need for analytic capacity at the top level of agencies, such as the FDA, with responsibility for food safety. However, the center's creation would eliminate the need for each agency involved in food safety to develop its own comprehensive expertise in risk analysis independently. As discussed in Chapter 11, a longer-term alternative would be the creation of a unified national food safety agency, which, as part of an overall consolidation of food safety activities (possibly though an intermediate office of food protection) would integrate the risk-based efforts of the multiple agencies currently involved in food safety.

Closely related to the personnel issue is the need for targeted research activities to permit the development of the information infrastructure required to support risk-based food safety management (see Chapter 5). At a basic level, the software needs for these activities are daunting, as most risk-modeling tools are not off-the-shelf software but highly customized. The FDA, alone or in collaboration with other agencies, must commit the resources required for the applied research needed to develop and test software and computer systems that are integral to infrastructure development. Again, the agency may want to support the creation of a risk-based analysis and data management center that would provide these services across all agencies involved in food safety.

Foodborne Disease Attribution Data and Models

The IOM/NRC report *Scientific Criteria to Ensure Safe Food* states that "science-based food safety criteria must be clearly linked to the public health problem they are designed to address. To accomplish this, a cause/effect relationship needs to be established between contaminants in foods and human disease, that is, to allocate the burden of foodborne disease among foods and food groups" (IOM/NRC, 2003, p. 250). This statement forms the basis of what is now referred to as foodborne disease attribution, defined as "the capacity to attribute cases of foodborne disease to the food vehicle or other source responsible for illness" (Batz et al., 2005, p. 993; EFSA, 2008, p. 5). While the concept is valuable, the committee recognizes the lack of truly reliable attribution data and the somewhat limited scope of this definition. A description of the current sources of foodborne disease attribution data as well as approaches to foodborne disease attribution and their advantages and limitations as reported by a recent NRC committee are summarized in Box 3-5 and Table 3-2, respectively. It is clear that substantially more

BOX 3-5
Sources of Foodborne Disease Attribution Data

Data on foodborne disease attribution generally come from three major sources: (1) outbreak reports, (2) case control studies, and (3) source tracking.

Outbreak Reports: Outbreak investigations have traditionally served as the primary means of identifying food sources for pathogens. When outbreaks are carefully investigated, such data can be extremely valuable. In the United States, however, almost all outbreak investigations are conducted by local health departments, which tend to be overworked and to lack either the laboratory or epidemiologic resources to identify a source. There are significant biases involved in the choice of which outbreaks get investigated (generally those that are large or involve an "interesting" pathogen), and the percentage of outbreaks reported and investigated ranges widely both among and within states. Outbreaks may also not be representative of routine foodborne disease cases: they generally represent a significant breakdown in food practices rather than the endemic pattern of transmission of pathogenic microorganisms. There are issues with timeliness as well: the U.S. Centers for Disease Control and Prevention tends to compile data from outbreak reports only on a sporadic basis, which often results in multiple-year gaps between reporting of national summary data. The United Kingdom has tended to rely on outbreak data in its food attribution/food safety efforts; however, its data collection is more standardized than that of the United States, without the wide variability in reporting from local health department to local health department (Batz et al., 2005).

Case Control Studies: When FoodNet was first established, the importance of food attribution in the calculation of food-specific incidence rates was recognized. Consequently, the system was designed to include ongoing case control studies to identify specific foods/food groups that might be consumed more commonly by ill persons infected with a specific

resources will be needed for further characterization of foodborne disease attribution in support of risk-based food safety management.

Simply knowing the proportion of the occurrence of a particular disease that is associated with a specified hazard is not enough. For example, contamination and agent proliferation (and inactivation) can occur at all stages throughout the food chain. There is a need for attribution estimates across the chain—for example, what proportion of salmonel-

pathogen than by well controls. Under the FoodNet program, six case control studies have been conducted. While many have yielded useful epidemiologic data (Friedman et al., 2004; Marcus et al., 2007; Varma et al., 2007), it has become apparent that this is not an effective means to determine attribution percentages: it is expensive and labor intensive, and it yields only crude estimates of the relative contribution of various food categories to disease incidence. Concern has also been raised about possible biases inherent in the selection control process (which has generally involved random digit dialing techniques).

Source Tracking: Food safety agencies in the Netherlands and Denmark have pioneered work in the source tracking of pathogens, that is, using molecular markers/typing to link human disease with animal sources. The process requires careful monitoring of isolates from food animals, with appropriate typing, and application of identical typing methods for human isolates. Data are then entered into models that permit real-time calculation of the relative public health impact of various food–pathogen combinations. These data have been used effectively, particularly in the Netherlands, to guide regulatory actions designed to deal with new and emergent problems in the national food safety system. However, this work has dealt almost exclusively with animal sources for pathogens; virtually no work has been done with pathogen contamination of produce, and produce generally has not been included in the source-tracking models. In the United States, some initial efforts were made to develop such a system, focusing primarily on salmonella. However, results have not been impressive, in part because of the incompatibility of data sets (and lack of data sharing). The U.S. Food and Drug Administration has sponsored intramural research on molecular-typing methods that might be utilized in these systems, but to date, efforts to develop appropriate risk models have not led to useful results.

losis cases attributable to the consumption of contaminated leafy greens is associated with poor personal hygiene practices of food handlers versus preharvest contamination on the farm? Likewise, because agents can be transmitted by multiple routes, more defined data on transmission are needed—for instance, what proportion of human norovirus infections is attributable to foodborne routes as compared with person-to-person transmission? These are simply examples of important questions about

TABLE 3-2 Summary of Approaches to Food Attribution

Approach	Data Needs	Advantages	Limitations	Examples
Foodborne disease surveillance Based on the use of aggregate data from epidemiologic investigation of outbreaks.	Coordinated surveillance systems with similar data collection efforts throughout a specified location, region, or country. Takes many years to accumulate sufficient data. Must include food vehicle information.	Usually applied to multiple foods and pathogens. Outbreak data are a measure of attribution at the point of consumption. Able to take into account other routes of transmission (such as travel, contact with animals). Addresses a broad range of microbes and foods. Data are collected routinely on a national basis for a large number of pathogens over many years.	Assumes equivalence of pathogen-specific contributions of each food type to disease. Adequately classifying multicomponent foods is challenging. Serious gaps in databases exist.	Batz et al., 2004; Adak et al., 2005; DeWaal et al., 2006
Case control study Analytic epidemiologic study that compares diseased (cases) with nondiseased (controls) persons with respect to previous exposures; relative role of exposure is determined by comparing frequencies in cases and controls.	Systematic review of published case control studies and case series to identify relevant risk factors for disease; calculation of population-attributable risk to estimate relative importance of different exposures.	Identification of sources of sporadic infections. Classic strengths of case control study design, including ability to explore multiple exposures (specific foods, food preparation practices, cross-contamination, travel, other risk factors).	Classic weaknesses of case control studies, including misclassification, recall bias, limited resolution for commonly consumed foods, establishment of temporality. Many cases required for adequate statistical power. Usually limited to a single microorganism rather than multiple agents. Expensive.	Multiple examples, but specific applications to food attribution are sparse (see EFSA, 2008)

Microbial subtyping Based on a combination of strain typing collated with epidemiologic surveillance data and mathematical modeling; underlying hypothesis is that control of ultimate reservoir (usually occurring before harvest) will prevent human exposure.	Integrated, active surveillance of most major sources (food, animals); reliance on extensive collection of representative strains for comparison; information on amount of animal or food product available for consumption.	Best suited to pathogens that are clonally disseminated through the food chain. Useful in identifying original reservoir and setting priorities for interventions when contamination occurs during production.	Usually applied to a single pathogen. In current use, but not well suited to organisms that have relatively unstable DNA. Does not take into account effects of other contamination risk factors (such as human handling, cross-contamination). Assumes equivalence of relative pathogen-specific contribution of each food type to disease. Expensive. Requires extensive libraries of isolates from a range of foods or reservoirs.	van Pelt et al., 2003; Hald et al., 2004, 2007
Quantitative microbial risk assessment Yields mathematically derived estimates of risk.	Information on estimates for parameters to use in modeling and uncertainty distributions for estimates; logic model of how parameters are related to each other.	Allows a high level of detail with respect to specific food commodities. Theoretically, can integrate data obtained from national surveillance programs.	Serious data gaps. Substantial uncertainty (should be accompanied by uncertainty analysis). Resource intensive.	CFSAN/FSIS, 2003 (*Listeria monocytogenes*); Evers et al., 2008
Expert elicitation Experts combine and weigh data from different sources to estimate attribution.	More explicit, structured, quantitative methods (including well-calibrated methods and performance-based weighting) are being used and are increasing resolution and transparency.	Best suited to filling in data gaps. Able to combine information from multiple sources (different experts with different knowledge bases).	Subjective in nature. Potential for bias (based on respondent background, personal bias), although use of structured approaches decreases bias. Best methodological approaches (calibrated, highly structured) require a high degree of expertise and are resource intensive.	Hoffmann et al., 2007a,b; Havelaar et al., 2008

SOURCE: NRC, 2009b.

attribution that must be answered if food safety risks are to be understood and characterized.

Foodborne disease attribution data and models are essential to support a risk-based food safety management approach. They directly support Steps 1 (strategic planning), 2 (public health risk ranking), and 6 (monitoring and review); they also support the other steps of the process indirectly. From a planning perspective, for example, risk ranking must be based on the hazard–food combinations that generate the greatest burden of disease and/or the most significant negative impact on public health. It is difficult to perform such risk ranking without reliable foodborne disease attribution data. Similarly, it is difficult to evaluate and implement risk-based intervention approaches without knowing the most likely means by which a contaminant enters the food chain or which specific practices contribute to its proliferation and/or inactivation. Finally, in monitoring and reviewing the efficacy of risk management strategies that have already been implemented, it is necessary to determine whether public health objectives are being met. Attribution is a logical metric in this regard, perhaps the most important one, as a reduction in the burden of disease associated with a specific food–hazard combination provides the best evidence that interventions are working. The availability of comprehensive epidemiological attribution data also aids in transparency. In short, solid epidemiological attribution data form the cornerstone of risk-based prioritization, management, and evaluation.

KEY CONCLUSIONS AND RECOMMENDATIONS

The committee defined a risk-based food safety management system as "a systematic means by which to facilitate decision making to reduce public health risk in light of limited resources and additional factors that may be considered." The committee went on to define the key attributes of such a system and produced a stepwise approach to its design. The committee recognizes that some of the variables to be considered in models used to rank risks from imported foods will be different from those considered for domestic foods. Variables for models used to rank intentional contamination will be different as well. However, the committee believes the recommended risk-based approach is broad enough to apply to all hazards, whether intentionally introduced or not, and to all foods, whether domestically produced or imported. The committee recognizes that this comprehensive risk-based approach is a relatively new concept that will take time and resources to implement.

While the committee commends the FDA for recent steps taken and progress toward risk ranking and prioritization described in this chapter, the FPP falls short of providing a comprehensive vision for a risk-based food safety management system. Much of the agency's current decision-

making process appears to be based on crisis management rather than a systematic preventive approach. Furthermore, although the FDA states in many of its documents that it operates under a risk-based framework, many of the attributes of a risk-based system that the committee regards as necessary (in particular, strategic planning, comprehensiveness, transparency, external review of risk assessment and intervention analysis programs, and risk communication) are not sufficient in the agency's current approach. The resources (personnel, data, models) necessary to design and support a risk-based food safety management system are extensive, and the FDA does not have the human capacity, data infrastructure, or organization to support such a function at the present time. The provision of these resources is essential to the success of the FDA's future food safety risk management activities.

The committee offers the following recommendations to enhance the management of food safety at the FDA.

Recommendation 3-1: The type of risk-based food safety approach outlined by the committee in Box 3-2 should become the operational centerpiece of the FDA's food safety program. This approach should be embraced by all levels of management and should serve as the basis for food safety decision making, including prioritization of resources dedicated to all agency functions (e.g., inspections, promulgation of regulations, research). This approach should be applied to all domestically produced and imported foods and to all food-related hazards, whether due to unintentional or intentional (i.e., with intent to harm) contamination. The FDA should work with local, state, and national regulatory partners to facilitate the incorporation of these principles into their programs.

Recommendation 3-2: The FDA should develop a comprehensive strategic plan for development and implementation of a risk-based food safety management system. The agency should also develop internal operating guidelines for the conduct of risk ranking, risk assessment, risk prioritization, intervention analysis, and the development of metrics with which to evaluate the performance of the system. The strategic plan and guidelines should include descriptions of data, methodologies, technical analyses, and stakeholder engagement. Further, the strategic plan and all guidelines for the risk-based system should be fully supported by the scientific literature and subjected to peer review. When appropriate, the FDA should adopt guidelines already established by other federal agencies or international organizations.

The following recommendations encompass essential steps that need special attention in the implementation of a risk-based approach.

Recommendation 3-3: The FDA, in collaboration with partners, should identify metrics with which to measure the effectiveness of the food safety system, as well as its interventions. The FDA should include these metrics, and plans for any related data collection, as part of strategic planning. The metrics should have a clearly defined link to public health outcomes.

Recommendation 3-4: The FDA should identify expertise needed to implement a risk-based approach. This includes training current and/or hiring new personnel in the areas of strategic planning; management of data; development of biomathematical models and other tools for risk ranking, prioritization, intervention analysis, and evaluation; and risk communication.

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4

Sharing the Responsibility for a Risk-Based System: Models of Governance and Oversight

The safety of the U.S. domestic and imported food system is a responsibility shared by suppliers, farmers, food handlers, processors, wholesalers and retailers, food service companies, consumers, third-party organizations, and government (federal and state) agencies in the United States and abroad. Given the size and scope of the system, it is unrealistic to expect the U.S. Food and Drug Administration (FDA), or any agency at the federal level, to be everywhere and to do everything necessary to ensure food safety through surveillance and inspection without the help of those who share this responsibility.

The design of approaches to governance to achieve society's goals has been the subject of much debate and experimentation in a wide range of areas, from the financial system to public safety. The published literature on the subject addresses the pros and cons of various approaches to sharing responsibility, factors to be considered, and lessons learned from the implementation of these approaches. Models of governance that deviate from the traditional enforcement of rules through the imposition of penalties include voluntary approaches whereby regulators work with industry to develop codes of practice, third-party audits, management-based systems in which firms are responsible for adhering to plans that limit harms, and performance-based approaches that emphasize results rather than the use of specific technologies or actions. These alternatives may serve to distribute accountability across all parties that might affect outcomes.

Innovative governance approaches have already been applied to the environment, building safety, consumer product safety, nuclear power plant safety, transportation safety, and health care, among many other areas, with

BOX 4-1
Examples of the Use of Alternative Governance Approaches

Nuclear Power Safety

Before the Nuclear Regulatory Commission (NRC) focused attention on issues essential to protecting public health, the Atomic Energy Commission was often criticized for its dual role in protecting public health while also avoiding imposing requirements that would inhibit the growth of the industry. With respect to nuclear reactors, the NRC took the traditional approach of creating standards and requirements to protect public health, eventually giving operators the sense that accidents would be prevented as long as compliance with these standards and requirements was verified by an inspector. This traditional prescriptive approach, however, was criticized as being unable to promote uniform levels of safety. The NRC then moved toward a risk-based system, whereby accountability is placed on the operator's side. However, the Government Accountability Office has noted major challenges to the success of this system, including the need to encourage a shift to a culture of safety, significant human capital needs and costs, and methodological challenges (GAO, 2006).

British Railway System

Potential limitations of implementing novel governance approaches in the health and safety arena may be evident in the experience of the British railway system. Hutter (2001) suggests that such a move may have led to breaches in public safety. Often, a self-regulatory regime is seen as a superior governance model in that it relies not only on government accountability, but also on the capacity of corporations to regulate themselves and develop systems tailored to their specific operations. Innovation is encouraged, and companies are more likely to follow their own rules than rules imposed on them. Hutter argues that in the case of the railway industry in Britain, enforced self-regulation was not appropriately monitored and ended up being itself the source of risk. In fact, the self-regulation was more procedural than substantive; although rules were in place, they were not well understood. Lack of communication was a major explanation for the failure of the system in a company that was fragmented functionally and geographically.

both failure and success. Examples are presented in Box 4-1. These examples illustrate that developing criteria for selecting a governance approach, making the selection, and evaluating performance outcomes are essential activities for regulatory agencies. These two examples are but a small sampling of the many models of regulation and oversight that exist, and the

selection of the most appropriate model for specific circumstances is a subject of active debate. Even within the area of food safety, several different models of governance are evolving worldwide (Batz et al., 2005; Garcia-Martinez et al., 2007; Treasury Board of Canada Secretariat, 2007).

Chapter 3 describes the elements that are essential to the operation of a risk-based food safety system, as concluded by the committee. A governance model for the FDA must articulate criteria for deciding who is responsible for overseeing the various elements, for choosing and implementing policy interventions, and for evaluating the performance of the system. Defining the nature and range of shared responsibility is central to implementing several of these elements. This need for clearly reasoned models for shared responsibility and oversight is the subject of this chapter. The chapter reviews approaches to making governance decisions and developing a regulatory philosophy, as well as choosing policy interventions and assigning responsibility. The discussion includes the committee's observations on how the FDA selects models of governance.

OVERALL APPROACH TO MAKING GOVERNANCE DECISIONS AND DEVELOPING A REGULATORY PHILOSOPHY

The Food Protection Plan (FPP), written in 2007 under the leadership of the Office of Food Protection, contains the FDA's general philosophy with respect to food safety and focuses on what the agency considers to be the core elements of food safety: prevention, intervention, and response (see Box 4-2). The FPP also outlines the following four cross-cutting principles for a comprehensive food protection approach: (1) focus on risks over a product's life cycle from production to consumption, (2) target resources to achieve maximum risk reduction, (3) address both unintentional and deliberate contamination, and (4) use science and modern technology systems. To operationalize these elements and principles and to strengthen its ability to protect Americans from foodborne illnesses, the FDA proposes internal administrative changes and recognizes the need to make legislative changes (Box 4-3). The FPP is a platform for initiating a transformation at the FDA, whereby policy decisions are based on prevention and risk. However, it does not provide detail on how the principles it outlines will be achieved. The committee supports the findings of the U.S. Government Accountability Office (GAO) (GAO, 2008a,b) that the plan does not offer specific strategies for many of the actions proposed. For example, although it refers to risk-based inspections, detail on analytical risk models or even factors that will be considered in developing such models is absent. The terms "risk" and "risk-based approaches" are understood in different ways, underlining the importance of detailed articulation of such factors. Indeed, Chapter 3 explains the importance of a regulatory agency's delineating in detail a broad strategic

BOX 4-2
Three Core Elements of Food Safety in the U.S. Food and Drug Administration's Food Protection Plan

Prevent foodborne contamination:
- Promote increased corporate responsibility to prevent foodborne illnesses.
- Identify food vulnerabilities and assess risks.
- Expand the understanding and use of effective mitigation measures.

Intervene at critical points in the food supply chain:
- Focus inspections and sampling based on risk.
- Enhance risk-based surveillance.
- Improve the detection of food system "signals" that indicate contamination.

Respond rapidly to minimize harm:
- Improve immediate response.
- Improve risk communications to the public, industry, and other stakeholders.

approach that explains its philosophy, that is, the factors it will weigh in making decisions about prioritization of efforts, allocation of resources, and selection of interventions. The committee concluded that the FPP should be supported by the kind of detailed strategic planning (both broad and specific) outlined in Chapter 3. To illustrate this shortcoming, this section describes the committee's understanding of the FPP's vision for the responsibilities of different parties involved in food safety and how it could be improved.

As part of the strategic planning process (Step 1 in the risk-based system described in Chapter 3), the responsibilities of all parties in achieving the desired level of food safety must be articulated. Because these responsibilities will vary with the situation, and new situations are always arising, there must also be a road map for assigning responsibilities based on a defined set of factors. These elements of a risk-based system constitute an agency's regulatory philosophy.

The FPP makes several statements about the responsibilities of different parties in the food safety system. A major plank of its prevention strategy is a call for promoting increased corporate responsibility to prevent foodborne illness. The plan notes that examples of enhanced corporate responsibility might include "evaluating safety and security vulnerabilities and possible impacts; when appropriate, implementing preventive measures—

BOX 4-3
Additional Protections That Involve Legislative Changes to the U.S. Food and Drug Administration's (FDA's) Authority

Prevent foodborne contamination:
- Allow the FDA to require preventive controls to prevent intentional adulteration by terrorists or criminals at points of high vulnerability in the food chain.
- Authorize the FDA to institute additional preventive controls for high-risk foods.
- Require food facilities to renew their FDA registrations every 2 years, and allow the FDA to modify the registration categories.

Intervene at critical points in the food supply chain:
- Authorize the FDA to accredit highly qualified third parties for voluntary food inspections.
- Require a new reinspection fee from facilities that fail to meet current Good Manufacturing Practices.
- Authorize the FDA to require electronic import certificates for shipments of designated high-risk products.
- Require a new food and animal feed export certification fee to improve the ability of U.S. firms to export their products.
- Provide parity between domestic and imported foods if FDA inspection access is delayed, limited, or denied.

Respond rapidly to minimize harm:
- Empower the FDA to issue a mandatory recall of food products when voluntary recalls are not effective.
- Give the FDA enhanced access to food records during emergencies.

both required and voluntary—to ensure that food is produced safely and securely; and developing a contingency plan to aid in a response in the event of contamination" (FDA, 2007a, p. 14). The plan states that an increased emphasis on prevention "will require close interaction with growers, manufacturers, distributors, retailers and food service providers, and importers. These partners have the ability to implement preventive approaches and to require them of their suppliers" (p. 11).

The FPP also states that:

> [t]hose with the biggest stake in food safety, after the consumers who eat the food, are the people and companies who grow, process, and sell

> food. Their livelihood depends entirely on the confidence of their customers. A poor reputation for proper food handling can drive a company to bankruptcy. Promoting increased corporate responsibility is key in shifting FDA's food protection effort to a proactive rather than a reactive one. The FDA will seek partnerships with industry to enhance consumer confidence. FDA will continue to work with industry in a) developing food protection plans that address safety and defense vulnerabilities, b) implementing prevention steps, and c) developing contingency plans to improve response to an outbreak of foodborne illness. (p. 15)

In addition, the FPP supports exploring new roles for third-party certification as part of the overall system of food safety assurance. As to working with other responsible parties, the plan states:

> FDA will continue to work with industry, state, local, and foreign governments to further develop the tools and science needed to identify vulnerabilities and determine the most effective approaches. With regard to imports, FDA will also work with foreign governments, which have a greater ability to oversee manufacturers within their borders to ensure compliance with safety standards. (p. 11)

Finally, concerning consumer responsibility, the plan notes, "Consumers protect themselves and their families from foodborne illness by responding promptly to FDA alerts" (p. 23).

The above statements indicate that the FDA is focusing on the need for shared responsibility in designing its food safety program. In several exchanges with FDA staff, however, the committee did not find that the FDA has a well-thought-out approach to defining food safety responsibilities beyond these general statements. On several occasions, for example, the committee invited FDA officials to further articulate what the agency sees as the substance and consequences of the FPP's call for placing more responsibility on the corporate sector. The officials were unable to do so, nor did their answers recognize the need for a systematic approach (a road map) to making these decisions. The agency's approach appears to be ad hoc and its regulatory philosophy unclear.

Describing the role of each responsible party is an important activity for a regulatory agency and an essential element of its strategic plan. A model for choosing modes of governance is integral to the subsequent choice of interventions and their design and implementation (Steps 4 and 5 of a risk-based system). This model should account for a range of factors that will differ across risks, such as the sources and controllability of risks and the structure of the supply chain, and will affect what mix of shared responsibility will address the risks most effectively.

A generic list of governance options is a useful starting point for think-

ing about shared responsibility for food safety. An example of such as a list is shown in Figure 4-1 (adapted from Garcia-Martinez et al., 2007). On one end of the spectrum, food safety is entirely an individual, private responsibility, and there is no intervention by public agencies. On the other end of the spectrum is direct regulation, whereby public agencies prescribe what companies must or must not do in ensuring food safety, for example, with respect to production practices, product standards, or labeling. This end of the spectrum is frequently referred to as a "command and control" approach. Between these extremes is a range of public–private mixes. Self-regulation involves the use of industry voluntary codes of practice and farm assurance schemes with self- or third-party certification. Information and education entails the government's generating and communicating information for the use of private parties. Coregulation denotes programs in which responsibility is shared in a public–private partnership, for example, when statutes incorporate industry codes of practice. Finally, incentive-based

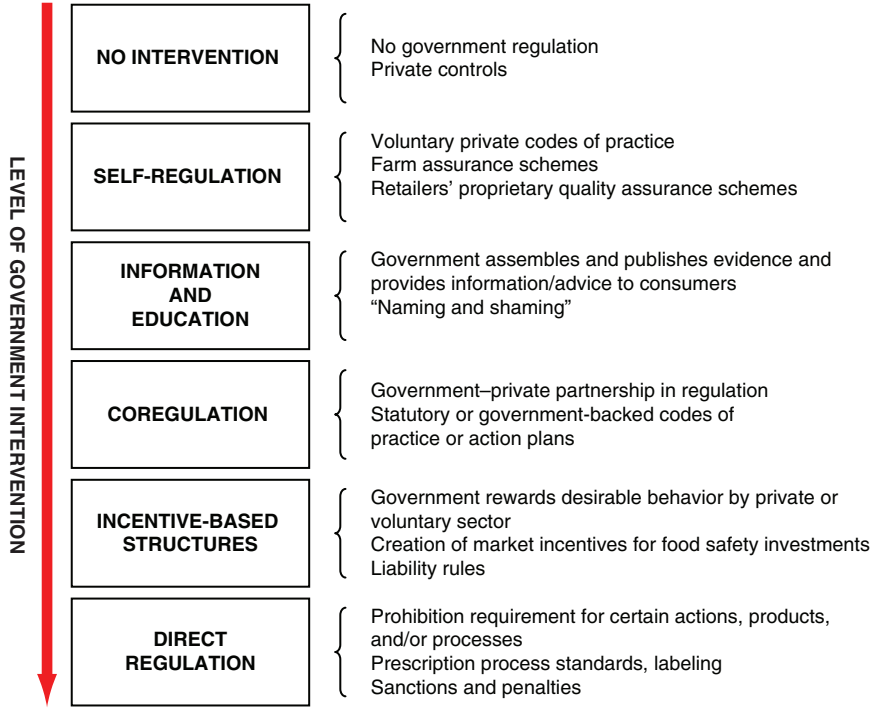


FIGURE 4-1 Options for assigning private–public responsibility to ensure food safety.
SOURCE: Adapted from Garcia-Martinez et al. (2007).

structures vary the amount and type of regulatory oversight based on how well a company performs; this is frequently referred to as a performance approach and also includes the setting of liability rules and related concepts, such as due diligence.

The nature of shared responsibility for the management of food safety risks will evolve over time as legislation is passed, new circumstances arise, knowledge grows, stakeholders express different priorities, and constraints

BOX 4-4
Managing the Safety of Produce:
An Example of Evolving Shared Responsibility

An example of how the U.S. Food and Drug Administration (FDA) has modified its governance philosophy over time is the case of produce safety. While the FDA has jurisdiction over produce, in the past it did not exercise this authority through direct regulation. This lack of direct oversight occurred in part because the FDA gave priority to its efforts to control contaminants in foods known to present such problems, and at the time fresh produce was not recognized as an important vehicle for pathogens. Until recently, there were no guidelines, codes of practice, or regulations directed toward ensuring the safety of fresh produce during production and processing.

The FDA started to pay more attention to produce safety when various produce items were identified as vehicles for foodborne illness outbreaks. Recent examples of FDA attempts to manage the safety of fresh produce include the Tomato Safety Initiative (FDA, 2007b), the Lettuce Initiative (FDA, 2009a), and Produce Safety from Production to Consumption (FDA, 2004). Important efforts common to all these initiatives were continuing to reach out to the produce industry, facilitating and promoting research, and working with federal, state, and local public health officials in illness detection and outbreak response. These efforts are examples of an information and education approach to intervention (see Figure 4-1).

The FDA first developed Guidelines for Agricultural Practices in 1998. They were followed by guidelines for minimizing or eliminating microbial contamination in commodities that appear to present the greatest risks: tomatoes, leafy greens, and melons. As guidelines, however, none of these documents are enforceable. To encourage the farm community to accept and adopt them, the FDA has engaged in information and education programs, for example, through dedicated efforts by cooperative extension offices.

The lack of strong regulatory action by the FDA drove some states to

shift. Based on outcomes, the mix of responsibility chosen initially may prove to be too reliant on voluntary action, at one end of the spectrum, or too focused on prescriptive government regulations, at the other end. A salient example of this evolution is the FDA's regulatory approach to the safety of produce (see Box 4-4). The committee notes that an evolving approach makes sense, but found that the FDA's approach frequently

implement stricter measures. For example, the Tomato Good Agricultural Practices (Florida Department of Agriculture and Consumer Services, 2007) are now included in a rule aimed at enhancing the safety of fresh tomatoes produced or handled in Florida; this is an example of direct regulation. Although voluntary, the California Leafy Greens Marketing Agreement (LGMA, 2010), overseen by the California Department of Food and Agriculture, is a mechanism for verifying that participating growers (99 percent of leafy green vegetable production volume) follow specific food safety practices. A similar program implemented in Arizona covers approximately 75 percent of leafy green vegetables produced in the state (AZLGMA, 2008). These efforts are a form of coregulation.

In fall 2009, the FDA announced that the agency will issue regulations setting enforceable standards for fresh produce safety at the farm and packing house, based on prevention-oriented public health principles and on current knowledge and guides (HHS/FDA, 2009). The FDA's proposed rule would establish standards for the implementation of preventive controls, emphasizing the importance of environmental assessments and recognizing the need to tailor preventive controls to particular hazards and operations. This shift in the FDA's governance approach to produce safety from an educational model to direct regulation could be due to many factors, including new research findings, an increased rate of foodborne illness that suggests higher risk attributed to produce, a low rate of implementation or effectiveness of FDA guidelines, or a change in general philosophy about the management of food safety within the agency. In fact, communications from the FDA about what is expected of industry and regulatory approaches taken over the years have not clearly articulated the rationale for changes or provided a road map that would enable stakeholders to participate in and anticipate such changes.

cannot be tied systematically to an underlying regulatory philosophy and related road map for making these decisions.

Regardless of the governance models selected or policy interventions used to achieve them, food safety will always be the responsibility of many partners. Thus cooperation and collaboration are key not only in the collection, analysis, and sharing of information and data but also in the enforcement and oversight of policies. A lack of cooperation and collaboration among the many entities with responsibility for food safety results in an inefficient food safety system. To be credible, the development of governance models must be done with transparency and stakeholder involvement.

CHOOSING POLICY INTERVENTIONS AND ASSIGNING/SHARING RESPONSIBILITY

A risk-based approach entails identifying important risks to target and stating the means that will be used to control them. Many factors enter into the selection and design of policy interventions (Steps 4 and 5 in a risk-based system). Given the complexity involved (multiple risks, multiple candidate interventions, uncertainty of information), regulatory agencies benefit from having a risk-based road map for identifying and selecting interventions. Once policy interventions have been selected, assigning responsibility to different parties in the system is an important aspect of their implementation.

The Policy Interventions Tool Kit

Governments and their regulatory agencies can chose from a broad range of possible interventions to influence the performance of markets. It is useful to think of these interventions as a tool kit offering multiple options, depending on the job at hand. In its main document on intervention choice, the Treasury Board of Canada Secretariat (2007) uses the term "policy instruments" to refer to this set of interventions, defined as follows:

> Instruments for government action are the means a government has at its disposal to achieve public policy outcomes—to govern. While several definitions of "instruments for government action" exist, this document uses a broad interpretation, defining them as the **"means by which policy objectives are pursued"** [emphasis in original]. Instruments for government action set up relationships between the state and its citizens. In some cases, such as criminal law, the relationship is of a coercive nature. In other cases, such as legal agreements, the relationship is reciprocal. (p. 3)

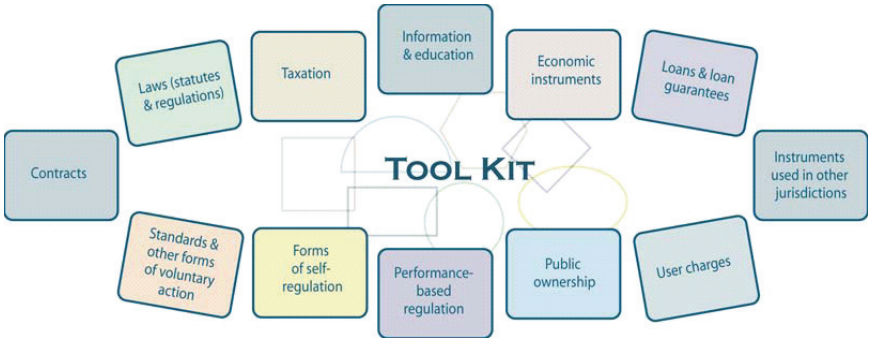


FIGURE 4-2 The interventions tool kit.
SOURCE: Treasury Board of Canada Secretariat, 2007.

Figure 4-2 shows the classes of interventions outlined in the document. These tools are frequently used in combination to achieve the desired performance outcomes.

Road Maps for Choosing Policy Interventions

Deciding what policy interventions to use in different situations and determining the associated assignment of responsibilities is facilitated by having a road map of factors to consider in the selection process. It is common for multiple interventions to be in place simultaneously. For example, processing standards may ensure food safety, while consumer labeling educates about safe use. Referring to Figure 4-1, explicitly thinking about which level of intervention or mix of levels to use and why can lead to choices that enhance the effectiveness of the food safety system.

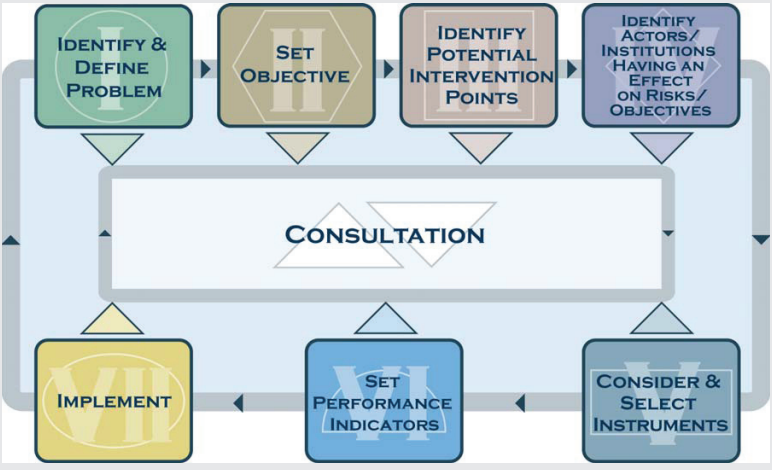
As mentioned above, the committee asked FDA officials to explain the FDA's thought process in selecting interventions. From these discussions and a review of FDA documents, the committee concluded that the FDA does not have a systematic method for making these decisions at Step 4 of the risk-based approach. Several countries have developed road maps of the type suggested by the committee. For example, the United Kingdom's Food Standards Agency has in place a regulatory framework[1] (FSA, 2006), and a set of detailed impact assessments has been completed (FSA, 2010).[2] Box 4-5 presents an example of a road map for choosing interventions, developed by the Treasury Board of Canada Secretariat (2007).

[1] See http://www.food.gov.uk/foodindustry/regulation/betregs/regframe (accessed February 12, 2010).

[2] See http://www.food.gov.uk/foodindustry/regulation/betregs/ria (accessed February 12, 2010).

BOX 4-5
Example Analytical Framework for Selecting Policy Instruments

The Treasury Board of Canada Secretariat (2007) has developed a framework (see the figure below) for selecting policy instruments (its term for what this report calls interventions) for use by all departments and agencies, which may use the framework as is or as a template for developing their own framework for their respective areas of responsibility. The framework is intended to facilitate a disciplined approach to assessing, selecting, and implementing instruments. According to the Secretariat, the framework establishes a sequence of enquiry, specifies a methodological foundation, and provides guidance for each step in the instrument choice process. The benefits identified as flowing from the use of this framework are



Assigning/Sharing Responsibility

The FDA or any agency charged with managing food safety must have mechanisms for overseeing food safety both domestically and internationally (for imported foods). Different intervention choices incorporate different assignments of responsibility for ensuring that the desired level of food safety assurance is achieved. The key parties to whom different levels of responsibility for food safety may be assigned include the private sec-

- greater transparency in decision making by providing an explicit rationale for instrument choices,
- greater cohesion in decision making by providing a disciplined approach for assessing and selecting instruments,
- overcoming risk aversion by using a risk-based analysis that will assist in understanding the challenges and the most appropriate means of addressing risks, and
- better outcomes by selecting an appropriate mix of instruments.

The Secretariat states that the framework is based on two overarching rationales:

(1) The process of analyzing a situation or problem and considering means by which the government could take appropriate action is iterative.
(2) The contribution of consultation (e.g., risk communication) throughout this iterative process is crucial. It enhances government transparency, promotes knowledge sharing, and supports the integrity of government action.

The framework is not intended to be a sequential road map of where and how officials should assess instruments to achieve public policy objectives. The process is inherently iterative in that the accumulation of information and knowledge concerning a problem or situation and the objectives the government is aiming to achieve will require officials to revisit each of the steps in the framework repeatedly. The framework document presents simple but complete approaches to each step of the instrument choice process.

SOURCE: Treasury Board of Canada Secretariat, 2007.

tor, third-party or other accrediting organizations, governments of other countries, and the states.

The Private Sector

A regulatory agency needs to set clear food safety standards and enforce those standards. At the same time, industry has, and must have, the primary

responsibility for ensuring food safety because it is the sector that actually makes or grows the products and is in closest touch with problems as they occur. Industry has broad roles to play; for example, it conducts research on mitigation strategies to produce solutions for food safety practices. Another role of industry is to innovate and explore management approaches. For example, systems analogous to the Hazard Analysis and Critical Control Points (HACCP) system were already in existence and had been applied in some food processing operations prior to being considered by the government as a preventive approach (IOM/NRC, 2003).

In HACCP-based systems, industry formulates control plans that the regulatory agency oversees. When reviewing a HACCP plan, the agency can determine whether the technologies proposed are adequate for food safety protection and are being used appropriately.

Private-sector responsibility is carried out within the range of intervention strategies outlined above. For example, industry responsibility may vary if the government has no intervention strategy. It may take the form of complying with information interventions, for example, with the new requirement of a reportable food registry. Tort law, tax incentives, subsidies, other incentive-based interventions, and direct regulation are other strategies for producing the desired level of food safety. As noted above, the preferred choice of interventions and related assignment of responsibility evolve over time. Box 4-6 describes a current example of this evolution in the area of traceability.

Third-Party Certification

Interest has grown in the use of quality assurance by accreditation bodies (third-party certification) to ensure food safety rather than (or in addition to) relying on government agencies. These assurance/accreditation bodies may be an industry group (the self-regulation option of Figure 4-1) or a third party that is independent of individual firms or the government. They can develop and accredit standards, providing assurance to buyers in the supply chain and/or to consumers. In coregulation interventions, such bodies can partner with the government to ensure food safety. In incentive-based interventions, they can be used as a means of credibly signaling lower risk to the government and may lead to streamlined oversight (e.g., to a fast track for imports).

The use of third-party accreditation as an aspect of government interventions is controversial and, at this time, is more accepted in some countries than in others. Significant questions arise as to how and by whom the accreditation bodies themselves are audited, how transparent they are, to what extent they solicit and use stakeholder input, and whether the audits are reliable (Albersmeier et al., 2009). In the context of a risk-based food safety

BOX 4-6
Example of the Evolution of
Shared Responsibility for Traceability

The term "food traceability" can be defined generally as the ability to identify where a food comes from. In the area of food safety, traceability refers to the ability to identify a food product's history (e.g., processes, locations, manufacturers). Past experience with foodborne illness or contamination investigations has demonstrated that determining the history of a food product from production to consumption can be a daunting, time- and resource-consuming effort in the United States, but one that is absolutely necessary to making decisions during and after a crisis.

With the idea of providing food agencies with prompt, necessary information, Section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires the establishment and maintenance of records that allow for identification of the immediate previous sources and subsequent recipients of food.[a] This information, along with labels that identify the contents of the package and the name and address of the manufacturer, packer, or distributor must be made available to the U.S. Food and Drug Administration (FDA) within 24 hours when food contamination is suspected.

However, the lack of guidance for best practices and the fact that companies already follow their own traceability procedures for other purposes (e.g., safety, quality, marketing) have resulted in a diverse system with limited value for the FDA. Food traceability for safety purposes is an example of a situation in which simply letting individual food companies establish procedures with little guidance, coordination, or leadership has not led to a well-functioning system.

For traceability to be useful during a crisis, procedures need to be seamless and effective. Setting standards is essential. Because both industry and government play distinctive roles (i.e., the system needs to be feasible and practical for industry but also needs to be usable by government investigators), it may be necessary for them to set the standards in collaboration, with a clear definition of the roles of the partners. As this report is being written, the FDA and the U.S. Department of Agriculture have engaged in a joint dialogue with industry to address past inefficiencies by developing procedures that will be useful during investigations (*Federal Register*, 2009). Collaboration of this type can move systems forward to meet both societal and industry needs.

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[a]*Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)*, Public Law 107-188, 107th Cong., 2nd sess. (January 23, 2002), 306.

system, a key question is whether these systems meet standards for being risk based and, in particular, how well they address public health issues.

The rapid growth of auditing platforms (e.g., those of the Global Food Safety Initiative, the International Organization for Standardization, Safe Quality Food [SQF], the British Research Consortium [BRC], the Global Partnership for Good Agricultural Practice [GlobalGAP]) shows that supply chains see value in these systems. Interest in leveraging these systems in government regulation and oversight stems from a desire to gain possible efficiencies in the production of food safety through the elimination of duplication of effort. Increased reliance on these systems, however, requires regulatory agencies to institute a system for auditing the auditors and setting standard criteria for these operations.

The FDA has been exploring this issue. For example, as noted earlier, the FPP calls for new legislative authority to authorize the agency to accredit highly qualified third parties for voluntary food inspections. This legislation would authorize the FDA to accredit independent third parties (or to recognize accrediting bodies) to evaluate compliance with FDA requirements, allowing the agency to allocate inspection resources more effectively. According to the FPP,

> FDA would use information from these accredited third-party organizations in its decision making but not be bound by such information in determining compliance with FDA requirements. Use of accredited third parties would be voluntary and might offer more in-depth review and possibly faster review times and expedited entry for imported goods manufactured in facilities inspected by accredited third parties. Use of accredited third parties may also be taken into consideration by the FDA when setting inspection and surveillance priorities. (p. 18)

The FDA proposes to oversee these independent third parties by auditing their work to ensure that FDA requirements are consistently assessed, reviewing their inspection reports, and providing ongoing training criteria to ensure that they maintain their skills and knowledge (FDA, 2007a). It should be noted the FPP defines third parties much more broadly than is the case in this report. Included in its definition are other federal departments and agencies, state and local government agencies, foreign government agencies, and private entities without financial conflicts of interest (FDA, 2007a). The committee believes the FDA's definition is too broad (see Chapter 7).

The FDA's 2009 Guidance for Industry on Voluntary Third-Party Certification Programs for Foods and Feeds[3] describes the agency's views on the

[3] See http://www.fda.gov/RegulatoryInformation/Guidances/ucm125431.htm (accessed February 16, 2010).

general attributes of a third-party certification program. The FDA regards this guidance as one of the steps in its future recognition of voluntary third-party certification programs for particular product types, and it has stated that it will recognize a certification program only if it has sufficient confidence in the certification body (FDA, 2009b). The FDA also has explored the use of third-party certification for imported foods, as discussed in the following section. It should be noted that, although GAO reports on food safety programs recommend exploring the development of a third-party certification program, they also recommend taking lessons from the FDA's medical device program, in which the lack of incentives resulted in weak participation and few inspections (GAO, 2008a,b).

The potential value and legitimacy of third-party certification is a topic of debate internationally as well. For example, private standards have been on the agenda of the World Trade Organization's (WTO's) Sanitary and Phytosanitary (SPS) committee since 2005, and their role in the process of public standards setting is under discussion at the Codex Alimentarius Commission, where a position on the matter has not yet been taken. During its last meeting in 2009, Codex decided to conduct an in-depth evaluation of the role and impact of such standards, based on comments about the negative impact of private standards on economies and questions about the science and transparency of the process (Henson and Humphrey, 2009). There is published evidence of the comparatively higher costs of meeting private standards versus European Union (EU) standards (Plunkett and DeWaal, 2008). Overall, however, third-party efforts are clearly an important part of a risk-based system of shared responsibility for food safety.

Governments of Other Countries

There have been only limited, initial efforts to compare food safety performance across countries (Charlebois and Yost, 2008); therefore, no evidence exists to support the idea that vulnerability will increase with the growth of international trade in food and agricultural products and the import share of food consumption. The enforcement of food safety regulations in foreign countries is challenging.

Importing countries ensure import safety through a combination of controls in place in the exporting countries and border inspections. It is unrealistic to expect the FDA to have an effective inspectional presence in countries around the world as border inspection is a difficult, expensive, and sometimes ineffectual means of monitoring food safety. Inspectors cannot check every grape, or even every box of grapes. In this situation, a U.S. regulatory agency may leverage its efforts by verifying and then relying on the safety control systems of other countries. This approach has the added advantage of responding to the call of WTO's Agreement on the

Application of SPS Measures for recognition of equivalent systems across countries.

An additional challenge in the oversight of imported foods is the inability of a government to interfere with a foreign country's laws. Exporting countries are outside the FDA's jurisdiction, and therefore enforcing U.S. food laws with respect to their products is problematic. For example, inspecting foods and facilities in situ not only is impractical but also might not be welcomed or allowed by the exporting country. A regulatory agency needs oversight mechanisms that can overcome these barriers while remaining in line with WTO trade agreements. The current system by which the FDA manages the safety of food imports (mainly inspections at the border) is ineffective (only 1.28 percent of shipments were inspected in 2007) and could use additional tools (GAO, 2009).

As Appendix E describes, with the expansion of the global market for foods and the signing of the WTO agreements, preventive mechanisms have been instituted to ensure the safety of imported foods. Those mechanisms include monitoring and directed sampling (Canada); third-party audits, and equivalency agreements, and limited entry posts for high-risk products (EU countries); inspection based on food risk categories (Australia and New Zealand); and import certificates (New Zealand). Presentations made to the committee and its own investigation further support the existence of a broad range of approaches to allocation of responsibility and coordination with other countries to ensure food safety (Appendix E). Designing a coherent approach to working with other countries to ensure the safety of imports is clearly important.

The committee found that the FPP does not articulate a clear approach to the roles of private parties and other governments in ensuring food safety for products imported into the United States. As discussed in Appendix E, the United States maintains that its approach to imported foods stands on the same general principles as its approach to domestic foods. It is the responsibility of companies and importers to know the U.S. food laws and regulations and to comply with them. However, the U.S. government will ultimately be held accountable for a safe supply of both domestic and imported foods.

The States

Given the size, complexity, and growth of the food industry in the United States (more than 156,008 domestic food facilities [FDA, 2010], more than 1 million food establishments [including restaurants and retail stores[4]], and more than 2 million farms), it is unrealistic to expect that the

[4] Personal communication, Chad Nelson, FDA, October 13, 2009.

FDA could have enough resources to provide adequate surveillance and inspection of the entire U.S. food supply (Mavity, 2009). The regulations and programs of state and local (including tribal and territorial) governments have been a strong component of the U.S. food safety system for the past century. State surveys conducted in 2001 and 2009 indicate the broad scope of food safety activities conducted by the states, from collecting data on food contamination and outbreak surveillance, to performing food and feed inspections, to enforcing the laws and issuing recalls (AFDO, 2001, 2009). In fact, the FDA's food safety knowledge (and therefore management) could be enhanced by leveraging data collected by state and local authorities on food safety inspections, disease outbreak investigations, product safety, consumer perspectives, and enforcement actions. Doing so, however, would require that programs be standardized and harmonized; for example, standards for training of inspectors and data collection would need to be in place. In the absence of truly harmonized programs at the state and local levels, the FDA has instituted some mechanisms that facilitate cooperation, such as the signing of confidentiality agreements, contracts, or memorandums of understanding. Although these mechanisms facilitate shared effort, they also have limitations in that funding is not always available, and they are not always utilized.

As with the assignment of responsibility to industry, third parties, and other countries, the FDA needs an overall strategic vision for when it is desirable to rely on or partner with the states to ensure food safety as well as what allocation of appropriate areas and levels of responsibility is optimal. The committee found that the FDA lacks an overall regulatory philosophy or road map for these choices. With a clear approach, the agency might be able to expand its collaborations with state and local food safety programs so these programs would be better recognized and utilized in the national food safety system (see Chapter 7).

Examples of Mixes of Public and Private Responsibility

Clearly options for the choice and design of policy interventions (Steps 4 and 5 in a risk-based system) are broad, cutting across different mixes of public and private responsibility for ensuring food safety. Researchers have begun to analyze these diverse models for shared responsibility, particularly as several countries have expressed their interest in newer, hybrid forms of governance as a means of ensuring food safety more efficiently. As yet, there have been no comprehensive comparisons of the effectiveness of these alternative models, but several studies shed some light on the options currently in use.

The structure of private standards for food safety management has been developing particularly rapidly in the last decade (Henson, 2008). Histori-

cally, a no-intervention approach characterized by private standards set on a business-to-business basis was predominant. These approaches were either national (e.g., Nature's Choice by Tesco in the United Kingdom, Field-to-Forks by Marks and Spencer in the United Kingdom, Filière Agriculture-Raisonnée by Auchan France) or international (e.g., Wal-Mart and Nestlé). Recently, a self-regulatory approach characterized by joint standards used by a group of suppliers or retailers, frequently with third-party certification, has been gaining ground. Examples of these joint standards include, at the national level, the Dutch HACCP, the BRC Global Standard, Assured Food Standards, Qualität und Sicherheit (the "QS system"), and Integrate Keten Beheersing. At the international level, they include the International Food Standards, SQF 1000/2000/3000, and GlobalGAP (formerly EuroGAP) (Henson, 2008).

A study conducted for the Food Standards Agency in the United Kingdom documents a mix of private and public responsibility in use across the United Kingdom, the United States, Canada, and Australia (Fearne et al., 2006; Garcia-Martinez et al., 2007). The United Kingdom has been active in thinking about and experimenting with different mixes of responsibility. An example is the Zoonoses Action Plan Salmonella Programme for pigs. In this case, standards setting was private (voluntary), with funding from the government and a multistakeholder group advising on ongoing developments. Implementation was private, with funding and facilitation from the government. Enforcement and monitoring were private as well (as part of farm assurance scheme requirements), with the public sector providing on-farm support and advice to high-risk producers. A further example of exploration of alternative public–private mixes is the voluntary HACCP Advantage program in Ontario, Canada. Here, the standards setting was public–private, the system was introduced through educational programs led by the government, and enforcement and monitoring were conducted through private, third-party audits.

An example of exploration of different mixes of public and private responsibility from the United States is a series of efforts the FDA has conducted to assess the value of third-party certification systems as a tool to verify the compliance of foreign food companies with U.S. food laws. Such exploratory efforts are recommended in the *Action Plan for Import Safety: A Roadmap for Continual Improvement* (Interagency Working Group on Import Safety, 2007), as well as in the 2007 FPP. The FDA conducted a pilot study to evaluate voluntary third-party certification programs for imported aquaculture shrimp. The FDA envisioned that such a program could help the agency make decisions about the safety of imported foods, such as prioritizing inspections and sampling. The pilot program was conducted in two phases. During Phase I, participants were paper audited and selected on the basis of a set of criteria, with six certification bodies selected. Phase II,

involving onsite audits and targeted sampling, was scheduled to be completed and evaluated in July 2009. The committee was not given any results of this pilot program and was unable to evaluate it as an approach to shared responsibility for food safety.

KEY CONCLUSIONS AND RECOMMENDATIONS

Food safety in the United States is the responsibility of suppliers, farmers, food handlers, processors, wholesalers and retailers, food service companies, consumers, third-party organizations, and government (federal and state) agencies in both the United States and abroad. It is, therefore, unrealistic to expect the FDA, or any government agency, to have sufficient resources to manage food safety without the help of others who share this responsibility.

A risk-based approach to the choice and design of interventions (Steps 4 and 5 in a risk-based system) requires a comprehensive understanding of the policy intervention tool kit and a road map for choosing and designing interventions. Further, developing an approach to defining the roles of other responsible parties is a component of strategic planning in a risk-based food safety system. In essence, this road map should also serve to assign shared responsibility among the federal government, the private sector, third parties, the governments of other countries, the states, and consumers. The design of novel approaches to governance to achieve food safety is currently the subject of experimentation by other governments and debate by scholars.

The committee found that the FDA has made ad hoc efforts in this direction but does not have a clear regulatory philosophy for assigning responsibility for food safety or a comprehensive strategy for choosing the level and intensity of interventions as part of strategic planning in a risk-based approach. The committee offers the following recommendations to address these shortcomings.

Recommendation 4-1: To ensure food safety, the FDA should develop a plan for defining the extent of and form for sharing responsibilities with the states, the private sector, third parties (e.g., independent auditors), and other countries' governments.

Recommendation 4-2: The FDA should develop a comprehensive strategy for choosing the level and intensity of policy interventions needed for different food safety risks. Criteria for choosing the level and intensity of policy interventions and a plan for evaluating the selected interventions should be developed with transparency, stakeholder participation, and clear lines of communication.

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Part III

Implementation of the New Food Safety System

5

Creating an Integrated Information Infrastructure for a Risk-Based Food Safety System

Information science—a term that refers to the collection, organization, storage, retrieval, exchange, interpretation, and use of information—and information technology (IT) are critical to the success of a risk-based decision-making system.[1] If the U.S. Food and Drug Administration (FDA) is to implement a risk-based approach in fulfilling its regulatory mission, it must know what is happening in the arena it regulates; that is, data from the food enterprise must be appropriately collected, integrated, and analyzed. To allocate resources, understand and prevent food safety problems, and drive continual improvements in public health, a risk-based system requires accurate, reliable, secure, and timely information that is accessible, within appropriate limits, to all stakeholders in the food safety system. The importance of information to the food safety enterprise has been recognized by the White House Food Safety Working Group as one of the three principles guiding the development of a modern, coordinated food safety system: "High-quality information will help leading agencies know which foods are at risk; which solutions should be put into place; and who should be responsible" (FSWG, 2009, p. 3).

As described in this chapter, large quantities of data related to food safety are already being collected. Yet, as has been highlighted by others, the FDA is facing an information crisis and currently lacks the necessary infrastructure to efficiently process, manage, protect, integrate, analyze, and leverage the large volume of data to which it has access. This deficiency hampers the agency's ability to achieve its mission and increases both costs

[1] In this chapter, the terms "data" and "information" are used interchangeably.

and the likelihood of regulatory errors (FDA Science Board, 2007). Much of the data is "stovepiped" into stand-alone databases that are not accessible within and across government agencies, including the FDA (Taylor and Batz, 2008; FDA Science Board, 2009). A lack of resources, legal constraints, nonstandardized data collection, varied data formats, incompatible IT systems, a sense of ownership by the group that collects the data, and a culture that often uses publication rather than rapid information release as the basis for evaluating performance have been identified as contributing to the persistent problems with data sharing (Taylor and Batz, 2008; FDA Science Board, 2009). For example, the FDA apparently has the regulatory authority to require that all data be submitted electronically and to specify the format of these data submissions, but it may not have sufficient resources to implement such electronic standards (FDA Science Board, 2007). It has been noted that inspection reports are often handwritten and take a long time to enter into the electronic system, databases sometimes contain incorrect or contradictory information, and data analysis is slow (FDA Science Board, 2007; GAO, 2009). The Science Board has also stated that requirements need to be developed in conjunction with stakeholders who will be making the submissions. Finally, the FDA lacks the necessary tools to store, search, model, and analyze data (FDA Science Board, 2007).

Generating and providing timely access to the appropriate data is challenging for any food regulatory agency because of the complexity of data needs, coupled with the diverse types of information from multiple sources and scientific disciplines. Also, the committee recognizes the challenge for government officials to be expeditious about communicating with stakeholders while also ensuring accuracy. In some instances, moreover, depending on the nature of the data and the needs of the user, release to others may justifiably be delayed because of the time needed to either interpret data or mask confidential information. As explained later in the chapter, however, the committee found that some delays that occur in the current system are not justifiable.

Recognizing these challenges, moving forward with a risk-based food safety system will require the development of an integrated information infrastructure that provides a relatively uninhibited flow of high-quality, relevant information (see Chapter 3). In the context of this report, an integrated information infrastructure refers to one that is strategically designed to facilitate the systematic collection, integration, management, storage, analysis, interpretation, and communication of the information needed to support a risk-based food safety management system, and also one that has the flexibility and accessibility to meet the varied and changing information needs of a diverse set of users.

This chapter outlines the key types of data needed to support risk-based decision making. In addition, it briefly illustrates the breadth of food safety

data that are being collected by government and other parties as well as gaps and challenges in the collection of these data. A particular barrier to achieving an efficient, risk-based food safety system that is discussed extensively in the chapter is the lack of data sharing. Finally, the chapter describes the elements that are critical to designing and implementing an integrated information infrastructure that can support a risk-based food safety management system. These elements include strategic planning to assess data needs and plan study designs as well as data analysis and communication, mechanisms to allow for timely sharing of quality data, a modern IT infrastructure, and the human capacity to collect, analyze, manage, and communicate the data.

THE ROLE OF DATA IN A RISK-BASED FOOD SAFETY MANAGEMENT SYSTEM

At its core, the FDA is a public health agency, and the ultimate goal of protecting the public health should be its highest priority. To support the achievement of this goal, the FDA's information infrastructure should provide a foundation for risk-based decision making in all aspects of food safety management.

Data will be needed to implement the steps in the risk-based approach delineated in Chapter 3. In strategic planning (Step 1 of the risk-based approach), the FDA will need access to high-quality and timely data to identify the key public health objectives on which its food safety program will be centered. At the highest level, these public health objectives will be consistent with national public health objectives, such as those articulated in Healthy People 2020, which include "reduc[ing] the number of outbreak-associated infections caused by food commodity group" (including dairy, fruits/nuts, and leafy vegetables)[2] (HHS, 2009). However, the FDA will also pursue specific intermediate outcomes, such as the reduction of methyl mercury in foods, that will serve as the basis for its targeted risk management programs. The establishment of these objectives should be based on data acquired in the field, such as data on contamination or foodborne illness.

The process of public health risk ranking (Step 2) will also require data. For example, as discussed in Chapter 3, foodborne illness attribution models are crucial to public health risk ranking because they provide the bridge between public health impact and risk in the food continuum. However, developing such models requires a comprehensive data collec-

[2]See http://www.healthypeople.gov/hp2020/Objectives/ViewObjective.aspx?Id=487&TopicArea=Food+Safety&Objective=FS+HP2020%e2%80%937&TopicAreaId=22 (accessed October 8, 2010).

tion system that integrates data from various sources and harmonizes the categorization of foods, as well as the methods used to produce, process, and distribute those foods (NRC, 2009).

Data collection and subsequent analyses are the outcomes of Step 3 of a risk-based system (targeted information gathering). In carrying out this step, risk managers must identify and consider additional criteria upon which risk-based decision making will be based and, for each high-priority and/or uncertain risk, determine the need for collecting additional information. Such additional data may encompass virtually any (and all) of the data types noted below. These data then form the basis upon which intervention analysis (Step 4) can proceed, which may also involve the collection of even more information in an effort to evaluate the efficacy and feasibility of candidate control options.

Finally, data must be collected to measure the efficacy of specific interventions, the overall food safety system, and the risk-based approach in achieving national and agency-specific public health objectives (Step 6). Crucial to this process is the collection of information that can directly relate interventions to specific public health outcomes, including epidemiological data and associated attribution models.

Ultimately, the FDA's purpose in collecting food safety data is to better understand the distribution and determinants of foodborne illness, prioritize the determinants based on their public health impact, and develop interventions for the determinants and thereby control foodborne illness. In fact, understanding the epidemiology of foodborne illness is necessary to support the ability to make informed, risk-based policy decisions and allocate food safety resources appropriately. In turn, a risk-based decision-making process will improve knowledge of the epidemiology of foodborne illness and drive continual improvements in public health. As defined by Last (1995, p. 62), epidemiology is "the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to control of health problems." As noted by Havelaar and colleagues (2006, p. 9), "epidemiology is now largely a quantitative science that extensively uses statistical (associative) models to explore the relation between risk factors and disease."

DATA NEEDS FOR A RISK-BASED SYSTEM

To meet the needs of a risk-based system, data would ideally be collected at each point along the food production continuum—on the farm, in processing, during distribution, at retail, and in the home. A variety of data sources can contribute to an understanding of the epidemiology of foodborne illness, including data collected through surveillance, behavioral studies, analytical research, and traditional epidemiological studies. The types of data collected

might include foodborne pathogen levels and transmission routes in animals, plants, food products, humans, and the environment; current industry and consumer practices, including behaviors and attitudes; and the efficacy of candidate intervention approaches at all phases of the continuum. There is also a need for epidemiological data to support estimates of the overall burden of foodborne illness and the proportion of such illness associated with specific vehicles (foods) and transmission routes (i.e., foodborne illness attribution). A regulatory agency might decide to include other factors in its risk-based approach as well, such as the costs and benefits of implementing specific interventions, even though those factors are not directly related to public health. These data types can be broadly categorized as behavioral, economic, food production, and surveillance data. The importance of each type of data for a risk-based system is discussed further in the following subsections. To maximize the utility of these diverse surveillance systems, there must be an integrated information infrastructure that, through strategic planning, facilitates informed data collection and promotes standards for data exchange. Effective collection of these types of data will require active research—including basic, population, and clinical research—as outlined in Chapter 6.

Behavioral Data

Behavioral data are critical to understanding routes of transmission, implementing intervention strategies to change behavior, developing risk communications, improving public health response, and evaluating interventions. As discussed in Chapter 9, behavioral data are ultimately essential for developing strategies that will enable the FDA to communicate effectively with diverse audiences under a wide range of circumstances and through multiple communication channels. For example, the attitudes, perceptions, and behaviors of the general public and food industry personnel can impact their compliance with recommended food safety interventions, such as safe food-handling practices (Medeiros et al., 2001; Pilling et al., 2008). Likewise, understanding the attitudes, perceptions, and behaviors of public health personnel—including physicians, laboratory personnel, and government officials—can help identify ways to improve public health response.

Economic Data

In a risk-based system, data on benefits and costs are combined for use in cost-effectiveness and cost–benefit analyses of alternative policy interventions. Economic data can be used to measure and understand several important dimensions of a risk-based food safety system. These data may

be thought of as measuring factors that affect the demand for safer food by individuals and by society as a whole on the one hand and factors that affect the supply of safer foods on the other. The demand for food safety arises in part from the costs of foodborne illness in terms of medical treatment, lost productivity due to mortality and morbidity, and other costs, such as loss of leisure time or burden on family members due to illness (Majowicz et al., 2004; Frenzen et al., 2005; Kemmeren et al., 2006; USDA/ERS, 2009). In addition to avoiding these costs, individuals or society may be willing to pay for (i.e., demand) improved safety based on the well-being or peace of mind associated with safer foods (Shogren et al., 1999). On the supply side, economic data can be used to measure the potential and actual costs of actions intended to supply safer foods, as well as to gain insight into incentives for countries and companies to invest in food safety. These data on incentives include domestic and international market impacts from the incidence of foodborne pathogens, from outbreak incidents in total, and as distributed across the supply chain. Examples of such impacts include the loss of market share by food producers in domestic markets due to the loss of reputation for safety and loss of export markets. Data that can help in understanding these effects include farm cash receipts, total value at retail, value of exports, value of imports, proportion of domestic consumption of food products produced domestically, and information on key export and import markets (Ruzante et al., 2009).

Food Production Data

To support risk-based decision making, the FDA needs to have information that relates to the production, processing, and storage of foods, including the size of the regulated industry and the distribution channels. For example, the FDA needs to understand current industry practices, including best practices, intervention strategies, and emerging technologies. The agency also needs to know the prevalence of foodborne pathogens throughout the food production, processing, and distribution chain. In fact, in support of the functions of the Office of Regulatory Affairs (ORA), including routine inspection activities, the FDA collects a large amount of data for both regulatory and nonregulatory purposes that may address these types of questions.

Data are also collected by the industry in support of safety control systems such as Hazard Analysis and Critical Control Points and routine microbiological monitoring. In addition, industry data collected by the academic and government research sectors are a rich source of information that can be used to estimate the prevalence and levels of pathogens and toxins in the food supply, evaluate the efficacy of intervention strategies, model risk and its mitigation, and identify consumer behaviors and market trends. All these data collected throughout the food production continuum

can be used to inform attribution and risk models, aid in the allocation of agency resources, and provide evidence of data gaps to inform future data collection efforts, among many other purposes.

Surveillance Data

For purposes of this report, "surveillance" refers to the ongoing, systematic[3] collection and analysis of contaminant, public health, and molecular data throughout the farm-to-fork continuum for use in preventing and controlling foodborne illness. Surveillance is a critical component of a risk-based food safety system in that it improves overall understanding of the epidemiology of foodborne illness. Specifically, surveillance can be used to establish a baseline level of foodborne illness, identify goals for its reduction, and provide a means by which to measure the impact of interventions on its control. Given resource limitations, the risk-based approach recommended in this report is essential as a tool to prioritize surveillance efforts.

Animal, food, environmental, human, public health, molecular, and behavioral (see p. 151) surveillance are all needed to respond to food safety crises, monitor food safety outcomes, and assess the effectiveness of the food safety system. Surveillance of animal populations, the food supply, and the environment is almost always undertaken with an eye to identifying sources of contamination and their subsequent transmission from a food animal to product(s) that will ultimately be consumed by people. Surveillance of human populations is used to better characterize the burden of foodborne illness and identify the relative importance of particular exposures (e.g., foods, transmission routes). Public health surveillance provides important insights into current medical, laboratory, and general public health practices, such as reporting and outbreak investigations. Molecular surveillance systems, such as PulseNet and VetNet, combine the methods of molecular biology with those of epidemiology to establish associations between contaminated food and illness when they are separated in space or time.

GAPS AND CHALLENGES IN THE CURRENT DATA COLLECTION SYSTEMS

Implementing an effective risk-based system, and developing the foodborne illness attribution models needed to support such a system, will require a comprehensive information infrastructure that integrates data

[3] In this context, the term "systematic" means that the surveillance is conducted in an orderly fashion, not haphazardly. For example, under certain circumstances, passive surveillance can be considered systematic, if it is conducted under some minimum established standards.

from various sources, harmonizes the data collected through the use of data standards, and finally analyzes, interprets, and disseminates those data in such a manner that they can be used to monitor and evaluate the overall food safety system. As evidenced by the following discussion, such a comprehensive system does not currently exist in the United States, compromising the FDA's capacity to fulfill its mission of protecting public health from hazards transmitted through the food supply. Current efforts to develop a risk-based food safety system are significantly limited, despite the fact that vast amounts of food safety data are already being collected. In recent years, several studies have evaluated the state of the FDA's science and information infrastructure and identified a number of problems (see Appendix B). While these problems have been well documented, it has been suggested that they persist because of a lack of commitment and inadequate investment that stem from legislative and policy inaction (FDA Science Board, 2007; Taylor and Batz, 2008).

A detailed description of the complexity and challenges of the data collection systems currently used to ensure food safety in the United States is given in the report *Harnessing Knowledge to Ensure Safe Food: Opportunities to Improve the Nation's Food Safety Information Infrastructure* (Taylor and Batz, 2008[4]). These challenges are discussed briefly below.

Fragmented Data Collection

The data needs of the nation's food safety system are currently being met through a patchwork of diverse data collection systems and networks that generate vast amounts of food safety data (for an extensive review see Taylor and Batz, 2008). Often, the collection of data is not comprehensive or designed to support a risk-based approach. Table 5-1 illustrates the breadth of the salient data by listing examples of U.S. public health–related data collection programs and networks in which the FDA is the lead or participates. Table 5-2 shows examples of the systems currently used to collect the different types of data outlined in the previous section, including some of the systems listed in Table 5-1, as well as shortcomings of these systems identified by the committee.

As part of its food regulatory function, the FDA collects some data, including microbiological samples, for the food products it regulates. With coverage in every state and territory, the FDA's field personnel and delegates are well positioned to generate and provide data that could be used in the agency's risk-based decision making. However, because field personnel do not have a daily presence in the regulated facilities, the FDA has limited opportunities to collect data outside of its routine regulatory efforts. With

[4] See www.thefsrc.org.

TABLE 5-1 Examples of U.S. Public Health–Related Data Collection Programs and Networks

Aflatoxin Testing Program	Under memorandums of understanding (MOUs), the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) provides appropriate U.S. Food and Drug Administration (FDA) district offices with the results of aflatoxin analysis for domestic and imported peanuts, imported in-shell pistachios, and imported in-shell brazil nuts in lots that may be subject to action under the Federal Food, Drug, and Cosmetic Act (FDCA) and with an analysis certificate on any lot upon request. The FDA will also notify the Agricultural Marketing Service (AMS) of the criteria it will use concerning total aflatoxin levels in lots to determine whether they may be subject to action under the FDCA.
CAERS (CFSAN Adverse Events Reporting System)	The Center for Food Safety and Applied Nutrition (CFSAN) Adverse Events Reporting System (CAERS) team monitors all individual postmarketing surveillance adverse event reports related to CFSAN-regulated products. Reviewers in CFSAN's program offices assess these reports and work closely with program experts and researchers throughout CFSAN and the FDA. CAERS tracks what products and ingredients may be harmful and conveys this information to industry, consumers, and other interested parties. The CAERS adverse event data permit CFSAN to do trend analysis on multiple adverse events and to track rarer product-related adverse events that may occur over several years.
CIFOR (Council to Improve Foodborne Outbreak Response)	CIFOR is a working group that seeks to improve performance and coordination among federal, state, and local agencies with respect to routine surveillance of foodborne illness, foodborne outbreak detection and response, laboratory methods for detecting and measuring foodborne pathogens, and foodborne illness prevention, communication, and education at the state and local levels. The council includes representatives of the U.S. Centers for Disease Control and Prevention (CDC), the FDA, USDA, the Association of Food and Drug Officials, the Association of Public Health Laboratories, the Association of State and Territorial Health Officials, the Council of State and Territorial Epidemiologists, the National Association of County and City Health Officials, the National Environmental Health Association (NEHA), and the National Association of State Departments of Agriculture. CIFOR also includes an industry workgroup composed of 16 leaders from food production, restaurant, and retail companies.

continued

TABLE 5-1 Continued

EHS-Net (Environmental Health Specialists Network)	EHS-Net is a CDC-coordinated collaborative forum of environmental health specialists who work with epidemiologists and laboratories to identify and mitigate environmental factors that contribute to foodborne illness and other disease outbreaks. Its goals include translating investigatory findings into improved food safety prevention efforts using a systems-based approach and strengthening relations among epidemiology, laboratory, and environmental health programs.
eLEXNET (Electronic Laboratory Exchange Network)	This web-based information network, coordinated by the FDA, allows federal, state, and local food safety officials to compare, share, and coordinate laboratory analysis findings. It is also the data capture and communication system for the Food Emergency Response Network (FERN). eLEXNET provides the necessary infrastructure for an early warning system that identifies potentially hazardous foods and enables health officials to assess risks and analyze trends.
Epi-Ready	This nationwide team-training initiative, led by CDC and NEHA, provides up-to-date foodborne illness outbreak investigation and surveillance training to public- and private-sector environmental health professionals, as well as other professionals who collaborate in conducting foodborne illness outbreak investigations.
Epi-X (Epidemic Information Exchange)	Run by CDC, Epi-X is a web-based surveillance communication tool for public health professionals. It enables public health professionals to access and share preliminary health surveillance information and notifies them rapidly of health events as they occur. Key features of Epi-X include scientific and editorial support, controlled user access, digital credentials and authentication, rapid outbreak reporting, and support for multijurisdictional peer-to-peer consultation.
FERN (Food Emergency Response Network)	FERN is a network of local, state, and federal food-testing laboratories that responds to emergencies involving biological, chemical, or radiological contamination of food. It provides a national surveillance capability designed to offer an early means of detecting threat agents in the American food supply, prepares the nation's laboratories to respond to food-related emergencies, and offers surge capacity for responding to widespread, complex food contamination emergencies. FERN is coordinated by both the FDA and USDA/FSIS.

TABLE 5-1 Continued

FoodNet (Foodborne Diseases Active Surveillance Network)	A collaboration among CDC, the FDA, USDA, and the ten states participating in CDC's Emerging Infections Program, FoodNet has the goal of providing more accurate estimates of foodborne illness associated with pathogens by conducting active, population-based surveillance for foodborne illness cases at ten sites. FoodNet has contributed to the standardization of methods among laboratories and performs targeted case control studies to identify risk factors for pathogen-specific illnesses.
FoodSHIELD	FoodSHIELD's mission is to support federal, state, and local government regulatory agencies and laboratories through web-based tools that enhance threat prevention and response, risk management, communication, asset coordination, and public education.
MDP (Microbiological Data Program)	MDP is a national foodborne pathogen database program implemented in 2001. Through cooperation with state agriculture departments and relevant federal agencies, MDP is meant to collect, analyze, and report data on foodborne pathogens for selected agricultural commodities. The FDA provides technical assistance to enhance methods used by MDP participants. Additionally, USDA/AMS informs the FDA of any positive pathogenic findings detected through MDP.
NARMS (National Antimicrobial Resistance Monitoring System)	NARMS was established in 1996 to monitor changes in the susceptibility of select bacteria to antimicrobial agents of human and veterinary importance among foodborne isolates collected from humans, animals, and retail meats. NARMS is a collaboration between three federal agencies including FDA's Center for Veterinary Medicine (CVM), CDC and USDA. NARMS also collaborates with antimicrobial resistance monitoring systems in other countries, including Canada, Denmark, France, Mexico, the Netherlands, Norway, and Sweden, so that information can be shared on the global dissemination of antimicrobial resistant foodborne pathogens. Molecular fingerprints of select foodborne bacteria (*Salmonella* and *Campylobacter*) recovered via NARMS are deposited into the CDC PulseNet databank for use in identifying sources and spread of foodborne outbreaks. The information from NARMS forms the basis for public health recommendations for the use of antimicrobial drugs in both food producing animals and humans. NARMS data also are vital in disease outbreak investigations and can be used to help create treatment guidelines for foodborne pathogens, thereby ensuring better health outcomes.

continued

TABLE 5-1 Continued

OutbreakNet/NORS (National Outbreak Reporting System)	OutbreakNet is a national CDC-coordinated network of local, state, and federal public health officials who investigate outbreaks of enteric illness, including foodborne outbreaks. State OutbreakNet members report findings of their foodborne outbreak investigations to CDC through NORS, a national web-based reporting system that tracks foodborne, person-to-person, animal contact, waterborne, and norovirus outbreaks. Prior to NORS, states reported foodborne outbreaks through the Electronic Foodborne Outbreak Reporting System. In 2008, the FDA and CDC executed an MOU under which the FDA provides two contract employees to the OutbreakNet unit at CDC for the purpose of mining and analyzing CDC data to address the FDA's policy and programmatic questions and support its regulatory mission and public health interventions. A plan of work was developed and implemented beginning in late fall 2008. Biannual reports are made to the FDA on progress in the plan's implementation. Examples of topics being addressed are attribution of outbreaks due to raw milk and raw milk cheese versus all dairy and produce attribution classified by produce type.
PDP (Pesticide Data Program) and National Residue Program	Under USDA/AMS's PDP, a collaboration with the U.S. Environmental Protection Agency (EPA), the FDA is notified of apparent food-related violations that are detected by PDP for follow-up, as warranted. Under USDA/FSIS's National Residue Program, the FDA is notified of apparent residue violations in meat, poultry, and egg products for follow-up with the responsible firms. The FDA's pesticide residue data are provided to and used by EPA to support EPA's pesticide tolerance reassessments, required under the Food Quality Protection Act of 1996. When FDA pesticide residue findings indicate pesticide misuse (a violation of the Federal Insecticide, Fungicide, and Rodenticide Act, which is enforced by EPA), the FDA notifies EPA for follow-up as warranted. Currently, as mandated by the Food and Drug Administration Amendments Act of 2007, an MOU among the FDA, USDA's AMS and FSIS, and the U.S. Department of Commerce is being developed so that AMS and FSIS pesticide residue monitoring data will be included in the FDA's pesticide residue monitoring program.

TABLE 5-1 Continued

PetNet	PetNet is a proposed network that would be developed by CVM to report disease outbreaks in companion animals or contamination incidents concerning pet food or animal feed. In March 2009, a working group—including representatives of CVM, CDC, USDA, the U.S. Department of Homeland Security, and public health and feed control officials from the states—was formed to combine expertise in epidemiology, veterinary medicine, emergency response, feed regulation, and laboratory analyses and charged with the development and implementation of PetNet. The target date for implementation is August 2010.
PulseNet (National Molecular Subtyping Network for Foodborne Disease Surveillance)	Established by CDC in collaboration with state public health laboratories, PulseNet is an early warning system for outbreaks of foodborne illness, consisting of a national network of public health laboratories that perform deoxyribonucleic acid (DNA) fingerprinting on foodborne bacteria. Comparison of DNA patterns permits analysts to connect cases to a common source.
Total Diet (TDS) Study	In this ongoing market basket survey, conducted by the FDA, samples of approximately 280 core foods in the U.S. food supply are collected and analyzed to determine levels of various contaminants (such as acrylamide and perchlorate) and nutrients in those foods. Data provided by the TDS have been used by regulatory agencies to estimate exposures to chemicals in foods, to perform risk assessments, and to establish policy.
VetNet	VetNet, a database maintained by USDA's Agricultural Research Service (ARS), was modeled after PulseNet and serves as USDA's pulsed-field gel electrophoresis (PFGE) pattern library. VetNet uses PFGE to subtype animal specimens submitted to NARMS and samples collected from federally inspected meat and poultry establishments for nontyphoidal *Salmonella* and *Campylobacter*. Combined data from VetNet and PulseNet could be used in outbreak investigations and surveillance efforts; however, data sharing issues have limited the usefulness of VetNet in this way. In 2007, an MOU among FSIS, ARS, and CDC was signed to help improve data sharing, but the effectiveness of this agreement has not been evaluated.

TABLE 5-2 Examples of Current Data Collection Systems and Associated Shortcomings

Type of Data	Examples of Current Data Collection Systems	Shortcomings
Behavioral (see Chapter 9)	Food Safety Survey	• Government funding is not adequate. • Substantial delays are incurred because of the 1990 Paper Reduction Act, which includes unnecessary barriers to approval of study designs.
Economic	Only ad hoc collection of this type of data	• Data often are not collected or are collected ad hoc to meet Office of Management and Budget requirements. • Estimates often have many uncertainties.
Food Production (nonregulatory, collected by industry)	Data on levels or presence of pathogens (or pathogen indicators) in ingredients	• Industry is reluctant to share data for fear of regulatory action if a contaminant is found. • Industry fears that competitors will derive some advantage from the information shared. • The amount and type of data collected vary among and within sectors of the food industry. • Smaller producers, processors, etc. have limited ability to collect and analyze data. • Problems with using data may occur when data standards do not exist or are not followed. • The capability for electronic reporting of data is lacking.
Food Production (regulatory or nonregulatory, but collected by government)	Data collected by industry with regard to juice Hazard Analysis and Critical Control Points or low-acid canning process Data collected on traceability to comply with Bioterrorism Act Selected pathogens in domestic and imported fresh produce	• Data collected at the state level are not utilized to drive a risk-based approach. • At the U.S. Food and Drug Administration (FDA), collection is led by the Office of Regulatory Affairs and based on an annual work plan. Participation of the FDA program centers with regard to data needs for a risk-based approach is questionable. • Data collection opportunities are minimal because of the low rate of inspection. • Problems with using data collected for regulatory purposes may occur if design or data standards are inadequate. • Adequate information technology systems with which to share and analyze data on a real-time basis are lacking.

TABLE 5-2 Continued

Type of Data	Examples of Current Data Collection Systems	Shortcomings
Surveillance	Molecular-based • VetNet • PetNet • PulseNet (National Molecultar Subtyping Network for Foodborne Disease Surveillance)	• Collection of data is especially lacking at the farm and retail levels. • VetNet consists of data on isolates obtained through the U.S. Department of Agriculture's regulatory testing program for slaughter and processing establishments. • VetNet is not integrated with PulseNet, hindering the ability to use the data to develop attribution models. • PetNet is in development, and how it will be integrated with VetNet and PulseNet is unclear. • Clinical data, which would be useful for risk ranking, are not collected. • Data cannot be used to estimate the incidence of specific pathogens.
	Contaminants • Aflatoxin testing • Pesticide Data Program • Total Diet Study • Microbiological Data Program	• Most data are not collected routinely, except for some commodities (e.g., sprouts). • Very little data are collected on farms or retail establishments.

continued

TABLE 5-2 Continued

Type of Data	Examples of Current Data Collection Systems	Shortcomings
Surveillance (continued)	Acute clinical outcomes • Center for Food Safety and Applied Nutrition Adverse Events Reporting System • Foodborne Diseases Active Surveillance Network • Epidemic Information Exchange • Norovirus Outbreak • OutbreakNet	• Resources for food safety vary by state and local jurisdiction. • There are no standard procedures, only guidelines, for investigating a local or multistate outbreak. Although guidelines often are followed as if they were legal standards, procedures and participation still vary by state and local jurisdiction. • Lack of communication between epidemiologists and laboratory analysts may delay investigations. • Communication between the FDA and relevant industries varies by state and local jurisdiction. • Etiology is not identified in more than 50% of outbreaks. • Data availability is often delayed by months or years. • The reporting rate to state or local departments varies because of various factors, including a lack of testing or reporting by physicians or others. • Although summaries are available from the U.S. Centers for Disease Control and Prevention, raw data are not easily accessible.
	Long-term clinical outcomes	• Identification of the long-term effects of foodborne illnesses is not routinely performed in the United States.

the exception of a few high-risk products, such as sprouts, the FDA generally has not required routine microbial surveillance of the foods over which it has jurisdiction.

Molecular-based surveillance of microbial pathogens in foods is sparse, particularly at the farm and retail levels. Laboratory and personnel resources have not been made available for such testing and surveillance, and the FDA has lacked the analytic capability to utilize such data optimally even if they were collected. As part of the 1997 Food Safety Initiative, the FDA did conduct companion microbiological surveys of selected imported and domestic produce to examine the prevalence of selected foodborne pathogens. While the results of these surveys were used to guide regulatory activities, they could not be used in quantitative risk assessment because of

the low rate of contamination and the lack of quantitative and molecular subtyping data.

In addition to relying on its own data collection, the FDA utilizes data collected by systems (e.g., National Molecular Subtyping Network for Foodborne Disease Surveillance [PulseNet], OutbreakNet, Foodborne Diseases Active Surveillance Network [FoodNet]) managed by other groups, such as the U.S. Centers for Disease Control and Prevention (CDC). These systems, which collect data through nationwide passive or active surveillance in several sentinel sites that are representative of the whole population (IOM, 2003), are starting to address problems associated with the collection of human epidemiological surveillance data.

PulseNet is an example of a notable, albeit still imperfect, improvement in the coordination and sharing of laboratory data among states and federal agencies to conduct nationwide surveillance of foodborne pathogens. The system has been instrumental in recognizing national outbreaks by linking small numbers of cases in different states, which by themselves might not have been further investigated, to similar small clusters in other states. While other federal agencies have established companion data collection systems for animal and food isolates (e.g., VetNet), data sharing between these systems and PulseNet is inconsistent. Further, different methodologies for subtyping, naming, and classifying isolate patterns have complicated the FDA's ability to use data from these other systems even if they were to be fully accessible. As a result, it has not been possible to date to use molecular data to track specific pathogens from farm to table to patient. If PulseNet is to continue to play a significant role in the monitoring of disease occurrence, significant, ongoing funding must be committed to modernizing the system. For example, pulsed-field gel electrophoresis, the technology that serves as the basis for PulseNet, is increasingly antiquated.

OutbreakNet, another CDC system, also relies on information from state and local health departments and works in partnership with PulseNet. Foodborne outbreak reporting is useful for analyzing long-term trends for pathogens not captured in other surveillance systems and for providing summaries of outbreaks (IOM, 2003). OutbreakNet has played a pivotal role in the identification of several national, multistate outbreaks, including the 2006 *E. coli* O157:H7 outbreak associated with spinach. Recognizing the limitations of state and local data and their importance to the efficacy of nationwide foodborne illness and outbreak surveillance, the Institute of Medicine has recommended enhancements to the outbreak investigation and reporting of state and local health departments (IOM, 2003).

Unlike passive surveillance systems, CDC's FoodNet is an active population-based surveillance system that has improved foodborne illness estimates, contributed to the standardization of methods among laboratories, and identified risk factors for pathogen-specific illnesses through its

targeted case control studies. In addition, FoodNet is particularly advantageous for capturing data on illnesses that are underrepresented in passive surveillance systems. For example, *Campylobacter* or *Vibrio* infections rarely appear in outbreaks and often are not reportable (IOM, 2003). Even so, FoodNet has its own limitations. For example, case ascertainment is costly and currently neither rapid nor real-time, and the sentinel site approach restricts the system's geographic scope. It is also well recognized that large numbers of cases are not identified because those affected often do not seek medical attention. If medical attention is sought, the physician frequently does not order a stool culture, or, if a stool culture is ordered, the laboratory that receives the specimen may fail to screen for the pathogen that infected the individual. FoodNet attempts to quantify underreporting of foodborne illness through regular telephone-based community surveys as well as periodic surveys of physicians and laboratories.

Regulatory agencies, such as the FDA, are highly dependent on human disease surveillance systems, which in turn depend on data provided by state and local health departments. Reporting practices, the intensity of foodborne illness investigations, and the criteria for deciding which outbreaks to investigate depend on local interests and resources, resulting in foodborne illness reporting rates that can vary more than ten-fold among states in any given year (CDC, 2009). As a result, disease surveillance data available to the FDA are often inconsistent in quality and timeliness. Reporting in general is slow, requiring weeks to months for data to be transmitted from the local to the state to the federal level. Consequently, summary data are posted and published intermittently, often many months or years after a reporting period ends. For example, CDC's 2007 Summary of Notifiable Infectious Diseases was not made available publicly until 2009. Further, because of the variability in reporting by the states, summary data cannot provide reliable estimates of disease prevalence. The lack of standardization in the collection and analysis of data and diverse state and local government capabilities have limited both the utility of these surveillance systems and the speed with which the FDA has been able to respond to recent outbreaks. Moreover, while data on public health practices among the general public, physicians, and clinical laboratories are critical to risk-based decision making, such data are collected only sporadically and usually do not include surveillance of the public health practices of federal, state, and local government agencies (e.g., reporting practices). The committee concluded that, if the FDA is to utilize state and local government data more reliably, standardization of state and local food safety programs will be necessary (see Chapter 7).

Clearly, numerous data collection systems that generate large quantities of data with direct applicability to food safety already exist. These systems were created largely in response to specific needs and often put in place with

no strategic forethought as to how the data would be analyzed and/or leveraged, through integration, to achieve the goals of the broader food safety system. Once established, data collection systems frequently have become institutionalized, even if the data being collected are of questionable quality and utility. When new questions arise, there is a tendency to try to retrofit existing systems to address them. While this approach may meet short-term data needs, it often compromises the ability to evaluate trends over time and limits the generalizability and interpretability of the data overall. In some cases, data collection systems simply do not exist (e.g., surveillance for the long-term health effects of foodborne illness) or are sparse (e.g., behavioral data). Some types of data, particularly those generated by industry, have been particularly difficult to acquire and will remain so until mechanisms that can overcome these challenges are put in place.

Lack of Data Sharing Among Government Entities

A wide variety of government entities collect data on food-associated hazards to humans and animals, but significant barriers to sharing those data have been extensively documented (Taylor and Batz, 2008). One barrier is federal and state laws, regulations, and policies that sometimes restrict the sharing of data among government entities because of such concerns as the protection of patient privacy, trade secrets, and confidential business information. These laws, regulations, and policies vary markedly among—and sometimes even within—different federal agencies. Personnel from government agencies performing field investigations frequently lack a firm understanding of the laws, regulations, and policies of their own agencies (and those of their partners), and this lack of knowledge often hampers coordination of efforts and leads to excessive withholding of information.

The failure of government entities to share food safety data sufficiently within the bounds of the law appears to result not only from a misunderstanding of legal obligations but also in part from institutional culture. This observation is illustrated by the sometimes tense relationship between the FDA and CDC. The two agencies agree (in theory) that they should share all information with each other. They have entered into a memorandum of understanding (MOU) (MOU 225-03-8001) that states the following:

> Although there is no legal requirement that FDA and CDC exchange information in all cases, FDA and CDC agree that there should be a presumption in favor of full and free sharing of information between FDA and CDC. As sister public health agencies within the Department of Health and Human Services, there are no legal prohibitions that preclude FDA or CDC from sharing with each other most agency records in the possession of either agency. (FDA, 2003)

The committee learned, however, that the actual relationship between the FDA and CDC falls far short of fulfilling this presumption of full and free data sharing (Morse, 2009; Osterholm, 2009). In response to written questions about information sharing between the agencies, the Center for Food Safety and Applied Nutrition (CFSAN) provided the following statement:

> To determine what foods may be responsible for causing outbreaks, FDA relies in part on epidemiological data from the [CDC] which, in large part, relies on the states. CDC redacts confidential private patient information from these data, as required by federal privacy laws, but otherwise there are no legal constraints to the sharing of this information between CDC and FDA because there is a signed confidentiality [MOU] between the two agencies that allows for the free exchange of information. However, sometimes there are delays in FDA's receiving epidemiological data from CDC because the states need to supply CDC with the data and CDC needs time to compile the data, redact any confidential patient information, and analyze, [sic] and interpret these data before sharing.[5]

CFSAN's response illustrates the real and perceived barriers to information sharing between CDC and the FDA. CDC appears to have informed the FDA that "federal privacy laws" require CDC to redact confidential patient information before providing data to the FDA. This redaction of information delays data sharing; at worst, it prevents or delays the FDA's use of the information to protect public health. Federal law does not require such redaction. The relevant statute, the Privacy Act, 5 U.S.C. 552a,[6] prohibits federal agencies from disclosing any personal record without the consent of the person to whom the record pertains, but it contains an explicit exception for disclosures "to those officers and employees of the agency which maintains the record who have a need for the record in the performance of their duties." CDC and the FDA, as sister agencies within the U.S. Department of Health and Human Services (HHS), fall within this exception.[7] Of course, none of this is to suggest that patient-identifying information should be shared between the agencies when there is no need

[5] Personal communication, Chad Nelson, FDA, July 25, 2009.

[6] *The Privacy Act of 1974*, 5 U.S.C. § 552a(b)(1); The Health Privacy Rule of the Health Insurance Portability and Accountability Act would not normally limit CDC's authority to share data with anyone because CDC is not a "covered entity" subject to that rule.

[7] The Privacy Act incorporates the definition of the term "agency" from the Freedom of Information Act, which in turns defines "agency" as "any executive *department*, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency [emphasis added]." *The Privacy Act of 1974*, 5 U.S.C. § 552a(f)(1).

to do so. But sharing of confidential information is appropriate when redaction by CDC would unduly delay the transmission of essential information to the FDA in an emergency situation or would completely deny the FDA information it needs to protect the public health. Consequently, it is important for the agencies to understand that such redaction by CDC is not legally required.

The MOU between CDC and the FDA (MOU 225-03-8001) appears to assume that such confidential information may be shared between the agencies, and it establishes a mechanism for doing so. For "routine requests for information," the agency seeking the information need only demonstrate, in writing, why it needs the requested information, and the responding agency "should only decide not to share information in response to [such] a request if it has credible information and a reasonable belief that the requesting agency may not be able to comply with applicable laws or regulations governing the protection of non-public information or with the principles or procedures set forth in this MOU." With respect to "emergency requests for confidential information," the MOU sets forth more flexible and expeditious procedures, which include oral requests. The MOU explicitly cites "a foodborne illness outbreak" as its one example of "emergency circumstances" (FDA, 2003).

CFSAN's quoted response to the committee's written questions suggests that CDC fails to live up to the MOU's presumption of "full and free sharing of information" not only because of real or perceived legal limitations but also, as suggested above, because of its institutional culture. The response states that CDC withholds food safety data from the FDA until it "analyzes" and "interprets" the data. There is no legal requirement or public health justification for such a delay. The perception among some witnesses questioned by the committee was that CDC employees are reluctant to disseminate data, even to a sister agency, if early release of those data might compromise their academic publishing opportunities.

The committee understands, but was unable to verify, that some states may have data-sharing agreements with CDC that prohibit CDC from sharing confidential data it has obtained from the states with additional parties, perhaps even sister federal agencies such as the FDA. If such provisions do in fact exist, in the new climate of a closer working relationship between federal and state food safety authorities, greater sharing of information and the development of ways to share information within the bounds of confidentiality would be beneficial. To the extent that state laws prohibit the sharing of confidential information with federal agencies altogether, even when such sharing is necessary to protect the public health, reassessing such laws to permit the creation of a truly cooperative and integrated food safety system would be warranted.

Problems also appear to exist with respect to information sharing

between the FDA and the U.S. Environmental Protection Agency (EPA), which, unlike CDC, is not a sister agency within HHS. CFSAN reported to the committee that during the 2008 incident involving the melamine contamination of dairy powder imported from China, the EPA declined to share the results of a melamine exposure assessment with the FDA because that assessment "contained confidential commercial information not disclosable outside of EPA."[8]

There is also evidence of substantial constraints and delays in the flow of food safety information from the FDA to state and local governments. The FDA's responses to the committee's questions on data sharing identify several federal laws that restrict what food safety information it can share with state and local authorities. These laws include the following:

- The Trade Secrets Act, 18 U.S.C. 1905, prohibits any federal agency employee from divulging "in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties . . . which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association."[9]
- Section 301(j) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 331(j), prohibits "revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of [an enumerated list of FDCA sections] concerning any method or process which as a trade secret is entitled to protection. . . ."[10]
- The Privacy Act, 5 U.S.C. 552a, prohibits federal agencies from disclosing any personal record without the consent of the person to whom the record pertains.

The restrictions on data sharing established by these laws are not necessarily as sweeping as they appear at first glance, however. For example, the Trade Secrets Act applies only to disclosures "not authorized by law," and the FDA could by regulation "authorize" its employees to share various types of information vital to food safety, provided it has been granted the requisite authority by Congress to do so. Section 301(j) of the FDCA applies, on its face, only to trade secrets and not to confidential commer-

[8] Personal communication, Chad Nelson, FDA, July 25, 2009.
[9] *The Trade Secrets Act*, 18 U.S.C. § 1905.
[10] *The Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. 331(j).

cial information that does not qualify as a trade secret.[11] Consequently, this provision appears to bar FDA officers and employees from sharing information concerning food formulas and manufacturing processes, for example, but not from sharing distribution data needed to conduct trace-back/trace-forward activities. The Privacy Act contains a number of potentially relevant exceptions, the most important of which is the "routine use" exception. Under this provision,[12] an agency can disclose a record containing information about an individual without that individual's consent if the disclosure is for a "routine use" defined by regulation. An agency may define the disclosure of a record as a "routine use" if the disclosure is for any "purpose which is compatible with the purpose for which [the record] was collected."[13] Each agency thus has broad discretion under the Privacy Act to decide when it is appropriate to disclose personal information.

These federal laws clearly present real obstacles to information sharing between the FDA and state and local governments. One possible method for facilitating such communications in light of these legal restrictions is through the liberal use of commissioned officials in state and local governments. According to its regulations, the FDA may share "data otherwise exempt from public disclosure" with "state and local government officials commissioned pursuant to 21 U.S.C. 372(a)," which states that:

> [t]he Secretary is authorized to conduct examinations and investigations for the purposes of this Act . . . through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department.

The FDA is understandably concerned that state and local officials

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[11] The FDA's own regulations draw a distinction between a "trade secret" on the one hand and "commercial or financial information that is privileged or confidential" on the other. According to the regulations,

> [a] trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process). 21 CFR 20.61(a)

By contrast,

> [c]ommercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs. (21 CFR 20.61(b))

[12] 21 U.S.C. 552a(b)(3) (incorporating by reference 21 U.S.C. 552a(a)(7) and 21 U.S.C. 552a(e)(4)(D)).

[13] 21 U.S.C. 552a(a)(7).

with whom it shares confidential information will disclose that information inappropriately. Under 21 CFR 20.84, commissioned officials are "subject to the same restrictions with respect to the disclosure of such data and information as any other [FDA] employee." Nevertheless, CFSAN, in its answers to the committee's questions, noted that "due to their sunshine [openness] laws, certain states are unable to keep such information confidential, which limits FDA's ability to share such information."

With regard to the provision of information by state and local governments to the FDA, CFSAN told the committee that:

> [t]here are legal restrictions on the sharing by state and local governments of epidemiological data that may contain patient information that is considered confidential. This occurs with every outbreak investigation. . . . We understand that these restrictions derive from state and federal patient privacy laws. . . .[14]

Federal law may in fact limit information sharing by state and local government entities in at least some instances. For example, the FDA public information regulations, 21 CFR 20.63(b), state that:

> [t]he names and other information which would identify patients . . . should be deleted from any record before it is submitted to the [FDA]. If the [FDA] subsequently needs the names of such individuals, a separate request will be made.[15]

The committee does not know whether this regulation has prevented or delayed the sharing of vital food safety information by state and local governments with the FDA.

One oft-cited federal statute that, regardless of perception, does not in fact appear to greatly inhibit the sharing of food safety information between state and local governments and the FDA is the Health Insurance Portability and Accountability Act (HIPAA). The HHS Privacy Rule implementing HIPAA, 45 CFR Part 160 and Part 164, Subparts A and E, applies only to "covered entities" specified in the statute, namely "health plans," "healthcare clearinghouses," and "healthcare providers."[16] Many state and local agencies possessing epidemiological data do not fall within any of these categories. To the extent that a state or local agency is a "covered entity," the Privacy Rule contains an explicit public health exception that would

[14] Personal communication, Chad Nelson, FDA, July 25, 2009.

[15] 21 CFR 20.63(b).

[16] *The Health Insurance Portability and Accountability Act of 1996*, Public Law 104-191, section 1172.

apply in the context of a food safety emergency.[17] HIPAA prevents the disclosure only of patient-identifying information, so even when the statute applies, it does not prohibit the dissemination of appropriately redacted data (although the redaction process may cause delay). However, it should be noted that state privacy laws may present a greater barrier to the sharing of food safety information by state and local governments. They may cover more types of entities and impose more stringent privacy requirements than does HIPAA.[18]

Access to Industry Data

Many food companies have carefully designed science-driven food safety systems that produce a substantial amount of data that would be of great value for risk-based decision making. Industry has, however, been reluctant to share its data with the FDA. Barriers that limit the ease with which data from industry could flow to the FDA include the proprietary nature of such data, the absence of an appropriate information infrastructure to manage the data, and potential regulatory ramifications, the latter of which is often cited as the most significant concern. In short, the FDA has generally not been successful in accessing industry data, and although the concept periodically arises as a point of discussion, the agency has made no coordinated effort to overcome the barriers involved.

MOVING FORWARD: DESIGNING AND IMPLEMENTING AN INTEGRATED INFORMATION INFRASTRUCTURE

Designing and implementing the integrated information infrastructure necessary to support a risk-based food safety system will require an investment in information science, as well as an infrastructure that improves data availability and quality and facilitates data standardization, harmonization, and analysis. In 2007, the FDA Science Board recommended that the agency collaborate with other government agencies to develop data standards and large-scale sustainable data-sharing infrastructures that would allow the timely integration and analysis of data critical to the agency's mission (FDA Science Board, 2007). Such an investment would reduce data gaps and facilitate risk-based decision making while improving communication, the integration of business processes, and interoperability. In the committee's

[17] 45 CFR 164.512(j). See also 45 CFR 164.512(f) (law enforcement exception).

[18] HIPAA itself does not limit how strictly states may protect patient privacy. The HIPAA Privacy Rule, by its own terms, does not preempt state law regarding the privacy of patient health information to the extent that the state law is more stringent than the federal regulations (45 CFR 160.203(b)). Moreover, some state laws may impose patient privacy limitations on state and local government entities not covered by HIPAA.

opinion, key elements necessary to initiate the transition to an integrated information infrastructure include (1) strategic data collection, (2) the accessibility of data, (3) the availability of a modern IT system, and (4) the analytic capacity to design and maintain the system as well as to analyze, interpret, and disseminate data generated by the system. These elements are discussed briefly below. Chapter 11 examines potential organizational changes to ensure that these elements are in place.

Strategic Data Collection

Accurate, reliable, secure, and timely data are the backbone of any risk-based decision-making system. The types of data collected and the methods employed in data collection should, ultimately, be driven by the specific objectives and goals of the system. The data that could be collected are virtually endless, making the strategic planning process critical. Strategic planning is readily applicable to data collection and analysis; in fact, it is necessary for the development of an integrated information infrastructure. The strategic plan must address the following:

- the goals and ultimate uses of the data (attribution, public health response, development of targeted interventions);
- the types of data needed to achieve those goals;
- an assessment of what data are currently being collected, as well as their limitations and appropriateness;
- the data issues and gaps that must be addressed to achieve the stated goals;
- the priorities for collecting additional data;
- the data collection methods and standards necessary for accessing, integrating, and analyzing the various sources of data;
- the analytic capabilities necessary for collecting, integrating, and analyzing the data; and
- the performance metrics that will be used to evaluate the data collection and analysis system, including a quality assurance system.

The first step in the strategic planning process should be a comprehensive inventory and review of existing data collection systems without regard for interinstitutional boundaries. Each data collection system should be reviewed by FDA and non-FDA scientists to evaluate its relevance, funding, productivity, and programmatic benefits as they relate to the agency's mission. Such an approach would provide valuable information for the strategic planning process and would, in essence, make data collection part of the set of risk management tools available for agency use. To be effective, the strategic planning process will require input from multiple federal,

state, and local government agencies, as well industry and nongovernmental organizations (NGOs).

Data collection should not be performed simply for its own sake. Decisions on data collection systems and the exact nature of the data to be collected must be driven by the needs of the underlying risk-based decision-making process. As discussed further in Chapter 11, the development of appropriate and cost-effective data collection systems should, ideally, be done in collaboration with other agencies and departments involved in work with food safety, potentially through a single, unified center focused on data collection and analysis. Data collection systems should be developed and evaluated within the risk-based decision-making process outlined in this report. In the absence of a single food agency, it will be challenging to formulate a strategic vision for developing and implementing the integrated information infrastructure necessary to support a risk-based food safety system. The FDA can and should take an active leadership role in the development and implementation of a system that is designed to suit its needs in the years to come.

Access to Data

Many different groups collect food safety data for different purposes that could be valuable to the regulatory mission of the FDA. The system should leverage data collected for a variety of purposes by various federal, state, and local government agencies, as well as by the food industry, the academic sector, and NGOs. To this end, it is essential that data be accessible to all stakeholders in a timely manner. The FDA's ability to effectively identify, investigate, and respond to food safety issues—including outbreaks, emerging pathogens, and the choice of intervention strategies—is dependent on timely access to quality data that are often collected by others.

As described above, substantial barriers to data sharing must be addressed before a risk-based system can be implemented effectively. Relevant government agencies should examine whether they currently withhold more food safety information than is required by law, and they should correct any current misunderstandings of the law. The FDA should take a leadership role in implementing the recommendations of Taylor and Batz (2008) for improving access to currently available data necessary to fulfill its mission. Chapter 11 outlines some approaches, such as a centralized risk-based analysis and data management center, that might alleviate some of the barriers to data sharing mentioned in this section. Regardless of the establishment of these approaches, many of the actions suggested below will still be needed to overcome data-sharing barriers. To the extent that legal changes are needed to allow sufficient data sharing, especially in the case of emergencies, Congress should consider amending the law.

To facilitate the sharing of food safety data relevant to protecting the public health, the Secretary of HHS should publish guidelines, including answers to frequently asked questions, concerning data sharing between different HHS agencies. In addition, the FDA and CDC should jointly provide training to their food safety employees regarding the actual limits on such data sharing imposed by federal law. There would be some benefit in having FDA and CDC employees present at the same training sessions. This training should address in detail the data-sharing MOU entered into by the two agencies. The FDA should also assist state and local food safety agencies regarding the provision of such training to state and local employees. Further, the FDA should, as recommended elsewhere in this report, consider greatly expanding the use of its commissioning authority to create a cadre of state and local commissioned officers throughout the nation, which, in addition to increasing the size of the agency's inspectional force, would facilitate data sharing between the FDA and state and local governments. Entering into formal data-sharing agreements with other federal agencies with which the FDA has shared or might share food safety information (e.g., EPA) is also advisable. In terms of legal barriers to sharing data, the FDA should determine whether federal law preempts state openness laws with respect to information provided to FDA-commissioned state and local officers and, if necessary, ask Congress to revise the relevant statutes and regulations to ensure that the agency can share confidential data without concern that those data will later be made public under state openness laws. The FDA should also determine whether its public information regulations, such as 21 CFR 20.63(b), have prevented or delayed state and local governments' sharing of vital food safety information with the agency. If necessary, the regulations should be revised to permit state and local governments, as well as other entities, to submit records to the FDA in emergency situations or when there is a legitimate need without first redacting patient-identifying information.

In terms of accessibility of industry data, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 gives the FDA access to industry records only when they are related to food that "presents a threat of serious adverse health consequences or death to humans or animals."[19] In Chapter 10, the committee recommends that the FDCA be amended to require that every food facility prepare a food safety plan and that this plan and its implementation records be made available to FDA inspectors. The FDA should identify the kinds of industry data that are needed for risk-based decision making and develop mechanisms for collecting and ensuring the quality of those data. The FDA should also

[19] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)*, Public Law 107-188, 107th Cong., 2nd sess. (January 23, 2002).

consider regulatory changes, to the extent necessary to ensure food safety, that would authorize it to release some trade secret and confidential commercial information under the Trade Secrets Act. To help promote the trust and cooperation of industry, advances in tracking, masking, and analyzing information should be explored to enable the FDA and its partners to protect such information while sharing information that specifically helps protect public health.

Information Technology and Personnel Needs

Information Technology

A critical component of the implementation of a risk-based decision-making system is the underlying technology necessary for the collection, processing, and delivery of information. The inability to collect, integrate, and deliver information can result in inefficient use of resources, redundancy, ineffective information sharing, and delayed or inappropriate regulatory decision making, all of which impact public health (FDA Science Board, 2007; GAO, 2009). The ability to access, integrate, and analyze numerous and varied data sources depends on the development, harmonization, evaluation, and adoption of an electronic data exchange environment that supports data standards.

Several recent reports have found critical gaps in the FDA's centralized IT infrastructure, which has been described as obsolete, redundant, and unstable (FDA Science Board, 2007; GAO, 2009). In 2007, the FDA Science Board described the agency's IT situation as "problematic at best—and at worst it is dangerous" (FDA Science Board, 2007, p. 5).The FDA's IT workforce has been deemed insufficient to meet the agency's needs (FDA Science Board, 2007). Further, the FDA's IT infrastructure lacks the necessary backup systems to provide continuity of operation in case of system failures (FDA Science Board, 2007). During the 2006 spinach-related outbreak, for example, failures in the FDA's e-mail system contributed to delays in responding to the outbreak (FDA Science Board, 2007).

Recent evidence suggests that the FDA is making progress, albeit slowly, in improving its information infrastructure (FDA Science Board, 2009). In 2008, the agency began an effort to consolidate its IT infrastructure and centralize its IT management with the creation of the Office of Information Management (GAO, 2009). As of this writing, the development of a comprehensive strategic plan for this office was under way and was expected to be completed by the end of fiscal year 2009 (GAO, 2009). Progress appears to have been made on developing an IT architecture design and on building the foundation for data standards and harmonization (FDA Science Board, 2009). Several initiatives to modernize the FDA's information infra-

structure and IT systems have been undertaken, with the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) model as a relevant example (see Chapter 3 and Appendix E). Workforce assessments have also been undertaken. Further, the FDA has established a Bioinformatics Board to oversee the agency's IT investments, as well as Business Review Boards for each of the core business areas that are responsible for the day-to-day oversight of IT projects. It has also created a project management office, developed criteria for evaluating prospective projects, and documented project monitoring and control processes.

Despite this recent progress, however, substantial challenges remain, including centralizing IT, developing a scientific computing infrastructure, addressing information security issues, and conducting strategic human capital planning. Of particular concern are the lack of a detailed, comprehensive strategic IT plan and the agency's segmented approach to developing its enterprise architecture. For example, the FDA started building PREDICT, a component of its enterprise architecture, without having a detailed plan or establishing priorities for the development of the overall enterprise architecture (FDA Science Board, 2009). Such an approach is contrary to the concepts outlined in this report and may ultimately result in a fragmented enterprise architecture that is incompatible with future systems.

The committee agrees with the recommendations in the FDA Science Board report. The committee emphasizes the importance of the development of a modern IT infrastructure and investment in the FDA's IT workforce (see section below regarding Personnel Needs) to meeting the agency's public health objectives and implementing its overall strategic plan.

Personnel Needs

The problems of fragmented data collection systems and inaccessibility of data are compounded by an inadequate pool of scientific personnel that can, even in times of emergency, effectively collect, manage, analyze, interpret, and disseminate the data to which they have access. Several reports have noted the problem of insufficient staff, as well as inadequate recruitment and retention and the failure to make an investment in professional development (FDA Science Board, 2007). Recently, the U.S. Government Accountability Office (GAO) recommended that the agency manage its workforce strategically by determining the critical skills and competencies needed to fulfill its mission, analyzing the gaps between current skills and future needs, and developing strategies for filling those gaps (GAO, 2009). While the FDA has increased its training budget and is conducting workforce assessments (FDA Science Board, 2007, 2009), however, it has not yet addressed the bulk of these GAO recommendations.

The FDA is underutilizing its field personnel. For example, field assignments could be used for the collection of data (e.g., who uses a specific piece of equipment in processing frozen peas) or the analysis of samples (e.g., a statistically representative sampling of bagged salads for microbiological analysis). Prior to 1994, ORA's Minneapolis Center for Microbiological Investigation conducted analyses in the field for the FDA; however, this dedicated function no longer exists. Given the agency's limited inspection capacity, most efforts of the inspectional force are dedicated to performing legally required inspectional duties.

As mentioned in Chapter 3, one way to meet the FDA's analytical personnel needs would be to create functional teams in support of the risk-based approach. In this case, for example, a surveillance team would be responsible for interacting with other federal agencies and state and local jurisdictions and for managing centralized epidemiological databases supporting modeling efforts. Such a group would include statisticians, epidemiologists, microbiologists, behavioral scientists, economists, risk analysts, biomathematical modelers, database managers, IT personnel, risk managers, and other experts as needed. Also, the agency should start implementing the above-mentioned GAO recommendation to address its IT human resource needs (GAO, 2009). Chapter 11 describes approaches for consolidating data and risk analysis, such as a centralized risk-based analysis and data management center that would meet the needs of all agencies with responsibilities for food safety. As outlined in Chapter 11, the committee sees clear potential advantages to the creation of such a center that would have access to food safety data from multiple agencies, the analytical capacity to deal with these data, and the ability to disseminate results of its analyses to agencies for policy development. Even with such a center, however, the FDA will need to maintain a core of experts in all the disciplines noted above.

KEY CONCLUSIONS AND RECOMMENDATIONS

Decisions on data collection systems and the characteristics of the data to be collected must be driven by the needs of the underlying risk-based decision-making process. The FDA has not adequately assessed and articulated its data needs. The agency currently lacks the capability to collect and integrate the data needed for effective implementation of a risk-based approach to food safety. For example, it lacks a dedicated cadre of analytical personnel to design, implement, and manage the collection of and analyze, interpret, and disseminate the data needed to support a risk-based system. It lacks a group of epidemiologists, statisticians, and data analysts that can work with risk modelers, analysts, and managers to support risk-based decisions about food safety.

In terms of sharing data with other relevant partners (e.g., CDC, the U.S. Department of Agriculture, the food industry), it appears that the legal regime now in place would permit a substantial increase in such data sharing. However, nonlegal obstacles, both technological (e.g., inadequate IT) and cultural (e.g., unnecessary delays in sharing data or a lack of trust), continue to limit the sharing of data among partners. To protect the public health, federal, state, and local agencies and industry must share more food safety information, and share it more rapidly, than is now the case.

In support of a risk-based approach driven by data, the committee makes the following recommendations.

Recommendation 5-1: Data collection by the FDA should be driven by the recommended risk-based approach and should support risk-based decision making. It is critical that the FDA evaluate its food safety data needs and develop a strategic plan to meet those needs. The FDA should review existing data collection systems for foods to identify data gaps, eliminate systems of limited utility, and develop the necessary surveillance capabilities to support the risk-based approach. The FDA should formulate and implement a plan for developing, harmonizing, evaluating, and adopting data standards. The FDA should also establish a mechanism for coordinating, capturing, and integrating data, including modernization of its information technology systems. To coordinate, capture, and integrate data, the FDA could lead the implementation of a multiagency food safety epidemiology users group as outlined by Taylor and Batz (2008). The centralized risk-based analysis and data management center proposed in recommendation 11-3 in Chapter 11 could serve the functions of data storage and analysis in support of a risk-based approach. Mechanisms should also be instituted to build trust with industry and, in partnership, collect and analyze industry data.

Recommendation 5-2: The FDA should evaluate its personnel needs to carry out its roles in collecting, analyzing, managing, and communicating food safety data. The agency should establish an analytical unit with the resources and expertise (i.e., statisticians, epidemiologists, behavioral scientists, economists, microbiologists, risk analysts, biomathematical modelers, database managers, information technology personnel, risk managers, and others as needed) to support risk-based decision making.

Recommendation 5-3: The FDA should evaluate statutes and policies governing data sharing and develop plans to improve the collection and sharing of relevant data by all federal, state, and local food safety agencies. For example, in collaboration with other food safety agencies, the

FDA should develop and implement technologies and procedures that will ensure confidentiality and facilitate data sharing. Congress should consider amending the law, to the extent that legal changes are needed, to allow sufficient data sharing among government agencies.

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6

Creating a Research Infrastructure for a Risk-Based Food Safety System

The U.S. Food and Drug Administration's (FDA's) food safety research functions are performed predominantly by three intramurally funded centers—the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the National Center for Toxicological Research (NCTR)—with some involvement of the Office of Regulatory Affairs (ORA). The agency's food safety research mission is also supported by external research centers in formal collaboration with academic institutions as well as a few other activities. The food safety research at these intra- and extramural centers is summarized by topic in Appendix F. The research authority of the FDA's food programs encompasses two major areas (Musser, 2009): (1) support for the Code of Federal Regulations, with a focus primarily on the development of improved and/or advanced detection methods, and (2) activities in support of specific food safety initiatives, such as the Food Protection Plan, counterterrorism efforts, and appropriations conference reports (Musser, 2009).

The FDA conducts a large research program in support of its food safety mission. According to the U.S. Department of Health and Human Services' fiscal year (FY) 2010 justification of estimates (HHS, 2010), total 2009 allocated research funding for the agency as a whole was $190,070,000. This total encompasses research in support of all FDA programs, of which the foods component is only a part. For the FDA's FY 2009 food programs, the congressional budget included $30,178,000[1] (approximately

[1] In addition to research, these figures include funding for buildings and equipment and personnel.

15 percent of the agency's total research budget) in base research funding for CFSAN and ORA, reflecting an increase of $2,862,000 over the previous FY(Musser, 2009). An additional $1,683,000 was budgeted for food protection research at NCTR for 2009. For FY 2010, center-specific resource allocations for research are summarized in Table 6-1. Overall, the agency's food safety research initiatives can be categorized as follows: (1) development of rapid detection methods, (2) development of confirmatory methods, (3) biotechnology, (4) virology, (5) in vitro testing, and (6) laboratory enhancement (Musser, 2009).

This chapter provides a summary of the research currently conducted under the FDA's food programs and considers how these research efforts do or do not mesh with the risk-based approach described in Chapter 3.

TABLE 6-1 FY 2010 Resource Allocations for Research, by FDA Center

Center	Research FTEs	Total Research Funding	Increase in Funding over Last Fiscal Year
Center for Food Safety and Applied Nutrition	30 (premarket applied research)[a] 140 (postmarket applied research)[a]	$9,478,000 (premarket applied research)[a] $54,222,000 (postmarket applied research)[a]	+$374,000 (premarket applied research)[b] +$8,006,000 (postmarket applied research)[b]
Center for Veterinary Medicine	16 (premarket applied research)[a] 44 (postmarket applied research)[a]	$3,043,000 (premarket applied research)[a] $8,195,000 (postmarket applied research)[a]	+$789,000 (premarket applied research)[b] +$1,208,000 (postmarket applied research)[b]
National Center for Toxicological Research	211	$58,745,000[c] $1,625,000 specifically for Protecting America's Food Supply[c]	+$6,234,000[c] +$1,625,000 specifically for Protecting America's Food Supply[c]
Office of Regulatory Affairs	Not available	$1,100,000[d]	No increase[e]

NOTE: FDA = U.S. Food and Drug Administration; FTE = full-time equivalent; FY = fiscal year.

[a] FDA, 2010b.

[b] FDA, 2010b,c.

[c] FDA, 2010d.

[d] This number applies to food research activities only (FDA, 2010e).

[e] FDA, 2009.

Much of the information on which the discussion is based was gathered from a report provided by CFSAN, which was written in response to an FDA Science Board task to review the center's research and related support programs.[2] A review of the research and related support programs at CVM was completed by the FDA Science Board in 2009 (FDA Science Board, 2009) and was also consulted in the preparation of this chapter, as was a packet of materials from the FDA with salient information about NCTR (NCTR, 2009a,b,c). In addition, information was obtained from the FDA website and consultation with FDA staff.

INTRAMURAL RESEARCH PORTFOLIO

CFSAN[3]

The FDA's largest food safety research portfolio is housed in CFSAN. In the above-referenced report provided to the Science Board, CFSAN describes the purpose of its research program as to "conduct applied and translational research that facilitates our enforcement of the Federal Food, Drug and Cosmetic Act, the U.S. Public Health Service Act, the Infant Formula Act, and the Dietary Supplement Health and Education Act." The report further states that "CFSAN takes advantage of the research capabilities of other federal research agencies, which allows it to focus its research infrastructure on the conduct of critical problem-solving research." These statements make clear that the center's research mission is applied in nature.

As of this writing, CFSAN had 170 research full-time equivalents (FTEs). For the purposes of this report, these FTEs are classified as primary researchers, engaged in the collection of original data. Information about the proportion of FTEs dedicated to food safety as opposed to nutrition was not available, but the vast majority of the research focus is food safety, with an emphasis on chemical and microbiological public health hazards and, more recently, food defense. Individuals are rarely dedicated solely to research. CFSAN research scientists, research managers, and directors also perform regulatory functions such as reviews (petitions, compliance, guidance, and policy), risk assessments, outbreak investigations, and training. This diversity is considered advantageous to the agency as research scientists become "authoritative sources of information in areas of regulatory review and policy implementation."

Most of the scientists and staff supporting the center's research mission are located at the headquarters building in College Park, Maryland. However,

[2] Personal communication, Chad Nelson, FDA, October 13, 2009.

[3] The discussion in this section is based on the personal communication with Chad Nelson, FDA, October 13, 2009.

the center also operates research facilities in Laurel, Maryland; Summit-Argo, Illinois; and Dauphin Island, Alabama. About 25 agency employees are housed at the National Center for Food Safety and Technology (NCFST) near Chicago, Illinois. NCFST and the other four extramural research centers are discussed in the next section.

As with research FTEs, the committee was unable to obtain information on funding allocated for CFSAN's food safety mission alone. As noted, however, most of the research at CFSAN has been devoted to food safety.

The intramural program at CFSAN is composed of research in the disciplines of chemistry, microbiology, molecular biology, food science, toxicology, immunology, epidemiology, social sciences, education, and risk assessment. Major research thrusts include the following: (1) development and evaluation of methods to recover, detect, and identify pathogens, chemicals, and biomolecules in foods, including evaluation of emerging technologies; (2) risk assessment; and (3) economics and consumer studies (Musser, 2009). CFSAN currently has about 96 active research projects related to food protection (Musser, 2009). Virtually all of these projects are considered applied in nature; in other words, they are "investigations aimed at developing and applying standards to public health needs" (Musser, 2009). Other important components of CFSAN's research program include nonlaboratory research on risk communication, labeling, education, and the economic impact of its regulations and enforcement programs.

Each intramural research project is, at most, 3 years in duration and may be adjusted as needed during this period. CFSAN did not provide the committee with a full listing of its intramural research projects; however, a list was available online[4] (CFSAN/FDA, 2008), and a listing on the state of the science at CFSAN was also made available to the committee. Referencing the two relevant areas (food safety and food defense), the committee was able to produce the table in Appendix F. Some common themes emerge from this table. Consistent with Musser's presentation (Musser, 2009), a large proportion of the research focuses on the development of detection methods. Other important themes include (1) a greater emphasis on pathogens as compared with chemicals/allergens; (2) relatively few projects focused on risk assessment and economics/consumer studies, despite these being mentioned to the committee as priority areas (Musser, 2009); and (3) a relative absence of research on control or intervention strategies.

[4] See http://www.fda.gov/Food/ScienceResearch/SelectedScientificPublicationsPresentations/ucm117721.htm#fs (accessed October 8, 2010).

NCTR

NCTR is located in Jefferson, Arkansas. The committee received very little information about NCTR's food safety functions. Therefore, much of the discussion here is based on the center's webpage.[5] The center as a whole receives approximately 28 percent of the FDA's total research budget, the second largest proportion of that budget (HHS, 2010). About 35–40 of the center's approximately 200 research FTEs are dedicated to food safety (NCTR, 2009a; FDA, 2010a). NCTR states that its vision is to provide "innovative and vital scientific technology, training, and technical expertise to improve public health," with a corresponding mission statement of "conduct[ing] peer-reviewed scientific research in support of the FDA mission" (NCTR, 2009a, p. 1) (see Box 6-1). In support of the center's mission, NCTR has identified seven Centers of Excellence (see Box 6-2).

As reflected in its name, NCTR's work is dedicated largely to toxicological research. A review of the program reveals that fundamental research appears to be the driving force. For example, the center houses a wide variety of state-of-the-art equipment and is addressing most of the "omics," all considered emerging transdisciplinary approaches to biological research. Clearly, this center's mission is much broader than food safety, and many of its initiatives are designed to support the FDA's drug and devices functions (FDA, 2010a).

The committee was not provided information with which to determine the proportion of NCTR's research budget dedicated to food safety. Nonetheless, one of the center's strategic goals is to "conduct research and develop strategic technologies to protect the food supply." To that end, investigators at NCTR are conducting research in the following areas: (1) food safety, food biosecurity, and methods development; (2) antimicrobial resistance; and (3) gastrointestinal microbiology and host interactions. A list of projects in support of these research initiatives is provided in Appendix F.

The committee reviewed information received from the FDA about NCTR, including the *NCTR Strategic Plan 2009–2013*, *FY2009 Accepted Publications*, *NCTR Food Publications 2005–2009*, and a breakdown of food safety spending and food safety research FTEs for 2000–2007 (NCTR, 2009a,b,c). These materials, especially the *Strategic Plan*, are clear in delineating the center's vision and mission and its strategic goals for accomplishing this mission (Box 6-1) (NCTR, 2009a). Of the five strategic goals, Goal 3 pertains directly to food safety, while Goals 4 and 5 involve broad support for the FDA's mission, which clearly includes food safety. Goal 1, while not related to food safety, does concern nutrition, which is in the domain of CFSAN. The two lists of publications (NCTR 2009b,c) show

[5] See http://www.fda.gov/AboutFDA/CentersOffices/nctr/default.htm(accessed October 8, 2010).

BOX 6-1
Vision, Mission, and Strategic Goals from the National Center for Toxicological Research (NCTR) Strategic Plan 2009–2013

Vision

NCTR is an internationally recognized U.S. Food and Drug Administration (FDA) research center that provides innovative and vital scientific technology, training, and technical expertise to improve public health. NCTR—in partnership with researchers from government, academia, and industry—develops, refines, and applies current and emerging technologies to improve safety evaluations of FDA-regulated products. NCTR fosters national and international collaborations to improve and protect public health and enhance the quality of life for the American people.

Mission

NCTR conducts peer-reviewed scientific research in support of the FDA mission and provides expert technical advice and training that enables FDA to make sound science-based regulatory decisions and improve the health of the American people. The research at NCTR supports FDA's goals: (1) to understand critical biological events in the expression of toxicity, (2) to develop and characterize methods, and incorporate new technologies to improve the assessment of human exposure, susceptibility, and risk, and (3) to increase the understanding of the interaction between genetics, metabolism, and nutrition.

NCTR is dedicated to supporting the FDA mission to protect and promote public health by:

- providing innovative and interdisciplinary research that promotes personal and public health
- developing novel translational research approaches to provide FDA/Department of Health and Human Services (HHS) with sound scientific infrastructure and multidisciplinary scientific expertise targeted towards addressing critical Agency, Department, and public-health needs such as personalized nutrition and medicine,

that the majority of the center's work is in toxicology, but it also performs significant work in food safety. It should be noted that many of NCTR's food safety publications are on non-FDA-regulated items, such as processed eggs and poultry (e.g., Kiess et al., 2007; Khan et al., 2009).

bioimaging, systems biology, bioinformatics, nanotechnology, food protection technologies, and biomarker development
- engaging with scientists across FDA and other government agencies, industry, and academia in cooperative learning to strengthen the scientific foundations vital to developing sound regulatory policy and leveraging resources in order to promote the international standardization and global harmonization of regulatory science
- participating in or leading national and international consortia for the development of harmonized standards for technologies and methods in risk assessment and for personal and public health

Strategic Goals

To accomplish its mission, NCTR has established five strategic goals:

Goal 1: Advance scientific approaches and tools to promote personalized nutrition and medicine for the public

Goal 2: Develop science-based best-practice standards, guidance, and tools to incorporate toxicological advancements that improve the regulatory process

Goal 3: Conduct research and develop strategic technologies to protect the food supply

Goal 4: Conduct bioinformatics research and development in support of FDA's regulatory mission

Goal 5: Strengthen and improve scientific and human capital management and expand training and outreach to retain and train scientific experts critical to address FDA's scientific needs

SOURCE: NCTR, 2009a.

CVM

The mission of CVM is to protect and promote the health of animals and, in so doing, to protect the safety of meat, milk, and other animal-derived products destined for the human food supply. Research in support of CVM's mission is carried out through the Office of Research (OR) in Laurel, Maryland. The OR campus houses approximately 70 research

BOX 6-2
National Center for Toxicological Research's (NCTR's) Seven Centers of Excellence

1. *Functional Genomics*—uses high-information content microarrays in the development of mechanistic and biomarker data.
2. *Hepatotoxicology*—addresses critical liver injury issues by applying a systems-toxicology approach.
3. *Innovative Technologies*—uses multi-faceted approaches to address issues such as counterterrorism, rapid detection of bacteria in food, and sensors and nanotube technology.
4. *Metabolomics*—aids in the assessment of preclinical and clinical safety issues as part of a U.S. Food and Drug Administration (FDA)-wide biomarkers-development effort.
5. *Phototoxicology*—assesses the toxic and/or carcinogenic potential of chemicals and agents when exposed to light, or when applied to photo-treated skin.
6. *Proteomics*—develops and evaluates novel proteomic technologies to facilitate the translation of basic science to medical products.
7. *Toxicoinformatics*—conducts research in bioinformatics and chemoinformatics and develops and coordinates informatics capabilities within NCTR, across FDA Centers, and in the larger toxicology community.

SOURCE: http://www.fda.gov/AboutFDA/CentersOffices/nctr/default.htm (accessed October 8, 2010).

scientists and support staff and is organized into 3 major sections: (1) the Division of Residue Chemistry, (2) the Division of Animal Research, and (3) the Division of Animal and Food Microbiology (FDA Science Board, 2009).

The FY 2009 CVM research budget was $9.241 million, which supported 57 research FTEs and constituted 5 percent of the agency's annual research budget (FDA Science Board, 2009). The FDA Science Board report on CVM activities states that roughly 40 percent of CVM activities are focused on food safety issues pertaining to animal feeds, pet foods, aquaculture, and antimicrobial resistance of foodborne pathogens, although research scientists are frequently diverted from this focus to address emergency issues (FDA Science Board, 2009).

As is the case for CFSAN, CVM's food safety research portfolio is diverse. Its *Three-Year Research Plan: FY2009–FY2011* (CVM/FDA, 2008) states that the center's food safety research program focuses on microbial hazards associated with the preharvest phases of the animal production environment, including animal feeds, with specific focuses on

- analysis of animal feeds for the presence of human foodborne bacterial pathogens;
- identification of factors associated with the presence and persistence of zoonotic bacterial pathogens in the animal production ecosystem;
- surveys of various food products for the presence of zoonotic foodborne bacterial pathogens;
- application of genetic typing methods to track the spread of specific zoonotic foodborne bacterial pathogens; and
- identification and comparison of antimicrobial resistance genes in foodborne pathogens isolated from different sources in an effort to characterize the spread of resistant bacteria via the food chain (CVM/FDA, 2008).

In addition, CVM supports the FDA's food safety mission by (1) developing and validating tests for drugs and drug residues, including newly prohibited drugs, and (2) conducting surveys of drug residues and pathogens in feeds and in animal-derived foods destined for human consumption. Based on the project descriptions given in the CVM *Three-Year Research Plan* (CVM/FDA, 2008), the committee itemized specific CVM projects designed to support the FDA's food safety mission (see Appendix F).

As is the case for CFSAN, many CVM projects support the applied research function of developing diagnostic methods for microbes and drug residues; a few studies address more fundamental issues, such as understanding the mechanisms by which antimicrobial resistance develops. Relatively little effort has been devoted to identifying emerging threats in the area of animal feeds and associated links to human health. While addressing analytical issues is important, some limited CVM efforts support risk-based food safety management. It could be argued that CVM's survey and microbial source tracking efforts do support the risk mission, but these efforts are minimal in comparison with its other research functions.

ORA

As explained in Chapter 2, ORA's role is to support the FDA product centers by inspecting regulated products and manufacturers, conducting sample analysis, and reviewing imported products. ORA also works with state and local (including tribal and territorial) governments, through grants and cooperative agreements, to inspect FDA-regulated food products. The resource allocation or priority for ORA research functions was not described to the committee. Although ORA's total budget for food activities conducted in laboratories is more than $90,000,000, its research budget is only $1,100,000 (with only 6 FTEs), representing just 1 percent

of the FDA's total research budget.[6] ORA maintains science advisors who are special government employees serving as consultants to the specific ORA laboratories to which they are assigned. Additionally, ORA has four staff members in risk management. (The information presented here was obtained from the FDA's written statements and the ORA webpage.[7])

With a limited research budget, ORA plays only a minor role in the FDA's food safety research. Its research functions are conducted at the 13 ORA laboratories, 10 of which conduct food-related work. These 10 laboratories focus primarily on developing and validating analytical methods to meet the immediate needs of the field laboratories, work that is highly applied in nature. There are two major ORA research initiatives: the Methods Development and Validation Program (MDVP) and the Analytical Tools Initiative (Glavin, 2008; Musser, 2009).

FDA field laboratory personnel are involved in work on method development and validation through the MDVP, although that program is not identified by the agency as "research." Nevertheless, the program is intended to support regulatory testing (both screening and confirmatory) by (1) identifying needs and priorities in method development to address emerging regulatory issues and (2) improving/updating current regulatory methods. The work includes method assessment and validation aimed at rapidly moving promising methodologies into ORA field laboratories for regulatory use. ORA's Division of Field Science monitors and coordinates all MDVP activities. Current initiatives include the development of rapid detection methods for foodborne pathogens such as *Salmonella*, *Escherichia coli* O157:H7, *Shigella*, *Listeria monocytogenes*, and hepatitis A virus, as well as detection of other adulterants using chemical, radiological, and other analytical methods. To illustrate the immediacy of the MDVP work, this program was responsible for the development of a real-time polymerase chain reaction (PCR) assay for high-throughput screening of *E. coli* O157:H7 during the 2006 spinach-related outbreak. ORA mobile laboratory deployments to Salinas, California, and Nogales, Arizona, to perform rapid screening of *Salmonella* and *E. coli* O157:H7 in fresh produce provide additional examples of this program's reach.

The Analytical Tools Initiative is a program for the assessment and validation of field and laboratory analytical tools addressing such critical issues as speed of analysis, increased sample throughput, improved sampling strategies, and development of field-deployable instrumentation (Musser, 2009). The ways in which the MDVP and the Analytical Tools Initiative differ was not described to the committee.

[6] Personal communication, Chad Nelson, FDA, October 13, 2009.

[7] See http://www.fda.gov/AboutFDA/CentersOffices/ORA/default.htm (accessed October 8, 2010).

EXTRAMURAL RESEARCH CENTERS

The FDA has five extramural research centers devoted to specific food safety initiatives. Each of these centers is funded at the level of $1–$2.5 million per year. The centers differ by structure and function; each is described briefly below.

National Center for Food Safety and Technology (NCFST)

Supported by a memorandum of understanding between the FDA and the Illinois Institute of Technology (IIT), NCFST is the oldest extramural center.[8] It was established in 1988 and remains a partnership among IIT, CFSAN, and the food industry. NCFST also houses the FDA Division of Food Processing Science and Technology, which was established by the FDA to form a link with industry to tap its expertise in food technology. NCFST is the only center in which the FDA can work collaboratively with industry and academia on projects related to food safety and technology. A fee-based membership in NCFST allows companies to gain early insight into emerging food safety issues from the CFSAN perspective and to assess the safety of new technologies that may be important for innovation. Such early collaboration with the FDA may also facilitate regulatory approval of new food processes, thereby reducing the time required for emerging processes to reach commercialization. Funding for NCFST for FY 2009 was $2.1 million (Musser, 2009).

The research performed at NCFST is organized into four primary scientific platforms,[9] three of which are particularly applicable to food safety:

(1) The Processing and Packaging Platform focuses on investigation of the effects of processing and packaging on food safety, quality, and nutrition. Included are projects focused on validation of traditional and emerging food processing and packaging technologies and the use of food safety objectives to facilitate regulatory approval and equivalency of novel processes.
(2) The Microbiology Platform is aimed at generating knowledge of the behavior of microorganisms in food and processing environments to improve food safety and quality and public health. Included are projects on *Clostridium botulinum* and other spore formers, the use of new molecular methods for studying microbial resistance, sample preparation and detection techniques, and detection

[8] See http://www.iit.edu/ncfst/ (accessed October 8, 2010).
[9] See http://www.iit.edu/ncfst/world_class_food_science/(accessed October 8, 2010).

and decontamination methods for food defense–related biological threat agents.

(3) The Chemical Constituents and Allergens Platform, focused on generating knowledge of chemical constituents for use by industry and regulators in making science-based decisions that influence food safety and quality and public health. This work includes a study of the effects of processing on chemical contaminants and the development of detection and validation procedures to prevent allergen cross-contact.

The primary goal of these platforms is to develop projects based on industry's needs. Research portfolios for each platform include collaborative, leveraged, and proprietary projects that balance the short- and long-term needs of NCFST, the FDA, and industry members. NCFST is well positioned to facilitate innovation in the food industry because of its long history, its strong buy-in from the FDA (including on-site FDA scientists), and its unique state-of-the-art equipment, which includes a newly constructed biosafety level-2 pilot processing facility.[10]

Joint Institute for Food Safety and Applied Nutrition (JIFSAN)

JIFSAN was established in 1996 as a partnership among the University of Maryland, CFSAN, and CVM.[11] JIFSAN research was intended to focus primarily on risk analysis. Since 1997, CFSAN has funded three 5-year cooperative agreements, the current period expiring in July 2012. In 2008, the funding level was $1,389,140. In 2009, the funding level was $1,896,200, with an additional supplemental award of $350,000 for a CVM project. As of this writing, the funding level in 2010 will be between $1.1 and $1.4 million.

JIFSAN's program can be divided into four primary areas: (1) Research, (2) International Food Safety Training, (3) Food Safety Risk Analysis, and (4) Workshops/Symposia. The Research program includes several components: faculty research, postdoctoral research, and graduate student research in collaboration with University of Maryland faculty, as well as an undergraduate internship program. JIFSAN has also provided funding for research conducted by non–University of Maryland faculty. Since 1998 JIFSAN has funded approximately 75 research projects, 15 of which have been funded since 2008. Current research areas include fresh produce safety, consumer behavior, allergens, microbiology, and risk analysis.

[10] See http://www.iit.edu/ncfst/world_class_food_science/food_processing_and_packaging/people_and_facilities.shtml (accessed October 8, 2010).

[11] See http://www.jifsan.umd.edu/ (accessed October 8, 2010).

JIFSAN's International Food Safety Training includes courses on Good Agricultural Practices (GAPs), Good Aquacultural Practices (GAqPs), and Commercially Sterilized Packaged Foods. JIFSAN conducted approximately 25 GAPs training sessions through 2009. The GAqPs training program was piloted in 2006, and three additional sessions were held in 2008–2009.

A major effort at JIFSAN is devoted to supporting its Risk Analysis Training Program and maintaining the FoodRisk.org website. The aim of FoodRisk.org is to serve as an information clearinghouse for risk analysis in the area of food safety. It contains tools for risk assessment and determination of contaminant and nutrition exposure, dose–response models, and tutorials, as well as many other invaluable tools.

Agricultural Products Food Safety Laboratory (APFSL) and National Center for Natural Products Research (NCNPR)

APFSL is housed at New Mexico State University and has been funded through earmarks at annual levels ranging from $1.65 to $2.35 million since FY 2005. Its purpose is to develop and evaluate rapid-screening methods for detecting microbiological and chemical contamination in food products, including methods for regulatory and/or counterterrorism purposes (Musser, 2009). The FDA provided little information regarding its function and productivity, perhaps because it is a relatively new extramural activity, and no relevant information could be found on the Internet.

NCNPR is housed at the University of Mississippi and is also funded through earmarks. Its work focuses on the discovery, development, and commercialization of pharmaceuticals and agrochemicals derived from natural products, and therefore has only limited relevance to food safety. NCNPR funding for FY 2009 was $1.6 million.[12]

Western Institute for Food Safety and Security (WIFSS) and Western Center for Food Safety (WCFS)

WIFSS is spearheaded by the University of California, Davis, along with partners (the California Department of Food and Agriculture; the California Department of Public Health, formerly California Department of Health Services; the U.S. Department of Agriculture [USDA]; and the FDA). Its primary mission is to devise better management practices for reducing the number and virulence of pathogens in the nation's food system, to ensure a safe and secure food supply, to grow the agricultural economy, and to protect the public health.[13]

[12] See http://www.pharmacy.olemiss.edu/ncnpr/site/index.html (no longer accessible).

[13] See http://wifss.ucdavis.edu/ (accessed October 8, 2010).

Housed in WIFSS is WCFS, which was established in 2008 as a cooperative agreement among the FDA; WIFSS; the University of California, Davis, School of Veterinary Medicine; the College of Agricultural and Environmental Sciences; and the greater academic community. The center's efforts focus on understanding the risks associated with the interface between production practices and food safety in fresh-produce systems. Administrative oversight of the center is provided in part by WIFSS and the FDA/CFSAN. Annual funding (for a total of 5 years) is in the range of $1.0 to $2.5 million, and some of these funds have been made available to the scientific community at large by way of a targeted extramural funding program in produce safety.[14]

Extramural Funding

Although the FDA pointed out that it is not an extramural funding agency, in actuality it does fund a small number of competitive research grants as well as cooperative research and development agreements, which are almost always focused on a specific stated need of the agency. There are currently 2 projects related to food defense, 31 related to food safety, and 15 related to improving nutrition,[15] funded through contracts, cooperative agreements, interagency agreements, and grants. Some of these are awarded to the extramural research centers (e.g., NCFST, JIFSAN), while others are awarded to universities, professional associations, or private consulting firms. Examples of the latter include contracts with RTI International (to support risk analysis efforts), the Association of Analytical Communities (to support methods validation), and the Institute of Food Technologists (to support the FDA's policies through evaluation of specific topics related to food safety and processing and human health). These extramurally funded projects currently focus on support of agency risk analysis efforts, development and implementation of novel detection methods, and control of pathogens in leafy greens and seafood products. The means by which the FDA determines which research questions should be addressed and funded through its small extramural program is unclear.

CFSAN has developed an automated, web-based tracking system for its intramural and extramural research programs called the CFSAN Automated Research Tracking System. The system, designed to improve the efficiency and timeliness of the documentation of research projects, provides a means for information sharing and provides for accountability of the

[14] See http://wifss.ucdavis.edu/headcontent/newsletter/2008November_newsletter.php.

[15] Personal communication, Chad Nelson, FDA, October 13, 2009 (accessed October 8, 2010).

center's research efforts. The database is open to all CFSAN employees but not the general public.[16]

INTERAGENCY COLLABORATION

In addition to its intramural and extramural research programs, CFSAN maintains collaborative agreements and interactions with other federal government research organizations to facilitate the sharing of information and resources in support of its regulatory mission and its obligations regarding international trade agreements. For example, CFSAN participates in the Interagency Risk Assessment Consortium (IRAC), which comprises 19 federal agencies or offices. The mission of IRAC is to enhance communication and coordination and to promote scientific research on risk assessment. Currently, CFSAN maintains approximately 50 collaborative partnerships with other federal research organizations, including the U.S. Department of Commerce's National Marine Fisheries Service; the U.S. Centers for Disease Control and Prevention; and USDA's Food Safety and Inspection Service (FSIS), Agricultural Marketing Service, and Agricultural Research Service.[17] In its report to the Science Board, CFSAN describes the reasons for the existence of its research program separate from those of other entities with large research capabilities, such as the National Institutes of Health (NIH). In the case of NIH, the reason given is differences in the mission and scope of the research of the two organizations. Nevertheless, CFSAN and NIH collaborate on a handful of projects, such as in the area of dietary supplements and long-term exposure to bisphenol A.

WEAKNESSES IN THE FDA RESEARCH PROGRAM

The FDA food safety research portfolio is diverse and vast. Some of the research efforts are quite relevant to the agency's mission, while the relevance of others is less clear. There is no central oversight of FDA research, and currently each of the four FDA divisions (CFSAN, CVM, NCTR, and ORA) performing the bulk of the agency's food research manages its own research portfolio.[18] Although the purposes and goals of these individual research programs differ, overlap in some of the efforts is likely. The committee found no evidence of coordination to prevent duplication of effort or to leverage the efforts of one investigator with those of others having complementary skills and interests.

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[16] Personal communication, Chad Nelson, FDA, October 13, 2009.

[17] Personal communication, Chad Nelson, FDA, October 13, 2009.

[18] Personal communication, Donald Zink, Senior Science Advisor, FDA/CFSAN, September 25, 2009.

The committee found that, in some cases, the role of the extramural research centers is poorly defined. Of these centers, NCFST has the most well-defined mission and, with its unique expertise and advanced equipment, is well positioned to continue to serve the agency into the future. It offers an invaluable service (evaluation of the efficacy of emerging processing methods with respect to foodborne pathogens), although its research portfolio appears to be somewhat haphazard. The mission of JIFSAN is admirable, and despite recent funding reductions, it continues to offer value in providing risk analysis training and serving as a data clearinghouse. However, JIFSAN's work represents a very small proportion of the risk analysis support the FDA will need to move toward a comprehensive risk-based food safety management strategy. WIFSS/WCFS is new, so predicting its performance or value is difficult; however, WCFS is addressing a high-profile food safety problem in what appears to be an aggressive manner. The remaining two extramural centers, APFSL and NCNPR, have produced little in the way of tangible results by which they can be evaluated.

Strategic planning for the FDA's food safety research needs has been limited in scope and in some instances nonexistent. The FDA Science Board reviews each center every 5 years;[19] a review was recently completed for CVM (FDA Science Board, 2009), and the review of CFSAN is currently under way.[20] CVM produced an extensive strategic plan for this review, a document that was made available to the committee (FDA Science Board, 2009). CFSAN did the same—its first strategic planning effort in more than a decade. NCTR also has a strategic plan (NCTR, 2009a). The status of strategic planning for ORA and the extramural research centers is unknown. Apparently the strategic planning process includes both "formal" and "informal" scientific planning, both within the agency and with other agencies having a food safety mission, but the means by which this is accomplished is unclear. In any case, it is apparent that no coordinated strategic planning initiative exists in which all FDA food safety research programs are addressed in a unified way.

In the absence of a coordinated agencywide strategic planning effort for food safety research, key questions have not been addressed, including the following:

- What is the tangible value of the FDA's food safety research program with respect to supporting the agency's mission?
- What is the appropriate balance between basic and applied research? Should the agency even be conducting basic research?

[19] Personal communication, Donald Zink, Senior Science Advisor, FDA/CFSAN, September 25, 2009.

[20] Personal communication, Chad Nelson, FDA, October 13, 2009.

- What are the agency's research needs, and do they address critical data gaps?
- Is the current organizational structure for management of the FDA's research functions appropriate? If not, what structure would be more so?
- How is research prioritized, and how are research resources allocated?
- Is the current approach to managing researchers effective? For example, does it make sense to divert researchers to other functions when a crisis arises? Or would it be better to have some individuals devoted solely to research and some devoted to other agency functions?

The committee believes that, until these basic questions are answered, a unified vision for the FDA's food safety research will not be achievable. The lack of such a vision results in a poorly coordinated research mission that does not support the development and implementation of a risk-based food safety management system.

USING RESEARCH TO SUPPORT A RISK-BASED FOOD SAFETY MANAGEMENT APPROACH

The committee recommends a risk-based approach to managing the agency's food safety research portfolio, as it does for virtually all FDA functions. Not only would this approach fulfill the mission of characterizing and acting on risks from food contaminants, but it would also target research to answering the most pressing (highest-risk) food safety questions and problems. Thus, management of the agency's research portfolio would benefit from application of the principles outlined in Chapter 3 and from implementation of the recommendations regarding information infrastructure in Chapter 5.

From a strategic planning standpoint (Step 1 in a risk-based food safety management system; see Chapter 3), it is important to address the role of the research mission as a whole, which entails identifying agencywide public health objectives and determining how research can contribute to achieving these objectives, as well as what proportion of total resources should go to research relative to other agency functions. Central to these deliberations should be a consideration of the importance of research in supporting risk-based food safety management and what specific role(s) research should play. It could be argued that the development of analytical capabilities (e.g., data analysis, risk and decision modeling) is a research function, and over the next 5 years, extensive resources will be required to develop these tools. Once such tools have been developed, public health risk

ranking (Step 2 of the risk-based approach in Chapter 3), which identifies and prioritizes the most pressing risk management issues, can be used to support the allocation of research resources. Although unlikely, it may be that the management of high-priority risks is best approached without the need for additional research, in which case the FDA's research portfolio could be substantially reduced. It is more likely, however, that research will be needed to address some high-priority issues that the FDA now does not study, and efforts carried out under Step 2 will direct resources to the areas of greatest need and relevance.

Research can also be used as a tool in support of targeted information gathering and analysis of interventions (Steps 3 and 4 of the risk-based approach, respectively). For example, information necessary to fill data gaps in risk-ranking or risk-assessment efforts is frequently collected as a research activity. Research can also be conducted to evaluate the efficacy of potential interventions or to aid in determining the feasibility of their implementation. Research can even be applied in monitoring and review (Step 6 of the risk-based approach) as the FDA seeks to evaluate the efficacy of interventions after their implementation. Finally, the identification and design of new and innovative ways to apply risk analysis methods to food safety management is a research function that underpins the entire risk-based structure.

On a more focused level, research can be used to address unanswered questions for any specific risk. An example is the almost decade-long problem of *Salmonella* in tomatoes. This would likely be a relatively high-priority issue in a public health risk-ranking exercise. However, there are key research questions, such as the reservoir(s) for the organism, contamination routes, and the persistence of *Salmonella* in the contaminated fruit, that will take substantial resources to tackle. Yet a decision to devote research resources to the problem of *Salmonella* contamination in tomatoes as opposed to another problem (e.g., hepatitis A in green onions) is inherently risk based. To take the argument a step further, if research is directed to the *Salmonella*/tomato problem, will the FDA get the most value for its investment if it focuses on identifying the reservoir(s) for the organism or on evaluating potential interventions during the postharvest phase? And how does the FDA identify the various ongoing research projects in the academic community that address its priority research areas? If answering such questions is supported by a risk-based approach, the decisions made become more transparent and justifiable even as the use of limited agency resources is optimized.

MOVING FORWARD

The first step in applying a risk-based approach within the context of the FDA's current food safety research portfolio should be to undertake a comprehensive inventory and review of the agency's existing research program without respect for interinstitutional boundaries (e.g., CFSAN, CVM, NCFST, ORA). Thereafter, each research area should undergo a comprehensive peer review, conducted by FDA and non-FDA scientists, whose purpose should be to evaluate such issues as relevance, funding, productivity, and programmatic benefits in direct support of the agency's mission. This review might be performed with tools similar to those used in cost–benefit analysis of interventions (Chapter 3) and would provide much-needed information before the strategic planning phase was initiated. Research would then become part of the set of risk management tools available for agency use. Although the documents provided to the committee included a list of priority areas of food safety research, the process used to arrive at this list was not clear.

The committee believes that reorganization of the FDA's research function is warranted and that such reorganization should be risk based. This reorganization may necessitate a creative approach to the management of research resources. A critical initial consideration is preventing duplication of effort. One area of concern for the committee that has also been highlighted by others (GUIRR/NAS, 2009) is the lack of coordination of the food safety and defense research portfolios in the nation. Better coordination will entail communication with other federal regulatory and research agencies (e.g., USDA's FSIS, the Department of Defense, the National Science Foundation, NIH) that conduct salient activities or projects. Coordination of research efforts between the FDA and other entities could be expanded to the international sphere as well. Within the agency, the research function should not be organized around specific areas of expertise—such as microbiologists who specialize in particular organisms (e.g., *Salmonella*, viruses) or scientists who specialize in certain techniques (e.g., molecular biology, biosensors)—or pet projects, but should be focused on key unanswered questions and problems whose resolution will have the greatest impact on improving the safety of the food supply by reducing the most significant public health risks. This means that well-trained researchers with specific disciplinary expertise will need to work interdependently in multidisciplinary teams that are designed to deal with particularly complex food safety issues. Individual research professionals will likely serve as members of more than one team. As is the case in academia, the FDA's research program should evolve to become multidisciplinary, interinstitutional, collaborative, translational, and flexible.

At the same time, it is essential that certain key research thrusts be con-

tinued, with an eye to their use in support of risk-based decision making. An example is the development and application of advanced mathematical modeling techniques. Likewise, qualified research staff will be needed to interpret data for appropriate use in support of risk-based food safety management. Other research areas may support the risk-based system tangentially and might better be outsourced. For example, improved analytical methods are critical to the generation of quantitative data that can be used in risk modeling and to the monitoring of production and processing control points. In fact, a large proportion of the research done by CFSAN and NCFST is in the area of methods development. However, these centers may not be the best places for such work. It could be argued that FDA scientists have worked on methods development for decades with only limited success. Perhaps the methods development function would best be outsourced to the academic and private sectors, where cross-cutting innovative approaches ultimately lead to scientific and commercial success.

It is also important to recognize that certain research efforts will be beyond the scope of current agency resources. For example, the collection of information on the prevalence or concentrations of microbes or chemical contaminants across the farm-to-fork continuum and research on the efficacy of candidate interventions may require collaboration with industry. Likewise, the agency cannot be expected to have all the necessary in-house expertise to develop novel risk-modeling techniques, support advanced information technology capabilities, or keep pace with the rapidly developing fields of proteomics and bioinformatics. Under these circumstances, the FDA should consider alternative means by which to foster research, such as interagency personnel agreements (for short-term expertise), public–private centers, and formalized extramural funding alternatives (e.g., cooperative agreements, grants and contracts, research institutes). Although the agency occasionally uses these mechanisms, the committee believes that additional efforts to reach out to the scientific community at large would provide much-needed expertise to solve complex food safety problems using innovative, multidisciplinary approaches. Further, engagement of entities outside of the FDA would go a long way toward promoting transparency of the agency's research agenda.

In conclusion, maintaining the appropriate balance between fundamental and applied research is critical. The FDA should be true to its research mission, which focuses on applied and translational research in support of science-based decision making. The entire research program should be viewed as supporting the risk-based function; in other words, research should not exist just for its own sake. This means any fundamental research that is undertaken should be aimed at answering questions relevant to controlling the highest-priority risks, and the outcomes anticipated from such research must have relevance to risk management decision

making. FDA scientists with interests in fundamental research should be encouraged to collaborate with academia, but the FDA's research resources should be used mainly to support risk-based food safety priorities.

KEY CONCLUSIONS AND RECOMMENDATIONS

Results from research allow the FDA to fill data gaps and address uncertainties and thereby help refine its risk-based decision making. The committee applauds the recent consultation of the Science Board with regard to reviewing the research portfolios of CFSAN and CVM. Based on the information provided by the FDA, however, the committee concluded that the FDA's current food safety research program is unfocused and fragmented. For almost a decade there has been no coordinated strategic planning initiative addressing all FDA food safety research programs as a whole. Coordination and leveraging of research at CFSAN, CVM, NCTR, ORA, and the five extramural research centers appear to be insufficient, and some overlap in their efforts is likely as a result. Many basic questions, such as the size of the overall research program or the balance of basic and applied research, need to be addressed if the FDA is to have a unified vision that reflects the recommended risk-based approach. The committee concludes that, in addition to enhancements to the FDA's research portfolio, better coordination of the food safety and defense research conducted in the nation by government agencies, industry, and academia is needed.

The committee offers the following recommendations to enhance the FDA's research portfolio.

Recommendation 6-1: The FDA should have a food safety research portfolio that supports the recommended risk-based approach. To this end, the agency's current food safety research portfolio should undergo a comprehensive review. Following this review and with consideration of the agency's broad strategic plan, the FDA should examine the relevance and allocation of its research resources by using public health risk ranking and prioritization. Future research should address the most pressing public health issues and directly support further characterization of risk and selection, implementation, and evaluation of interventions. In addition, research should be coordinated to prevent duplication of effort, especially for cases in which research efforts are better suited to the academic or medical sector.

Once the review and planning of the agency's research program have been completed, the committee recommends the following key implementation actions.

Recommendation 6-2: Implementation of recommendation 6-1 requires reorganization of the FDA's research portfolio, including reallocation of resources from irrelevant or poorly performing initiatives; hiring of new staff in critical areas and, where appropriate, retraining of existing staff; and identification of future resource needs to support risk-based food safety management. Although the committee recognizes the difficulty of transferring scientists from one research focus to another, the FDA should foster an environment of fluidity in which teams of scientists can be formed with ease to address different research initiatives as necessary.

Recommendation 6-3: Keeping in mind that the FDA will not be able to address all important research needs, the agency should continue to utilize alternative funding mechanisms (e.g., cooperative agreements, university-based centers, contracts) based on a competitive, peer-review process. These efforts could be expanded by establishing a competitive extramural research funding program.

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7

Integrating Federal, State, and Local Government Food Safety Programs

The regulations and programs of state and local (including tribal and territorial) governments have been a strong component of the U.S. food safety system for the past century. Their key regulatory programs in food safety address food and public health surveillance as well as food inspection and analysis.

The U.S. Food and Drug Administration (FDA) is responsible for more than 156,008 domestic food facilities (FDA, 2010), more than 1 million food establishments[1] (including restaurants and retail establishments), and more than 2 million farms (Mavity, 2009). Given the size, complexity, and growth of the food industry in the United States, both domestic and imported, it would be unrealistic to expect the FDA to have enough resources to provide adequate surveillance and inspection of the entire U.S. food supply and to encompass all areas of policy currently overseen by state and local agencies. In fact, the FDA has repeatedly been criticized by organizations and individuals both inside and outside government, including the U.S. Government Accountability Office (GAO) and the Congressional Research Service, for the lack of adequate surveillance and inspection of the U.S. food supply (GAO, 2004a,b,c; 2005a,b, 2008a,b,c,d, 2009a,b; CRS, 2007; Hutt, 2007, 2008; Becker, 2008, 2009).

In this context, it is clear that the FDA could better leverage its food safety knowledge through improved access to, and utilization of, data from state and local authorities (e.g., data from food safety inspections, disease outbreak and product safety investigations, enforcement actions).

[1] Personal communication, Chad Nelson, FDA, October 13, 2009.

The idea of integrating federal, state, and local agencies into a national food safety system has been espoused in reports of the Association of Food and Drug Officials (AFDO) (Hile, 1984; AFDO, 2001, 2009a,b), in the Institute of Medicine (IOM)/National Research Council (NRC) report *Ensuring Safe Food: From Production to Consumption* (IOM/NRC, 1998), by consumer representatives (DeWaal, 2003), and more recently in the report *Stronger Partnerships for Safer Food: An Agenda for Strengthening State and Local Roles in the Nation's Food Safety System* (Taylor and David, 2009).

The committee understands an integrated system to be one that (1) minimizes duplication of food safety activities (e.g., inspection, education, data collection) by leveraging efforts at the state and local levels; (2) follows a common risk-based approach to prioritize activities at all levels of government; (3) meets a minimum set of standards at all levels of government in various areas (e.g., collection, utilization, and reporting of data; equivalency of laws and regulations and their implementation; inspection procedures and training; foodborne illness investigations); and (4) accesses and utilizes data and information collected at the state and local levels. For the purposes of this report, the terms "collaboration" and "cooperation" are used interchangeably to mean "interaction between [entities] that is largely beneficial to all those participating."[2]

This chapter presents the committee's rationale for supporting an integrated food safety system and describes the steps necessary to facilitate such integration. It also delineates the role and responsibilities of the FDA and the actions necessary to achieve integration and cooperation with state and local food safety programs. Other chapters offer recommendations whose implementation would facilitate the integration proposed in this chapter. For example, the chapters on internal organizational changes (Chapter 11), increased the efficiency of inspections (Chapter 8), and the adoption of a risk-based approach to food safety (Chapter 3) provide the basis for the harmonization and integration recommended herein. For the majority of the committee's recommendations on this subject, the literature base is sparse. Most of the evidence supporting these recommendations was derived from information received from the FDA at the request of the committee, conversations with federal government employees, individual committee members' regulatory and other experiences, and past reports addressing this topic.

[2] Definition found at http://www.merriam-webster.com/.

PREVIOUS RECOMMENDATIONS FOR THE INTEGRATION OF FOOD SAFETY PROGRAMS

Many individuals and organizations are calling, once again, for reform of the nation's food safety system across all levels of government (local, state, and federal) and all phases of the food production continuum, including both domestic and international products. Multiple congressional and regulatory initiatives are aimed at making proposed reforms a reality (Hogan & Hartson, LLP, 2009). This section reviews the recommendations for integration offered by the IOM/NRC (1998) and Taylor and David (2009), who expanded upon previous recommendations by providing a road map for an integrated food safety system. The committee supports these recommendations, which are presented in greater detail in Appendix B.

Recommendations of the IOM/NRC

The IOM/NRC (1998) report *Ensuring Safe Food: From Production to Consumption* calls for an integrated, risk-based food safety system and modernization of federal food safety laws (IOM/NRC, 1998). The report further recommends that Congress provide the agencies responsible for food safety with the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety. While the report addresses the federal role in the food safety system, it states that "the roles of state and local government entities are equally critical" (pp. 14, 97, 99) and cites the need to ensure nationwide adherence to minimum standards.

In addressing the need for improved integration of federal, state, and local food safety programs, the report notes the lack of adequate integration among the activities of the main federal agencies involved in implementing the 35 primary statutes that regulate food safety and the activities of state and local agencies, as well as the need for reorganization (IOM/NRC, 1998). These findings remain true today, and the recommendations offered in that report, which were directed to Congress, have not been implemented.

After the 1998 IOM/NRC report was issued, and in response to the Clinton Administration's Food Safety Initiative, the FDA cooperated with other federal, state, and local agencies to improve partnerships by hosting a 50-state meeting in 1998, whose purpose was to examine the long-held vision of an integrated national food safety system (HHS, 1998). That meeting included a series of workshops that continued into 2001 with the purpose of identifying key areas in need of integration. These areas included laboratory operations, information sharing, outbreak investigation, the establishment of national uniform criteria for food safety programs, and the clarification of roles and responsibilities (NFSSP, 2001). One positive out-

come was the implementation of the FDA's Electronic Laboratory Exchange Network (eLEXNET), discussed later in the chapter.

In 2008, the FDA convened a similar 50-state meeting titled the Gateway to Food Protection. Its purpose was to reflect on progress and accomplishments made since the initial 1998 meeting (FDA, 2008) and to identify ways of strengthening the food safety system in a manner consistent with the FDA's 2007 Food Protection Plan (FPP) (FDA, 2007a). Both the 1998 and 2008 meetings were chaired by then Deputy Director of the Center for Food Safety and Applied Nutrition Janice Oliver, who stated: "We recognized that the states, the local governments, we all needed each other. Then, as now, we weren't trying to re-invent the system but to improve the system we had, and to work better together doing it" (FDA, 2008, p. 6).

The 1998 meeting led to a more cooperative relationship between state and federal agencies, which contributed significantly to the implementation of the Bioterrorism Act of 2002, in which the states had a key partnership role (see also Appendix D). On the negative side, the security threats of that decade caused agencies to rethink openness and sharing of sensitive information related to food safety (Strickland, 2005).

Recommendations of Taylor and David (2009)

The Taylor and David (2009) report *Stronger Partnerships for Safer Food* reiterates the vision of an integrated food safety system. The report was funded by the Robert Wood Johnson Foundation and spearheaded by the School of Public Health and Health Services at the George Washington University in collaboration with AFDO, the Association of State and Territorial Health Officials (ASTHO), and the National Association of County and City Health Officials (Taylor and David, 2009). During workshops leading up to the report, Michael Taylor, one of its authors, was quoted as saying, "State and local agencies occupy the critical frontline in the nation's food safety system. Food safety reform at the federal level will be incomplete and insufficient unless it strengthens state and local roles and builds true partnership across all levels of government." Dr. Paul Jarris, executive director of ASTHO, continued, "Protecting Americans and assuring them that the food they eat is safe is a fundamental responsibility of state and local health departments." Joseph Corby, executive director of AFDO and former state food regulatory official, further supported integration by saying, "Integrating the food safety efforts of federal, state, and local agencies is key to dramatically improve this country's food safety system. This report provides a clear plan for accomplishing this integration."[3]

The report begins by recognizing progress in integration: "Since the

[3] Personal communication, Joseph Corby, executive director of AFDO, August 25, 2009.

1990s federal, state, and local agencies have expanded their collaboration in some areas—such as illness surveillance and inspection—and there exists today among food safety officials at all levels a widely shared vision of an integrated national food safety system that operates as a full partnership among federal, state, and local agencies" (Taylor and David, 2009, p. 1). The report then presents 19 strategic recommendations for strengthening the system, which are detailed in Appendix B. A common theme is the dispersal of functions across many federal, state, and local agencies and recognition that while the states' systems are a valuable asset, challenges are associated with such a decentralized system. The need for strengthened collaboration, partnerships, standardization, and oversight is clearly articulated. The committee fully supports those 19 recommendations.

While the FDA has recently made progress toward implementing the recommendations in the Taylor and David report, the majority of the issues raised remain unresolved. Those recommendations on which significant progress has been made include the following:

- "Recommendation for Congress to establish and fund an intergovernmental Food Safety Leadership Council (FSLC) through which the federal government would collaborate with state and local governments to design and implement an integrated national food safety system including the development of a five-year integration and capacity-building plan to meet high priority state and local capacity needs" (Taylor and David, 2009, p. 2). The FDA is already moving to implement a new plan, the Integrated Food Safety System (IFSS), that focuses on instituting standards and mechanisms for data sharing, with oversight by a new FDA organizational structure (Steering Committee) (Solomon, 2009a). The White House Food Safety Working Group (FSWG) not only should be informed about progress on this plan but, with the enhancements outlined in Chapter 11, also could function as the proposed FSLC and provide leadership to the FDA Steering Committee to ensure integration of state programs in the next 5 years.
- "State and local governments should collaborate on the development and widespread adoption of a model state and local food safety law to parallel pending reforms at the federal level, clarify the role of state and local agencies in a more integrated system, and legally empower state and local agencies to work more collaboratively among themselves and with the federal government" (Taylor and David, 2009, pp. 17, 59). In 1984, the states, working through AFDO, crafted a Model Food, Drug, and Cosmetic Act for adoption by state legislatures, which continues to be updated for state adoption (Burditt, 1995). At the request of the Tomato Forum in

2006, AFDO began working with federal agencies and industry to draft the recently completed Model Code for Produce Safety for adoption by the states. States cooperate to provide positions and recommendations to the FDA on regulatory changes in food safety through their official representation in the Conference for Food Protection. The shellfish industry (through the Interstate Shellfish Sanitation Conference) and dairy producers (through the National Conference on Interstate Milk Shipments) have also embraced the conference mechanism as a means to foster collaborative partnerships between state and federal agencies and provide model food safety programs for widespread adoption. Although the level of success of these conferences varies, these conferences have provided a mechanism of past cooperation with the FDA.

- The U.S. Department of Health and Human Services (HHS), "in collaboration with the [FSLC], should establish a Food Safety Leadership and Training Institute focused on building among food safety professionals at all levels a common vision for the nation's food safety system and the leadership skills, network of relationships, and trust needed for an integrated system to succeed" (Taylor and David, 2009, p. 45). Although this recommendation was not meant to duplicate existing efforts in technical training, it called for greater coordination and support in developing training curricula, including those for inspectors. In 2009 AFDO received a $2 million grant from the Kellogg Foundation to create a food protection training institute. Established in collaboration with the International Food Protection Training Institute (IFPTI) in Michigan, it began offering a course in managing retail food safety in 2009. Congress provided a $1 million appropriation to establish a permanent home for this new institute in 2009 "to ensure that food safety inspectors would have the training and skills necessary to do their jobs and to keep consumers safe" (Upton, 2009). Many other organizations and governments offer food safety training. For example, the states help ensure that personnel are trained to implement seafood Hazard Analysis and Critical Control Points (HACCP) through the Seafood HACCP Alliance. See Chapter 9 for further discussion of training.
- "Congress should establish traceability requirements that permit federal, state, and local officials to rapidly obtain from food companies reliable information on the source of commodities, ingredients, and finished products" (Taylor and David, 2009, p. 17). Although some traceability systems are in place and others are in development for specific commodities, such as produce, concerns remain regarding many aspects of traceability. Most notable among these

concerns are the ability to link internal (within a company) and external traceability and the identification of key elements needed for an effective traceability system (IFT, 2009). Collaborative efforts between the FDA and the U.S. Department of Agriculture (USDA) have recently been initiated to advance widespread implementation of traceability, but many barriers remain. For example, in 2009 the FDA and USDA hosted a public meeting (HHS/FDA, 2009) to gather information on and engage stakeholders in the development of efficient and feasible food and feed tracing systems. The FDA acknowledged that with the current system, tracing the source of foodborne illness outbreaks at each step of the chain can be time-consuming and inefficient; hence a mandate to maintain records is critical (HHS/FDA, 2009). Many efforts are currently being devoted to developing traceability systems through collaboration among the FDA, academic institutions, and industry. An example of industry efforts is the Produce Traceability Initiative, sponsored by the United Fresh Produce Association, the Produce Marketing Association, and the Canadian Produce Marketing Association, which is working to develop a standardized electronic traceability system for all fresh produce (PTI, 2008).

STATES CALL FOR INTEGRATION

The states have historically called for greater partnership and integration with the federal food safety program and have sought to counter a lack of trust and acceptance. Many factors have contributed to this situation, such as the fact that state and local food regulatory programs are highly variable in quality, expertise, and resources. In addition, there is a pervasive federal view that only federal data or inspections will suffice for regulatory purposes. Further, there is a lack of willingness on the part of the states to surrender certain controls to meet what they believe to be bureaucratic and inflexible federal requirements.

The states have formed informal yet strong relationships through such joint associations as AFDO (established in 1896) and ASTHO (established in 1879), in which food regulatory officials from all states are represented. AFDO intensified its pressure for federal recognition of state programs in 1984 during an annual conference with the FDA, with a focus on creative partnerships between state and federal officials. Then associate commissioner for regulatory affairs Paul Hile spoke of the need to gain the FDA's acceptance of state inspectional and analytical findings beyond the limited case of contamination by the pesticide ethylene dibromide (Hile, 1984). At the time, the FDA had a limited pilot program with the Association of American Feed Control Officials that involved 10 to 12 states participat-

ing in a cooperative agreement on data sharing. Hile viewed the necessary components of federal–state cooperation to be based on the willingness of the parties to share knowledge, avoid unnecessary confrontations, fine-tune respective roles, foster understanding, build credibility, and establish an atmosphere of mutual trust. In the October 1984 *AFDO Quarterly Bulletin*, Hile went on to state: "These are the building stones on which effective partnerships of any kind are built. They are the attitudes that must prevail in our organizations if we are to achieve the efficiencies these times of fiscal restraint demand of us" (Hile, 1984).

ADEQUACY OF STATE AND LOCAL GOVERNMENT FOOD SAFETY REGULATORY PROGRAMS

Trust in the adequacy of state and local programs remains an issue. In a statement to the committee, Dr. Steven Solomon, Deputy Associate Commissioner for Compliance Policy, Office of Regulatory Affairs (ORA), FDA, said: "As we move with further integrating with the states [on the recommendations included in the Taylor report] we really need to build up an enhanced FDA infrastructure to meet the demands and maintain adequate oversight to make sure there is credibility in these programs" (Solomon, 2009a). Solomon further identified two major barriers to integration: (1) sustainability of resources and information and (2) difficulties with data sharing (see Chapter 5 for recommendations to minimize barriers to data sharing). When the committee asked Solomon how he envisioned being able to move from utilizing the limited data from state contract inspections to utilizing the vast amount of data and resources from all state inspections and data analyses, he responded: "The basis for that is standardization . . . there needs to be an accreditation program that oversees that and says, yes, everyone that's doing this work is up to these standards whether this is a laboratory, whether this is an inspector, whether this is a system. We need to have a robust auditing system to make sure there is credibility in such a program." Lack of trust in the ability of state and local programs also exists among groups representing consumers, supported by published reports indicating that, taken as a whole, food safety activities such as outbreak investigations and restaurant inspections have not been adequate (Kelly et al., 2007; Klein and DeWaal, 2008; CSPI, 2009; DeWaal et al., 2009; Moran, 2009).

Regulatory Structures and Laws for State and Local Food Safety Programs

The FDA's origins can be traced back to the analysis of agricultural products in the U.S. Patent Office around 1848, a function that was transferred to USDA upon its creation in 1862. The FDA became known by that

name in 1930 and was transferred to the Federal Security Agency in 1940, which became the Department of Health, Education and Welfare in 1953. Although the FDA is the oldest and most comprehensive food safety agency in the federal government, food safety programs in the states are also of long standing. For example, Florida enacted a food law in 1905, a year prior to passage of the 1906 Pure Food and Drugs Act. Even before that, Massachusetts passed the first general food law in 1784, and in 1850 California enacted "a pure food and drink law" (Darby, 1993).

The FDA is responsible for the safety of all foods in the United States, whether produced domestically or internationally, with the exception of meat, poultry, and unshelled egg products, which are under the legal authority of USDA. Likewise, each state food regulatory program is responsible for the safety of foods in its jurisdiction, whether produced domestically or internationally. However, state regulatory authority exists only within the borders of the state. Regulatory actions outside the state for products that enter interstate commerce are referred to the FDA for enforcement follow-up in other locations.

Table 7-1 lists the various sources of information on state agencies involved in food safety regulation. Currently, the food safety regulatory programs in most of the 50 states are either the responsibility of state departments of health or departments of agriculture (Table 7-2) (FDA, 1993; NASDA, 1999; AFDO, 2001, 2009b). State food regulatory programs, which have varying resources, conduct public health and food surveillance, inspections, and sample analyses on food products grown, processed, packed, held, or sold within the state. Where the food safety program is located in the state department of health, the epidemiological and outbreak investigation function also resides in that state agency as well as with the local county health departments (AFDO, 2009a,b).

Likewise, the FDA has the responsibility to conduct inspections in each state for any product (food, drug, cosmetic, or device) under its jurisdiction that will be, is, or has been in interstate commerce. The FDA's inspections and regulatory actions on foods can be duplicative of those of the states, and there is insufficient planning or coordination between federal and state agencies to prevent multiple agency inspections of food plants. The result may be, for example, the use of limited state or federal resources to inspect one facility multiple times; more important, other facilities remain with no regulatory oversight. Generally, the FDA has delegated enforcement activities at food retail and service establishments to state and local jurisdictions utilizing the Food Code (FDA, 2009a,b), which is published and updated periodically by the FDA. The Food Code provides a framework that local, state, and federal regulators can (but are not required to) apply to be consistent with national food regulatory policy. The FDA and AFDO now report

TABLE 7-1 Sources of Information on State Agencies Involved in Food Safety Regulation

Source	Year	Content
FDA, Office of Federal–State Relations	1993[a]	Details on state food safety laws; 45 states have laws based on the 1938 Federal Food, Drug, and Cosmetic Act; food safety law in Alabama, Iowa, Mississippi, Pennsylvania, and West Virginia was patterned after the 1906 Pure Food and Drugs Act.
FoodSafety.gov (interagency federal government website about food safety information)	2010	No clear delineation of state agencies' responsibilities on current site; links to state departments of health and agriculture.
National Association of State Departments of Agriculture Research Foundation Project (http://www.nasda.org/nasda/nasda/Foundation/foodsafety/index.html)[b]	1999	Detailed description of how foods are regulated in each state by agency.
FDA, State Retail and Food Service Code Regulations	Ongoing updates at www.fda.gov/Food/FoodSafety/RetailFoodProtection/FederalStateCooperativePrograms	Specific information on state agencies that enforce the Food Code at food retail establishments.
Individual State Agencies	Ongoing updates	Individual agency websites outline responsibilities.

[a] Until 1995, the FDA produced annual reports on state food safety laws. These surveys were discontinued because of a lack of resources. The last survey for which a record exists was conducted in 1993.

[b] Records for each state are located at the following address (with pertinent state inserted): http://www.nasda.org/nasda/nasda/Foundation/foodsafety/WestVirginia.pdf (accessed October 8, 2010).

TABLE 7-2 State Food Regulatory Programs: Leading Agencies Involved

Department of Agriculture[a]	Department of Health[a]	Other Agencies
Alabama	Arizona	Department of Environmental Conservation (Alaska)
Florida	Arkansas	Departments of Consumer Protection (Connecticut)
Georgia	California	Split between Departments of Health and Agriculture (Idaho)
Maine	Colorado	Department of Inspections and Appeals (Iowa)
Michigan	Delaware	Split between Departments of Commerce and Agriculture (South Dakota)
Minnesota	Hawaii	
Nebraska	Illinois	
New York	Indiana	
North Carolina	Kansas	
Ohio	Kentucky	
Oregon	Louisiana	
Pennsylvania	Maryland	
South Carolina	Massachusetts	
Tennessee	Mississippi	
Utah	Missouri	
Virginia	Montana	
Washington	Nevada	
Wisconsin	New Hampshire	
Wyoming	New Jersey	
	New Mexico	
	North Dakota	
	Oklahoma	
	Rhode Island	
	Texas	
	Vermont	
	West Virginia	
Total: 19 states	Total: 26 states	Total: 5 states

[a] Agency housing the predominant portion of food safety regulatory programs. Most states have some divided authorities between agencies.
SOURCES: FDA, 1993; NASDA, 1999; AFDO, 2001, 2009b.

that all 50 states have adopted all or portions of the Food Code (AFDO, 2009b; FDA, 2009c).

There appear to be no major fundamental differences between state and federal food safety laws, although some state laws are based on the 1906 Pure Food and Drugs Act and others on the 1938 Federal Food, Drug, and Cosmetic Act (FDA, 1993). The states, however, possess some authorities that are absent from the 1938 act. By 1993, for example, 48 states had the statutory authority to embargo or stop the sale of food products, but the FDA does not have that authority under federal statutes. In addition, many states have the authority to revoke licenses or permits for food companies that violate food safety requirements or to require destruction of

contaminated products. The FDA's Office of Federal–State Relations confirms that all states now have some form of legislative authority for food and drugs; however, there are wide variations among states, such as in the number of personnel. Because of a lack of resources, no annual surveys of state regulatory authorities have been conducted since 1995; the last survey of state food laws for which there is a record was conducted by the National Association of State Departments of Agriculture in 1999.[4]

State feed programs are an integral part of the food safety system since feed contamination, either chemical or microbiological, becomes a food safety issue for humans through the consumption of food animals or exposure to the contaminated feed. Likewise, humans are exposed to certain zoonotic diseases (those transmitted from animals to humans) through the food and feed chain. Surveillance for zoonotic diseases is a responsibility of state veterinarians. Coordination of state efforts to monitor food animals' feed supply and conduct surveillance for human exposure to zoonotic diseases is part of an integrated food safety system. The FDA has reported that it is currently developing process control regulations for animal feeds similar to the voluntary national Retail Food Regulatory Program Standards and Manufactured Food Regulatory Program Standards (FDA, 2007b, 2009d).

Nearly all feed mills manufacture medicated feeds; however, only those that produce medicated feeds with specific drugs and drug concentrations are inspected routinely by the FDA or contract state inspectors. Feed mills making nonmedicated feeds are generally regulated only by states; the exception is federal regulations concerning bovine spongiform encephalopathy (BSE). Most of these mills either produce organic feed or are species specific (e.g., horse feeds). The FDA stated during testimony to the committee that regulations addressing medicated animal feed are not uniform at the state level, and therefore medicated feed inspections under FDA contracts are conducted under federal law.

Level of Regulatory Activity in the States

Several publications have reported on the number of activities (e.g., inspections, enforcements) conducted at the local, state, and federal levels (AFDO, 2001; HHS/FDA, 2009), including food- and feed-related activities. AFDO is currently finalizing an additional survey of state and local food safety regulatory programs to update previous statistics (AFDO, 2009a,b). The preliminary results (corresponding to 64 of the total 75 state agencies in 47 states at the time of this writing) show that, as in

[4] Personal communication, Richard Barnes, Director, Division of Federal–State Relations, FDA, June 2009.

TABLE 7-3 State and Local Food Safety Activities

Food Safety Activity	2001
Inspections	
Food processing/repackaging facilities (including dairy)	68,162
Farms	159,794
Food service establishments (institutional and retail)	1,229,638
Retail food stores	516,033
Animal feed (feed manufacturers and distributors, bovine spongiform encephalopathy inspections, rendering plants)	23,984
Other (food warehouses, food transportation vehicles, food salvage operations, etc.)	47,697
Investigations	
Foodborne illness outbreaks	3,075
Other (trace-backs, complaints, chemical residues, etc.)	86,840
Enforcement (embargo, warning letters, food recalls, etc.)	128,430
Samples analyzed (food chemistry, microbiology, pesticide residue)	328,065

SOURCE: AFDO, 2001.

2001, the states conduct a substantial number of activities.[5] For example, 2.5 million state and local food safety inspections were reported for foods regulated by the FDA, with the majority being conducted in food service and retail stores, categories the FDA has delegated to the states. In all states, food processing and repackaging establishments are far fewer in number than these categories (Table 7-3).

Florida and Texas are two examples of states that devote substantial resources to food safety. In 2008, the state food regulatory program of the Florida Department of Agriculture and Consumer Services conducted 55,364 food safety inspections in various categories (Aller, 2009).[6] The department supports 184.5 full-time equivalents (FTEs) dedicated to food safety inspection and investigation and 62 FTEs providing administrative support. In 2008, the Texas Department of Health Services conducted 24,829 food sample analyses and took 1,918 enforcement actions (Sowards, 2009).[7] Both state food laboratories are International Organization for Standardization (ISO) 17025 certified.

As noted, state food safety programs are diverse. Data from the 2001

[5] Personal communication, Joseph Corby, Executive Director of AFDO, August 25, 2009.

[6] Personal communication, Marion Aller, Director of the Division of Food Safety, Florida Department of Agriculture and Consumer Services, April 20, 2009.

[7] Personal communication, Dan Sowards, Food and Drug Safety Officer, Division for Regulatory Services, Texas Department of State Health Services, May 19, 2009.

AFDO State Food Safety Resource Survey (AFDO, 2001) show that the numbers of inspections, enforcement activities, and foodborne illness outbreaks differ greatly among the states. Although these disparities could be due to the numbers of facilities/establishments in each state, they also suggest that the emphasis on food safety varies by state. AFDO collected data on inspections of all types of establishments and activities: food processing/repackaging facilities, dairy plants, milk plants, dairy farms, retail food service establishments, retail food stores, wholesale meat processors, meat plants, slaughterhouses, feed manufacturers and distributors, BSE inspections, rendering plants, food transportation vehicles, food salvage operations, farm production, and food warehouses. Based on this survey, the total number of inspections conducted in 2001 ranged from 80 in one state to more than 100,000 in others; the average number of inspections was approximately 50,000 per state.

Information on statutory and enforcement activities (embargo/seizure, stop sale, health advisories, monetary penalties, license/permit revocations, injunctions, criminal prosecutions, warning letters, and informal hearings) was also collected in the AFDO survey. Some states reported fewer than 20 activities, while others reported thousands. Likewise, 13 states reported 10 or fewer outbreaks of foodborne illness, while others reported hundreds (AFDO, 2001).

In contrast with the number of state and local inspections in processing and repackaging facilities (more than 50,000 reported in 2001), the FDA reported only about 16,000 food establishment inspections and 8,000 inspections of animal drug and feed programs for 2008 (HHS/FDA, 2009). The states performed about 60 percent of the food establishment inspections for the FDA and 73 percent of the animal drug and feed program inspections.

Public Health Surveillance and Outbreak Investigations

As stated in Chapter 3, rapid detection and investigation of foodborne illnesses, whether sporadic or outbreak associated, are critical to public health management and risk-based decision making. Development of the epidemiological surveillance system necessary to support this function requires effective and efficient communication and cooperation among a large number of partners, including scientists and laboratories at the local, state, and federal levels (see also Chapter 5). A further complicating factor is the high degree of variability in funding and data collection at the state level. This variability was illustrated in a recent survey conducted by Safe Tables Our Priority, which demonstrated wide variation in response to foodborne illness outbreaks. Nearly 60 percent (23 of 39) of the responding states reported that they did not have electronic capabilities to link inves-

tigative data (Produce Safety Project, 2009). This finding is similar to that cited in the December 2009 report of the Council of State and Territorial Epidemiologists: while 90 percent of the 46 states reporting had databases compliant with the National Electronic Disease Surveillance System, only 53 percent had automated electronic laboratory reporting and 41 percent web-based provider reporting. The report also documents a reduction in the workforce, with 10 percent fewer epidemiologists working in state health departments in 2009 than in 2006 (CSTE, 2009). Since the first-line response to foodborne illness outbreaks is investigations conducted primarily by county and state health departments, with pertinent information eventually flowing to federal agencies such as the FDA or the U.S. Centers for Disease Control and Prevention (CDC), this decrease in regional professional personnel is disturbing.

Food Analysis Data

Some states routinely analyze food samples for contaminants. These data can be invaluable in measuring the effectiveness of industry preventive programs and in providing much-needed information to support risk-based food safety efforts. If these data are to be used in a national food safety system, their quality must meet defined standards of sampling and analysis. To this end, AFDO recently completed a Food Laboratory Accreditation Survey designed to gather information on what is needed for acceptance of analytical results between allied state and federal food safety regulatory agencies (AFDO, 2009a,b). Many state laboratories are equivalent to federal laboratories with regard to staffing numbers and qualifications of both inspectional and analytical personnel and analytical capabilities (e.g., facilities, instrumentation). Some states' food analytical laboratories have achieved ISO/International Electrotechnical Commission (IEC) 17025[8] accreditation, while others are progressing rapidly through this demanding process (AFDO, 2009a,b). Solomon reported in November 2009 that all FDA laboratories were ISO 17025 accredited, as were nine states' food safety laboratories.[9]

Sharing food safety data remains a challenge for various reasons, both technical and cultural (see also Chapter 5), although some valuable initiatives to this end have been undertaken. The eLEXNET system, for example, is a web-based information network that allows the FDA to compare laboratory analyses of contaminants in food or food-producing animals from

[8] ISO/IEC 17025 is the main standard used by testing and calibration laboratories, originally issued by ISO in 1999 and revised thereafter. Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to produce valid results consistently.

[9] Personal communication, Steven Solomon, ORA, FDA, November 17, 2009.

different laboratories. It is also used as a repository for method validation and serves other roles in support of the Food Emergency Response Network (FERN) (FERN, 2009).[10] This initiative, coordinated by the FDA, began as a pilot with 8 participating laboratories and has grown to include 135 laboratories representing federal, state, and local government agencies in all 50 states. A needed enhancement and a specified goal of the FDA's ORA (FDA, 2009c,e) is for eLEXNET to have the capability to alert other users of the system about any significant findings (e.g., a contaminant in a food or a finding outside the normal parameters indicating a potential event) that might necessitate a rapid response.

Another initiative of note is an innovative database developed by the National Center for Food Protection and Defense in collaboration with AFDO, with the purpose of facilitating data sharing in the area of food defense (AFDO, 2009a,b). FoodSHIELD is designed as a web-based platform with a communication portal, a training center, and two databases that capture the capabilities, capacity, technology, and expertise of agriculture, health, environment, and emergency response agencies and their supporting laboratories. Users of FoodSHIELD are varied but are mainly government public health officials (FoodSHIELD, 2009).

FDA INTERACTIONS AND COLLABORATIONS WITH THE STATES

The FDA maintains various interactions and joint programs with state and local regulatory agencies involved in food safety. These include such activities as annual scope-of-work planning sessions, training courses, contracts for food and feed inspections, grants, cooperative agreements, confidentiality agreements, commissioning, inspector and program audits, and joint inspections. In addition, the FDA has memorandums of understanding (MOUs) with the states for various functions, which are issued chiefly to facilitate cooperation and planning.

Training of Inspection Personnel

The adequacy of state and local food safety inspectional programs and the associated training is poorly documented. Solomon (2009a,b) stated that the Office of Regulatory Affairs University (ORAU) offers 130 training courses to state food safety programs, but they are not mandatory. Since 1993, the ORAU program was initiated, 10,700 professionals have participated, and more than 83,000 courses have been completed. In 2009, for example, 37 courses were offered in food protection, including at the retail level and for milk and shellfish, 34 on manufactured foods, 6 on feed

[10] See www.fernlab.org (accessed December 30, 2009).

and veterinary medicine, and 23 on investigative responses, including incident command, rapid response, and farm investigations. However, access to this training is far from ideal, since an individual state has only one or two training slots available in locations far from home districts. In addition to the efforts of ORA, AFDO is now providing education and training to food protection professionals through the IFPTI, established by a $2 million grant from the Kellogg Foundation.[11] The establishment of minimal training requirements and the provision of appropriate training opportunities to meet those requirements are essential if state personnel are to be integrated successfully into the federal food safety program (see Chapter 8). The FDA Manufactured Food Regulatory Program Standards (discussed below) could serve as a basis for providing such minimal requirements as standards for state employees.

Grants, Cooperative Agreements, and Contracts

The FDA has awarded grants, cooperative agreements, and contracts to the states for more than three decades. A grant provides financial assistance to an eligible individual or group to carry out an approved project or activity in which the agency will have no substantial programmatic involvement with the recipient. In 2009, FDA grants provided $17.5 million in state funding to design and implement response, intervention, innovation, and prevention food safety programs—the four key tenets of the FPP. Cooperative agreements are similar to grants in that they give state and local governments the opportunity to enhance existing programs or develop new programs to improve public health. Currently, cooperative agreements are used in cases of substantial federal programmatic involvement.

According to Solomon (2009a,b), the FDA currently has about 43 contracts in 41 states covering a total of about 10,500 inspections. Of these inspections, 9,000 are related to Good Manufacturing Practices (GMPs), 1,100 to seafood HACCP, 47 to juice HACCP, and 53 to low-acid canned foods (see also Chapter 8). However, the total number of FDA-sponsored state contract inspections represents only 0.4 percent of the more than 2.5 million state and local food safety inspections conducted each year (AFDO, 2009a,b). In addition, 37 states currently have contracts or cooperative agreements to conduct feed inspections for the FDA. In fiscal year 2008, those states performed more than 6,000 contracted feed inspections (including GMP and BSE inspections), or approximately 76 percent of all FDA feed inspections. The FDA also has 18 contracts with states to perform tissue residue testing; the states have reported conducting 635 such

[11] Personal communication, Joseph Corby, Executive Director of AFDO, August 25, 2009.

inspections (Solomon, 2009a,b). The number of federal-led inspections is low compared with the number of state-led inspections.

States provide information on contract inspections through electronic access to the Field Accomplishments and Compliance Tracking System. For example, the FDA has a goal to audit 7 percent of contract inspections to determine their equivalency to FDA food inspections and ensure the proper performance of state partners. The FDA has been criticized in the media, most recently in 2009 (Burke, 2007; Schmidt, 2009; Scott-Thomas, 2009), for not meeting this oversight goal. If state and local programs were fully integrated, with adequate standardization and oversight, the FDA could raise its rate of inspection from once every 3–10 years to annually. Once state and local programs have been integrated, the committee suggests that the FDA meet this goal to ensure appropriate inspection and enforcement procedures. If this goal is met, and if the FDA increases its reliance on state and local inspections, the goal can be increased to a higher auditing rate.

State-led food inspections under FDA contracts are performed under state law since states have greater authority than the FDA to embargo shipments, remove licenses, or destroy products (Barnes, 2009). On the other hand, many states lack sufficient regulatory authority in the feed area, so they perform feed inspections under the FDA's commissioning (see below).

Cooperative agreements with the states fund rapid response teams and FERN. The rapid response teams are funded for a specified amount of time with the purpose of enhancing regulatory and surveillance programs for food protection at the state level. The agreements typically provide funds for program assessment, additional equipment, supplies, personnel, and training. The success of the teams depends on their ability to support the infrastructure needed to sustain extensive cooperation and coordination with FDA district offices, especially during emergencies. The first team was the California Food Emergency Response Team, established in 2003; since then, eight additional states (Florida, Massachusetts, Michigan, Minnesota, North Carolina, Texas, Virginia, and Washington) have been granted funds to establish such teams.

FERN encompasses state agricultural, environmental, public health, and veterinary diagnostic laboratories in partnership with federal agencies, including the FDA; CDC; USDA's Food Safety and Inspection Services, Animal and Plant Health Inspection Service, and Agricultural Marketing Service; the U.S. Department of Defense; the Federal Bureau of Investigation; the U.S. Environmental Protection Agency); and the U.S. Department of Homeland Security (FERN, 2009). FERN is organized into a national program office with regional coordination centers that, together with the laboratories, coordinate responses and ensure integration within the network. The FERN laboratories have assisted with method development and

technical expertise on limited occasions. The FERN system has been activated only on a limited basis, including the 2006 outbreak of *E. coli* O157:H7 in spinach, the 2007 outbreaks associated with melamine in infant formula and pet food, the 2008 outbreak of *Salmonella* Saintpaul in Mexican peppers, and the 2008 outbreak of *Salmonella* in peanut butter.

Confidentiality Agreements and Commissioning

Forty-four states are covered by annual confidentiality agreements. The individuals signing the agreements are bound to keep confidential any information designated as such by the FDA.

Commissioning of state officials is the process by which the FDA allows the sharing of confidential information between parties, such as between the agency and a state department of health or agriculture. Commissioning has historically been reserved for high-ranking officials, and only about 1,200 state officials and 9,500 Customs and Border Protection officials are commissioned (Solomon, 2009a,b). The program was designed to better utilize state and local officials in the performance of specific functions subject to federal jurisdiction and confidentiality requirements (e.g., the conduct of examinations or inspections). Commissioning is usually limited to a specified period of time.

In its deliberations, the committee discussed the limited benefits of the current commissioning mechanism. In particular, restricting the number of high-ranking officials commissioned by the FDA in each state leads to barriers in information sharing at the state level. The committee suggests expanding the use of the commissioning process as a mechanism in order to better leverage and integrate the resources of state inspectional personnel (see Chapter 8). The committee believes that expanding use of the FDA's authority to commission both food and feed inspectors would provide an excellent mechanism for delegating agency functions and, when combined with funding mechanisms to promote sustainability of state food safety programs, would facilitate the overall integration of state and federal food safety efforts.

Memorandums of Understanding

The FDA has MOUs with the states for various functions, chiefly to facilitate cooperation and planning. However, MOUs are not binding; are written in general language expressing broad goals, such as a commitment to joint planning and coordinated inspections; and often are not utilized. Previously enacted MOUs between the FDA and the states have basically been general statements of intent; GAO has previously reported on the underutilization of the FDA's interagency agreements (GAO 2004a,b,

2005b). The committee suggests that the FDA develop and utilize more detailed formal agreements, outlining specific expectations, with all states on all food and feed safety matters.

INTEGRATION THROUGH STANDARDIZATION AND OVERSIGHT OF FOOD SAFETY PROGRAMS

The integration and analysis of food safety information and data derived from the inspections and analyses of all partners and stakeholders are of the utmost importance for (1) understanding the food safety system in its totality, (2) ensuring the trust of the consuming public, (3) providing the public with the appropriate level of regulatory scrutiny of the U.S. food supply, (4) allowing the goals of the FDA's FPP to be accomplished, and (5) implementing nationwide the risk-based approach recommended by the committee in Chapter 3. Further, collaboration, partnerships, and data sharing with the states are essential when resources need to be prioritized, but these cannot occur without an adequate foundation in legal authority, standardization, and harmonization of FDA, state, and local programs. The recommendations offered in this report, as well as those of Taylor and David (2009), outline the steps necessary for such collaboration and partnership to occur and encourage the FDA to implement an integrated national food safety system. The FDA cannot be expected to fully achieve the goals of its FPP, in which the states are partners, without fundamental intra-agency changes in culture, structure, and function, as well as interagency integration with state and local partners.

Strategic Planning, Leadership, and Cooperation

Increasing FDA funding or personnel without incorporating the fundamental changes recommended by the committee will not be sufficient to enhance food safety as outlined in this report or to allow the goals of the FPP to be accomplished. Careful strategic planning is necessary before an integrated approach can be implemented. The FDA has produced a report of recent activities toward establishing an integrated national food safety system (FDA, 2009c,e). This document recognizes that "to be successful, an integrated national food safety system must build upon the work currently being done by FDA and our regulatory and public health partners" (FDA 2009c, p. 4).

Constructive changes in federal food safety programs are under way, such as the formation of the FSWG, new leadership in the FDA, creation of the agency's Office of Foods under the Office of the Commissioner, regulatory changes proposed by the FDA, and proposed congressional actions. Efforts are under way to establish task groups internal to the FDA

in the areas of national work planning, policy and procedures, national standards, training and certification, oversight, emergency response, performance outcomes and measures, and laboratories, with implementation expected over the next 5 years (FDA, 2009c,e). According to the FDA, a steering committee was established to maintain necessary communication with the FSWG via the deputy commissioner for foods (see Chapter 11). The committee supports this initiative and concludes that the FSWG, with the enhancements outlined in Chapter 11, needs to maintain a leadership role to ensure that these changes are accomplished. The committee also recognizes that integration will likely not be completed for some years, and it looks forward to seeing progress toward the system's ultimate implementation. The success of this initiative will depend on sustainable support and cooperation among the various organizational structures created (e.g., steering committees, coordinating committees, task groups, partnership for food protection work groups).

The process of integration will require a sustained spirit of collaboration. In the past, successful cooperation has depended mainly on personal relationships and trust among individuals and agencies. The committee recognizes the various ways in which cooperation is being attempted and the recent improvements in sharing of regulatory responsibilities among various jurisdictions (federal, state, and local). The committee recognizes the barriers to collaboration (including the fact that it cannot be mandated), and it emphasizes the importance of strong leadership in achieving and sustaining this important goal.

Standardization of State Programs

State and local governments have jurisdiction over the safety of food products that do not cross state or local boundaries. As noted above, despite similarities in the legal foundation for food safety, state and local programs vary. To integrate food safety as defined by the committee, these programs and their implementation must be evaluated against a minimum standard and ultimately standardized and harmonized. Two programs currently exist within the FDA for assistance that, if enforced, could be used in state standardization.

First, the Voluntary National Retail Food Regulatory Program Standards were introduced as a guide to designing and managing retail food regulatory programs. In 1998, as a pilot test, the states used these standards to assess their retail programs. However, many states failed to adopt the standards because, if the assessment indicated that a program was

inadequate, there were implications for state appropriations (FDA, 2007c). Nonetheless, states have expressed the desire for a review and modification of this program.[12]

Second, in 2000, the HHS Office of the Inspector General reported on the FDA's oversight of state contracts and recommended that the agency take steps to promote equivalency between federal and state food safety standards, inspection programs, and enforcement practices (Brown, 2000). Subsequently, the FDA worked with the states to formulate the Manufactured Food Regulatory Program Standards, which were intended to establish a uniform foundation for the design and management of state programs that are responsible for the regulation of food processing plants. The standards cover ten areas: regulatory foundation, staff training, inspection, inspection audit, food-related illness and outbreaks and food defense preparedness and response, compliance and enforcement, industry and community relations, resources, program assessment, and laboratory support (FDA, 2007b). In 2008, 5 states evaluated their programs against these standards, followed by an additional 25 states in 2009. The principles of this program have also been applied to evaluate foreign food safety programs, such as those in China (Solomon, 2009a,b). Solomon (2009b) reported that the FDA had used these standards in establishing agreements with China's Administration of Quality Supervision, Inspection, and Quarantine to enhance the regulatory structure in that country. The increased participation of states is promising, and the FDA should be encouraged to review the scope of the program to ensure that it covers all phases of the food chain from production to consumption.

The committee agrees with previous recommendations for standardization of all state programs (FDA, 2007b) that are established by the FDA to foster nationwide equivalence with respect to food safety management. As of this writing, 25 states are implementing the Manufactured Food Regulatory Program Standards, which leads the committee to conclude that the integration process is feasible (Solomon, 2009a). For other states, an infusion of resources, as well as increased training, will be necessary to meet those minimal federal standards.

Oversight of State Programs by the FDA

Once standards have been established, methods for standardization are in place, and integration has been achieved, the FDA's major role should be to maintain and revise the standards as necessary; to provide professional expertise, training, and oversight; and to audit the inspections and

[12] Personal communication, Marion Aller, Director of the Division of Food Safety, Florida Department of Agriculture and Consumer Services, April 20, 2009.

programs of its food safety partners. The FDA already performs limited oversight of state programs through either inspector or program audits. In an inspector audit, an FDA inspector observes a state inspector at work; a program audit consists of the FDA's evaluation of a state program. As noted earlier, the FDA has established a goal of auditing 7 percent of state contract inspections and has been criticized for not meeting this goal (FDA, 2006). To the committee's knowledge, there are no FDA audits of local food inspections.

The FDA's FPP (FDA, 2007a) proposes third-party auditing as a means by which oversight of food safety programs and of adherence to regulations and standards can be conducted (see Chapter 4). Large food retailers now require third-party auditing to confirm that food safety practices are being followed by their suppliers. This type of oversight is being conducted by industry in part because the FDA currently is unable to provide such auditing (GAO, 2008b).

In the FPP, the FDA recognizes the significant role third-party auditors now play and hence seeks to provide some level of standardization for these audits. Of interest, other federal, state, and local agencies are also proposed to have a role as third-party auditors (FDA, 2007a). In practice, the committee recommends that the FDA serve as auditor of all state inspections and food safety programs. However, the committee also concludes that there is a fundamental difference between the auditing role of other government agencies and commercial third parties in that other government agencies should be considered equal partners in governing food safety. Thus, the committee objects to the reference to other government agencies, including state and local agencies, as "third parties" in the FPP because the term implies that the FDA will not consider those agencies equal partners in ensuring food safety.

Equivalency of State and Federal Inspections

Regulatory officials are frequently asked to delineate the differences between state and federal food inspections in an effort to establish the meaning of equivalency. Although the legal requirements are roughly the same for state and federal food safety inspections, program implementation, resources, and capabilities vary substantially among the states, as suggested by the AFDO surveys. For example, both state and FDA inspections are based on the applicable Code of Federal Regulations (CFR), Title 21, requirements as they have been adopted by the states. Although states have adopted the CFR, they may have their own regulations as well. Examples are a standard of identity for honey, syrup, or some other food not present in the federal regulations (FDACS, 2009) or the requirement of HACCP plans for sprout production in the state of Florida.

In terms of program implementation, there are differences not only among states but also between the states and the federal government. As a relevant example, most states are unlike the FDA in that inspectors are dedicated solely to food safety, with no responsibility to perform drug or device inspections. An additional difference between federal and state inspections is that the latter focus primarily on reviewing operations in progress rather than on reviewing records, which is more often the focus of FDA inspections. As a result, federal inspections usually take longer than state inspections.[13] One similarity is that both federal and state inspections require internal auditing of inspectors by supervisors to ensure that appropriate inspectional methods are being used. Also, like federal inspectors, state inspectors are often trained through FDA courses; an important difference in this area in that the courses currently are not mandatory for states.

Given these differences, and in the absence of criteria for standardization, there appears to be a legitimate concern within the FDA about the quality of state relative to federal inspections as well as the qualifications and training of state inspectors. As detailed in Chapter 8, the committee recommends a review and update of the inspectional procedures and training curricula for both federal and state inspections and the standardization of all state food safety inspectional programs, including inspector training. The FDA should review and update curricula specific to general food inspections as well as to particular types of inspections (e.g., seafood HACCP) for state and federal inspectors and provide sufficient resources to deliver this training. As mentioned in Chapter 8, the committee supports the partnership of the FDA with others, such as the IFPTI, for the delivery of training for inspectors and auditors.

Risk-Based Approaches at the State and Local Levels

The states apply some of the concepts embraced by a risk-based approach to making regulatory decisions. For example, some use qualitative and quantitative risk assessments and prioritization models produced by the FDA and the academic sector, such as published risk assessments on *Listeria monocytogenes* and methyl mercury. Most state programs prioritize inspections and regulatory scrutiny based on the perishability or known contamination of a food, previous inspectional and analytical history for a firm, published problems with a particular food product, publication of federal recall records, and other knowledge. However, the implementation of a common risk-based approach to food safety management is

[13] Personal communication, John T. Fruin, Florida Department of Agriculture and Consumer Services, 2009.

unlikely until such an approach is instituted at the federal level. Once a risk-based approach is in place at the FDA, the agency should work with state and local governments to facilitate a uniform implementation of that approach.

KEY CONCLUSIONS AND RECOMMENDATIONS

State and local government food safety regulations and programs—including food and public health surveillance and data analysis, inspection, and outbreak investigation—remain a mainstay in protecting the U.S. food supply from unintentional and intentional contamination. An integrated food safety system would have many advantages, such as leveraging efforts, minimizing unnecessary duplication, improving responsiveness when crises occur, and ensuring a reasonable frequency of regulatory scrutiny.

Despite past calls for integration of local, state, and federal food safety programs, only limited progress has been made in this regard. Most of this progress has been accomplished just recently, as evidenced by the IFSS announced by the FDA in fall 2009. This delay has been largely a function of barriers including funding limitations; state-to-state variability in food safety programs, goals, and support; past legal interpretations that integration was not possible; and institutional resistance to change and cultural barriers. Also hampering full integration is the lack of a formal federal process to support, evaluate, or guide state and local food safety programs. Nonetheless, the FDA does have standards in place that, if broadened and properly implemented, could serve as a basis for the harmonization of state and local food and feed safety programs as well as their integration with federal programs. Based on the number of states that are implementing the Manufactured Food Regulatory Program Standards, it appears that the integration process is feasible. The FDA, working with the states, is moving forward to establish core competencies and the credentialing process necessary to ensure adequate performance by inspectors (Brown, 2000; Solomon, 2009a).

The committee recognizes that there will be initial and ongoing costs associated with the integration proposed in this chapter. Certain states will have difficulty achieving the recommended levels of funding and resources. However, mechanisms within the FDA (e.g., contracts, grants, incentives) can be used to enable state programs to meet federal standards in a relatively short period of time. The committee recognizes that questions of legal authority regarding the roles of the states, CDC, and the FDA in the investigation of foodborne illness could impede the flawless, full integration of all local, state, and federal food safety activities. The committee recommends that an appropriate panel perform an overarching analysis of the relevant authorities and that, if necessary, Congress provide clear authorities to the

FDA to achieve the goal of a full integration of local, state, and federal food safety activities to the benefit of the nation's public health.

Recommendation 7-1: The FDA should utilize the surveillance, inspection, and analytic systems and resources of state and local governments in a fully integrated food safety program. As a prerequisite to such integration, the FDA should work with the states and localities to harmonize their programs by providing adequate standards and overseeing their implementation, beginning with those states that meet such standards. Standardization and integration of state and local food safety programs should be conducted in an evolutionary fashion, with intermediate goals and associated performance measures. The White House FSWG should make integration of federal and state food regulatory programs a priority and provide leadership to the already established IFSS Steering Committee. The agency should provide training, auditing, and oversight of state and local programs and should facilitate nationwide implementation of the recommended risk-based approach.

Joint responsibilities of the FDA and the states should include the following:

- Both the states and the FDA should review the state statutory authorities in food and feed safety to ensure adequate protection. If deficiencies are found, the FDA should provide specific recommendations for any additional authorities needed by the states.
- The FDA should work with state and local governments to ensure that the risk-based approach is embraced at all levels.
- The FDA and the states should ensure integration of the feed regulatory program and, through the state veterinarians' offices, actively integrate surveillance of zoonotic diseases into the overall food safety program of each state.
- The FDA and each state and local government should enact formal agreements to delineate the responsibilities of each party and develop a timetable for integration. The FDA should also provide a mechanism (e.g., contracts, grants, incentives) whereby the funds necessary to support full integration are provided to each state government on the basis of its needs to achieve national standards. State programs will not be equal in size or inspection activity, as the location of food establishments is concentrated in certain geographic areas, and the supportive mechanism may be needed for multiple years based on the state's available resources and the number and nature of food firms within its boundaries.

The responsibilities of the states should include the following:

- The states should cooperate with the FDA in standardization processes and commit to obtaining sufficient resources and expertise to achieve standardization.
- The states should work with the FDA to ensure compatibility of communication systems and information technology to allow timely sharing of inspection findings and analytical data.
- The states should work to achieve certification of analytical and inspection programs and, when necessary, seek additional funding through the FDA to assist in this process.

The FDA's responsibilities should include the following:

- The FDA's role in food safety should focus on standards setting, nationwide implementation of the recommended risk-based approach, and training and oversight of state and local food safety regulatory programs, not on increasing internal resources to conduct all regulatory activities at the federal level.
- Accordingly, the FDA should provide appropriate training to state and local surveillance and inspection personnel, with a focus on supporting the risk-based food safety management approach.
- The FDA should provide the necessary standards. As a first step, a review of the Voluntary National Retail Food Regulatory Program Standards and Manufactured Food Regulatory Program Standards should be undertaken to ensure that they are adequate for all areas of food and feed regulatory programs, not just the retail and processing areas.
- As recommended in Chapter 8, after review by an independent body, the FDA's inspection procedures should be revised to promote greater efficiency and should be adopted as standards for all food and feed inspections.
- The FDA should oversee state and local food safety programs by performing regular audits of their inspections and other activities as appropriate at a prescribed annual rate. The agency should also work with the states to ensure coordination with regard to inspection of food facilities to avoid unnecessary duplication of effort.
- The FDA should immediately utilize analytical data from appropriately ISO 17025–certified state food laboratories. For those states not yet ISO-certified, the FDA should work, and assist with funding if necessary, to facilitate ISO 17025 certification over the next 10 years.

- State and local food safety programs should be fully recognized as partners in the nation's food safety program and not as third parties. The FDA's FPP needs to be revised to reflect this philosophical change.
- The FDA should identify intermediate goals with associated performance measures for the process of standardization and integration of state and local food safety programs as part of the plans for implementation. In addition, the FDA should certify and integrate state and local government programs as they meet the standards.

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8

Enhancing the Efficiency of Inspections

The word "inspection" is used by Congress, the U.S. Government Accountability Office (GAO), industry groups, individual scientists, and consumers as though it is a standard term. According to the *Business Dictionary*, the term denotes "critical appraisal involving examination, measurement, testing, gauging, and comparison of materials or items. An inspection determines if the material or item is in proper quantity and condition, and if it conforms to the applicable or specified requirements" (*Business Dictionary*, 2010). In reality, however, notions of just what the term means vary widely, and few understand what a U.S. Food and Drug Administration (FDA) inspection entails or what procedures are followed. As elaborated below, the FDA states that inspections are conducted with the purpose of enforcing regulations or collecting information in a processing or production setting. Instructions to investigators for how to conduct establishment inspections are contained in the *Investigations Operations Manual*[1] (FDA, 2009a). According to the FDA website, "The Investigations Manual is the primary guidance document on FDA inspection policy and procedures for field investigators and inspectors," last updated in June 2009 (FDA, 2009a), with numerous specific issuances from the Office of Regulatory Affairs (ORA).

As described in Chapter 2, ORA is the broad compliance and enforcement arm for all FDA-regulated products. It is the lead office for all FDA field activities, including inspections, sample analysis, enforcement, and development of policy on compliance and enforcement. In addition to

[1] See http://www.fda.gov/ICECI/Inspections/IOM/default.htm (accessed March 2, 2010).

staff located at headquarters, more than 85 percent of ORA staff work in 5 regional offices, 20 district offices, 13 laboratories, and more than 150 resident posts and border stations. In a presentation to the committee, the FDA clarified that ORA's work to foster compliance is often done in partnership not only with the FDA centers but also with industry. During an outbreak, for example, ORA field investigators work closely with the affected center, conduct investigations, and decide on courses of action (Kraemer, 2009; Wagner, 2009). In addition to its inspectional and enforcement activities, ORA hosts an online university that offers required basic courses and specialized training, such as seafood certification for federal investigators. Numerous courses, both web- and classroom-based, are also available to state investigators; however, the FDA has no requirement for state investigators to take them. The training covers such areas as retail establishments, food protection, milk, shellfish, manufactured foods, feed and veterinary medicine, investigation response, incident command systems, rapid response teams, and on-farm investigations (Solomon, 2009).

Prior reports have evaluated the adequacy and efficiency of U.S. food inspections and determined that inspections are insufficient, the basis for determining which facilities to inspect is poor (GAO, 2004; HHS, 2010), and there is a critical need to leverage resources to provide for a more efficient system (GAO, 2005a,b). Testimony offered to the U.S. Congress on numerous occasions has also spoken to this concern. An inefficient inspection process results in public health risks that could be avoided with appropriate inspection (for example, inspection of peanut facilities should have prevented the recent outbreak associated with contaminated peanuts). This chapter presents an analysis of the inspection process and explains the committee's conclusion that the process is inefficient for reasons that range from the cultural to the organizational. It should be noted that a full evaluation of the efficiency of the food safety inspection process cannot be conducted in isolation from similar processes performed by other government agencies, such as the U.S. Department of Agriculture and the National Oceanic and Atmospheric Administration (see Table 2-1 in Chapter 2). In accordance with its statement of task, however (see Chapter 1), the committee evaluated only the FDA's inspectional activities and refers to the inspectional activities of others only to the extent that they could contribute to improving the efficiency of inspections performed by the FDA. In this chapter, then, the committee offers recommendations for enhancing oversight of the food production system by improving the efficiency of the FDA's inspections and leveraging its inspectional resources. The committee comments as well on the FDA's potential use of third-party inspections (also discussed in Chapter 4).

BACKGROUND

As noted above, the FDA uses establishment inspections for either enforcement or information-gathering (surveillance) purposes. Inspections may be used "to obtain evidence to support legal action when violations [of the law] are found," or "they may be directed to obtaining specific information on new technologies, good commercial practices, or data for establishing food standards or other regulations" (FDA, 2009a, Subchapter 5.1, p. 213). Although this chapter focuses on the use of inspections as an enforcement tool, the collection of food safety data is essential to the implementation of the risk-based approach to food safety management recommended in Chapter 3.

The typical inspection begins when an inspector issues a Notice of Inspection (FDA form 482) to the management of a company to be inspected and presents his/her credentials. Inspections may be carried out by a single inspector or, if specialized techniques (e.g., microscopy, x-ray) are required, by a team. Inspectors begin by becoming familiar with the establishment's operations and products, its compliance history, pertinent safety factors, and the reporting requirements for the type of inspection to be undertaken. Other preinspectional activities are described in the *Investigations Operations Manual* (FDA, 2009a, Subchapters 5.4–5.9). General inspectional activities include observation, discussion with establishment management, label review, note taking, audio/video recording, sample collection (when appropriate), and reporting. Management of the establishment being inspected may invite outside observers as long as they do not impede the investigation. The sources of general inspectional procedures and techniques are given in the following quotation from the *Investigations Operations Manual*:

> The procedures and techniques applicable to specific inspections and investigations for foods, drugs, devices, cosmetics, radiological health, or other FDA operations are found in part in the Investigations Operations Manual (inspectional and investigational policy/procedure), various Guides to Inspections of . . . (a "how to" guidance series), and the Compliance Program Guidance Manual (program specific instructions). (FDA, 2009a, Subchapter 5.1, p. 216)

The *Investigations Operations Manual* describes the inspectional approach in general terms as follows:

> An establishment inspection is a careful, critical, official examination of a facility to determine its compliance with laws administered by FDA. Inspections may be used to obtain evidence to support legal action when violations are found, or they may be directed to obtaining specific informa-

> tion on new technologies, good commercial practices, or data for establishing food standards or other regulations. In order to facilitate on-the-job training, multiple points of view, and perspectives of firms being inspected whenever practical, those with assignment authority should consider assigning different Investigator/s or different Lead Investigators at different times. This is recommended particularly when there have been multiple sequential NAI (no action indicated) inspections or when the firm's management has been uncooperative. (FDA, 2009a, Subchapter 5.1, p. 213)

The investigation of an establishment ends with the issuance of FDA form 483, Inspectional Observations. That form is

> . . . intended for use in notifying the inspected establishment's top management in writing of significant objectionable conditions, relating to products and/or processes, or other violations of the Federal Food, Drug, and Cosmetic Act and related Acts . . . which were observed during the inspection. These observations are made when, in the Investigator's "judgment," conditions or practices observed, indicate that any food, drug, device, or cosmetic have [sic] been adulterated or are [sic] being prepared, packed, or held under conditions whereby they [sic] may become adulterated or rendered injurious to health. The issuance of written inspectional observations is mandated by law and ORA policy. (FDA, 2009a, Subchapter 5.2, p. 224)

The FDA defines two types of inspections—a comprehensive inspection and a directed inspection. Comprehensive inspections "direct coverage to everything in the firm subject to FDA jurisdiction to determine the firm's compliance status." Directed inspections "direct coverage to specific areas to the depth described in the program (compliance program), assignment (field assignment), or as instructed by [the] supervisor" (FDA, 2009a, Subchapter 5.2, p. 213). It is unclear what proportion of inspections is typically comprehensive and what proportion is directed. There are also two types of functionally distinct inspections: those based on Good Manufacturing Practices (GMPs) regulations and those based on Hazard Analysis and Critical Control Points (HACCP) regulations.

EFFICIENCY OF INSPECTIONS

Based on past authoritative reports alluding to this problem, the committee questioned the efficiency of the FDA's food safety oversight system. Further analysis of FDA-led inspectional activities revealed various reasons for this deficiency. Some of these reasons relate to the division of responsibilities between the FDA centers and ORA, which results in the centers' lack of authority over inspectors and inspectional priorities and procedures.

Also, inspectors are trained as generalists and do not specialize in, for example, food facilities. As a result, they cannot keep up with technological changes in all areas of FDA jurisdiction. Others reasons are related to the inspection procedures, which have not changed over time other than to become more burdensome with regard to paperwork and have not been adapted to the complexities of modern manufacturing establishments. The *Investigations Operations Manual* has not been reviewed externally to determine, for example, whether it is up to date, overly prescriptive, or otherwise less than ideal. Likewise, the time required for an establishment inspection either has not changed or has increased over time; thus, the number of inspections conducted annually has declined even though more inspectional full-time equivalents (FTEs) have been hired. Finally, the FDA's organizational structure, whereby ORA and the centers have various responsibilities from enforcing the law to writing risk-based regulations, is not conducive to the efficient implementation of regulations. This issue is of particular concern when roles and processes for collaborating are not completely clear and depend on maintaining good relationships between individuals.

The Role of the Inspector as an Investigator

One could argue that the inspector is the key to any required preventive food safety procedure (Gombas, 2009). As described by Givens (2009), the inspection process is part of a larger system that promotes compliance within the industry and sensitizes the industry to its responsibilities for ensuring that its products are safe. Inspectors are told which facility to inspect and are instructed that, in addition to following regulations and a compliance program, they are investigators. Thus, they must be observant, noting anything that appears irregular and following up on it while they are in the facility (Givens, 2009). Clearly, then, the instincts, judgment, and training of an inspector are valuable components of the inspection process. The committee concluded, therefore, that the FDA's food inspectors need the best available, up-to-date training in food safety. For example, although the agency has not proceeded rapidly with modernizing the GMPs, inspectors should receive training that is up to date with regard to the latest epidemiological intelligence, the latest information on pathogens, and any new technologies or techniques salient to the inspection process. Likewise, the FDA should have procedures in place to ensure that its auditors have the necessary experience, competencies, education, and continued training to perform their tasks.

In addition, inspectors have an educational function that is linked to the FDA's role in training the food industry in food safety and the interpretation of rules (see Chapter 9). This function includes directing food industry

managers to relevant FDA sources (websites or other information repositories). As recommended in Chapter 9, the FDA should develop a centralized repository for food safety educational materials for industry personnel, promote the accessibility of these materials, and provide technical support for the interpretation of rules and regulations. Inspectors should be trained in improving their communication skills so the transfer of their knowledge and communication with food managers will be effective. Inspectors should also be trained in communicating effectively with industry managers when they are requesting nonregulatory data. The purpose and terms for collecting the data, as well as whether regulatory action will be taken if a contaminant is found, need to be clearly stated (see Chapter 5).

Currently, inspectors are trained to inspect establishments that represent the breadth of FDA-regulated products (i.e., drugs, devices, foods, and sometimes animal feed), and specialization is lacking. For example, an inspector who is trained and certified to inspect food processing and storage facilities may be cross-trained to inspect feed facilities. In the past, regulations and manufacturing processes were simpler, and this approach may have had benefits (i.e., a flexible inspectional force capable of being deployed to address any emergency related to any FDA-regulated products). In today's more complex world, however, those benefits pale in comparison with the benefits of a more specialized inspectional force. Manufacturing operations have become more complex, automated, and computerized over time, and new hazards have been identified. To continue training inspectors in all FDA-regulated products results in inspectors who are generalists and lack the specialized training and knowledge to deal with this context. FDA inspectors are not unlike criminal investigators in this regard. Police departments are divided into specialty areas, allowing investigators to focus their talents and knowledge in one area (e.g., homicide, auto theft). FDA inspectors, like criminal investigators, must be trained to look for clues to violations, some of which may not be readily apparent given the technical complexities of manufacturing. The committee believes that, to have adequately trained inspectors now and in the future, the FDA must begin training inspectors within a single major commodity area (i.e., food or feed) of FDA responsibility.

The FDA should review and update curricula specific to general food inspections as well as to particular types of inspections (e.g., seafood HACCP). This specific training is essential so that inspectors will be readily available and prepared to conduct an inspection in any food facility. The committee supports the partnership of the FDA with others, such as the International Food Protection Training Institute, established in 2009, to deliver career-spanning food protection training for state and local food protection professionals. Federal employees with auditing responsibilities should also be provided with specific training.

Risk-Based Inspections

Since its inception, the FDA has lacked the manpower to place an inspector in every food manufacturing facility under its jurisdiction, let alone all facilities that pack, store, and sell such products. Therefore, the agency has used its inspection authority as a deterrent (Kusserow, 1991; Busta, 2009) since an inspection could occur unannounced at any time. The FDA has suggested prioritizing inspections based on such criteria as history of compliance (Chapter 3). At a more basic level, however, the attributes of a risk-based approach as outlined in Chapter 3 are not clearly incorporated in FDA's approach to inspection of food facilities.

The *Investigations Operations Manual* defines the "depth of inspection" (FDA, 2009a, Subchapter 5.1, p. 213), noting that the attention given to various operations in a firm depends on information desired or on violations suspected or likely to be encountered. The FDA suggests that inspectors consider the following: (1) current company compliance with regulations, (2) nature of the specific assignment (inspection or investigation), (3) general knowledge of the industry and its problems, (4) firm history, and (5) conditions found as inspection progresses. A walk through is suggested early in the process so the inspector can "become familiar with the operation and plan the investigation strategy" and determine the depth of inspection necessary (FDA, 2009a, Subchapter 5.1, p. 213). Thus in theory, an inspection could be limited to a walk through and expanded as needed for further investigation depending on findings. Giving inspectors flexibility with respect to the length and depth of inspections would make it possible to conduct shorter inspections of compliant establishments while maintaining an adequate presence in all firms, thus preserving the deterrent function of the inspection process. While it appears that the FDA has the statutory authority to allow shorter inspections, there are other barriers to doing so, related to resistance to changing conventional procedures.

In a way, risk-based inspections have always existed. However, such approaches need to be adapted to new knowledge in food safety. Before microbiological, chemical, and physical analyses became more or less routine, FDA inspectors used personal observations to detect possible problems with the basic hygienic conditions in an establishment and relied primarily on two of the adulteration provisions of the Federal Food, Drug, and Cosmetic Act for authority to take action on any findings of unhygienic conditions.[2] The GMPs for foods,[3] which include special provisions for infant formulas, were finalized in the 1980s. GMPs form the basis for many international standard procedures and principles (for example, the Gen-

[2] *Federal Food, Drug, and Cosmetic Act of 1938*, 342(a)(3) and 342(a)(4).

[3] *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food*, 21 CFR Part § 110.

eral Principles of Food Hygiene of the Codex Alimentarius Commission) and provide the foundation for establishment inspection based on sound hygienic principles, facility design, and product handling and processing. GMP inspections may generate adverse findings that are documented by the inspector and presented to a responsible individual in the establishment. Such adverse findings are expected to be corrected, and a follow-up inspection may be conducted to determine what actions were taken to that end. A criticism of GMP-based inspections, however, is that they constitute a "snapshot in time," and do not necessarily reflect the day-to-day operations of a facility (Givens, 2009).

In 2002, the FDA formed the Current Good Manufacturing Practices Working Group to determine whether the GMPs needed updating. The FDA solicited public comment, and the working group issued a report detailing areas in which modernization might be needed, such as training for supervisors and workers, food allergen control, environmental pathogen control, and written sanitation procedures. A major question was whether the food GMP regulations should be extended to facilities (such as farms) involved solely in harvesting, storing, or distributing raw agricultural commodities. To date, no apparent progress has been made on modernizing the GMPs (CFSAN/FDA, 2005), despite the fact that industry has asked the FDA to "revise its GMPs to include requirements for written sanitation plans, allergen controls, environmental monitoring programs for certain production facilities, and supervisor, manager, and employee training in hygiene and food safety measures" (Scott, 2009). The FDA itself has acknowledged the need to revise the GMPs for feed. *Fourth Draft: Framework of the FDA Animal Feed Safety System* (FDA, 2010) describes the need to update the GMPs for medicated feed. The committee recognizes that there is currently not enough information to justify separate GMPs for nonmedicated feed. As part of a risk-based system, if data indicate that the safety of nonmedicated feed is a concern, GMPs for this category of feed should be considered.

Since the promulgation of HACCP rules in the 1990s, in addition to a GMP inspection, a HACCP inspection is required for establishments that make HACCP-regulated products (seafood and juice). GMPs are one prerequisite for HACCP, since basic hygiene underlies specific preventive procedures (Scott, 2009). Because an establishment's HACCP plan, along with mandatory record keeping, is intended to reflect its daily preventive activities, inspection is viewed as more than the GMP-based inspection's snapshot in time. However, HACCP inspections are based on "snapshots" provided by the establishment's management; an inspector sees what management claims to be standard procedure within the facility.

For establishments that make HACCP-regulated products, a HACCP inspection is required in addition to a GMP inspection. HACCP inspections

are lengthier than GMP inspections because of the required analysis of the establishment's HACCP plan and its implementation and review of records for each day of operation (Kraemer, 2009). Some in industry believe that "while conducting a hazard analysis and implementing preventive controls should be required of industry, these activities may or may not be in the form of a HACCP plan" (Mavity, 2009). Others believe that for those processes without a kill step (critical control point), such as for preparing fresh-cut produce, a HACCP plan may be unnecessary. While it is true that not all industry processes will have critical control points, control points and limits in the form of performance standards might be possible, thus preserving the essence of HACCP. In Chapter 10, the committee recommends that the FDA be granted the authority to request preventive controls for all food facilities, mindful of the many forms such controls can take and the fact that their adequacy depends on the type of product and process.

As noted in Chapter 3, the FDA presented the committee with information on its efforts to develop models for a risk-based inspection system. The committee did not evaluate these models, but it noted the lack of stakeholder involvement in the process.

The Inspection Process

The committee deliberated about the criticism the FDA has received for the paucity of inspections it conducts on food establishments annually (GAO, 2004, 2005a,b; Halloran, 2009; HHS, 2010). This number appears to be decreasing even as both the number of establishments in the agency's inventory and the number of food program FTEs steadily increase (GAO, 2008). This paucity of inspections is also seen with animal feed. As noted in Chapter 7, feed mills making nonmedicated feeds are generally regulated only by the states, except in the case of the FDA's bovine spongiform encephalopathy regulations. These mills are relatively small in number and produce organic feed or are species specific (e.g., horse feeds). Currently, only feed mills that produce feed with specific concentrations of medication in the premix need a license and are inspected routinely by the FDA or contract state inspectors. The committee believes any feed mill that manufactures medicated feed should be subject to the same inspectional processes regardless of the concentration of medication in the premix.

One way to increase the number of inspections without new resources is to improve the efficiency of inspections. As stated in testimony to the committee, "inspection time can certainly vary on a number of factors—the type of operation, the complexity of the process and the product, the risk of the product, and the controls that the firm may have in place." Furthermore, with regard to a firm with a poor history of compliance, an inspector "might want to spend some time, because that firm is not getting it—that

may require some more time and attention to that facility" (Givens, 2009). Thus, as suggested earlier, the individual inspector's training, judgment, and intuition may also play a role in the length of an inspection. An applicable analogy might be a police officer making a traffic stop for a missing tail light. The officer sees the driver is nervous and asks more questions. During that extra time, the officer sees something in the car that prods him or her to ask the driver for access to the trunk, where drugs are found, making the stop a regulatory/legal activity that will take more time than usual.

The *Investigations Operations Manual*, developed mainly by ORA, is the primary guidance document on FDA inspection policy and procedures for field inspectors. There is no specific mechanism for obtaining input on inspection procedures from the centers, states, or other agencies. The committee is not aware of reviews of (or congressional requests to review) the *Investigations Operations Manual* and the efficiency of inspections, even in the face of the above-noted decrease in annual inspections despite increasing numbers of personnel (Plunkett, 2009). It is possible that, as new requirements have been added to the manual to prevent a specific new problem from recurring, the manual has become unnecessarily lengthy and the inspections costly. A single establishment inspection can take one or more inspectors many days to complete, even if the establishment has a history of compliance or appears to be in compliance when the inspector enters the facility. Likewise, an inspection of a facility that may be in violation because of the presence of insect fragments in food, for example, could be far more abbreviated than one for an establishment in which salmonella is thought to reside.

Inspections have become more complex and more onerous over time (Givens, 2009; Kraemer, 2009). Guidelines for inspectors have accumulated to reflect legal amendments, making the paperwork burden on the investigator increasingly time-consuming (Halloran, 2009). There has been no external study of inspection procedures in the United States, and there is no evidence of any innovative thinking applied to those procedures (Plunkett, 2009). By contrast, in 2005 the UK Treasury published a report reviewing the financial burden of government inspections and enforcement on businesses and offering recommendations for improving the efficiency of the country's inspection system (Hampton, 2005). These recommendations include devoting more resources to riskier businesses, streamlining data-sharing methods, and communicating clearly with businesses about how to comply with regulations. In the absence of such a study in the United States, questions arise as to whether it would be reasonable and more efficient to categorize inspections based on criteria that would take into consideration an inspector's experience and intuition. ORA appears to have thought about the latitude an inspector may have with regard to its high-risk product–hazard combination list (which was

developed to prioritize inspectional resources), asking what the inspector should do with this information—perform an inspection, collect samples, or conduct a field exam.

ORA also appears to have thought about "regulatory testing" versus "screening" with regard to sample testing. Solomon (2009) stated to the committee that "FDA is a regulatory agency and needs to have regulatory tests—but that's not a reason that we don't have rapid screening tests that we can use to quickly . . . focus on issues and then follow up with more regulatory tests." For example, the burden of some inspections could be alleviated by making a distinction between inspections conducted to oversee a facility's compliance with all food-related regulations and those conducted to screen a facility's food safety status more rapidly by determining adherence to GMPs.

Although the committee did not conduct a review of inspectional procedures, it concluded that such a review is warranted to identify approaches, including risk-based approaches, that could increase the efficiency of the inspection process. Such a review should include examining procedures and techniques employed by other federal, state, and local government agencies, both regulatory and law enforcement, as well as those used in other countries, to determine whether they might be of value to FDA inspectors.

Organizational and Cultural Barriers to Efficient Inspections

As mentioned in Chapter 2, policy setting for FDA food regulation resides in the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM), which are both headed by directors, while enforcement of policies and regulations is carried out by ORA, which is headed by an associate commissioner. The district offices and resident posts are staffed primarily by inspectors charged with conducting inspections of establishments' producing, packing, or holding products regulated by the FDA, including foods, cosmetics, medical devices, and drugs. ORA works with CFSAN and CVM to develop an annual work plan that provides overall guidance to the field on the types and levels of inspections and surveillance activities to be conducted. There are also five field committees, one for each product category regulated by the FDA, composed of field managers and field program experts. The Food Field Committee and the Veterinary Field Committee are expected to work with CFSAN and CVM, respectively, in preparing the annual work plan, and they continue to collaborate during the year as issues arise. In practice, however, the committee questions whether this arrangement results in decisions that meet the regulatory responsibilities of CFSAN and CVM. The committee reviewed testimony and reports suggesting that this organizational structure creates barriers to improving inspection procedures.

In a report on revitalizing ORA, Glavin (2008, p. 23) states that "ORA is perceived as being too rigid, resistant to change, . . . unresponsive to new or different ideas, and too concerned with losing its span of control or turf." If this observation is true, it does not bode well for effecting meaningful efficiencies in inspection procedures or establishing a system of science-based, policy-driven enforcement.

One expert, familiar with the FDA's component organizations through extensive dealings with both CFSAN and ORA, expressed the opinion that it is extremely difficult to work with those organizations during emergency situations, such as outbreaks, as communication and coordination between the two appear obscure (Osterholm, 2009). Industry-associated groups in particular have alluded to perceived friction between CFSAN and ORA. Interorganizational problems occurring during emergency situations such as disease outbreaks may be somewhat understandable; however, CFSAN and ORA have had decades to develop procedures to prevent or mitigate misunderstandings. The lack of clarity and procedures for their roles constitutes a barrier to efficient management, especially during times of crisis. It is quite likely that the split in administration of the FDA's food programs between CFSAN and ORA, or between enforcement and policy, fuels such internal miscommunication and misunderstanding (Osterholm, 2009).

In conversations with former FDA employees, including counsels, it became clear to the committee that the relationship between ORA and the centers depends largely on the personalities of the individuals who occupy leadership positions in those organizations as well as interpersonal relationships among many individuals at lower echelons of each organization. Natural competitive relationships have evolved as a result of perceptions of the value of field versus scientific experience; in addition, different missions, such as enforcement versus policy development and management, limit the sustainability of good relationships (Osterholm, 2009). Misunderstandings and inconsistencies with regard to an enforcement matter are known to occur not only between district offices within ORA itself but also between district offices and CFSAN. These occurrences are of concern, especially in cases when delaying a decision could jeopardize public health.

CAPITALIZING ON FOOD INSPECTIONS: USE OF STATE INSPECTORS AS PRIMARY FOOD INSPECTORS

In addition to the use of a risk-based approach, gains in inspection efficiency would be realized if food safety inspection activities at the federal, state, and local levels were coordinated (see Chapter 7). With regard to coordination at the federal level, the committee supports the GAO recommendations (GAO, 2004, 2005a,b) calling for concerted efforts in coordination of the inspectional activities of the various responsible fed-

eral agencies (see Appendix B). This section is focused on the utilization of inspectional resources at the state and local government levels.

The role of the states in the inspection of food establishments is discussed in detail in Chapter 7. Considered here is whether a system could or should be envisaged in which federally trained state inspectors would assume the role of primary food inspectors, with the FDA serving as auditor of state-conducted inspections. If such a governance model is explored, some functions in addition to auditing should remain in the FDA, such as maintaining experience in inspection methods, providing instructional materials and specialty expertise to state inspectors, developing and evaluating new inspection techniques and training, and serving as a backup corps in times of special need.

Preliminary data for 2008 indicate that states performed approximately 2,520,000 inspections (AFDO, 2009), including more than 50,000 in processing/repackaging facilities; the FDA performed only about 16,000, about 60 percent of which were conducted under contract with the states (FDA, 2009b). The committee concluded that recognition of the states as full partners in food safety assurance would be an effective way of greatly increasing the frequency of establishment inspections. Under current law, state inspectors can be commissioned as federal agents, a step that is usually taken for special assignments and is limited in time and scope. With appropriate training and oversight, state inspectors could assume a full-time role as federal deputies. The number of FDA inspectors would be limited to those required for training and auditing, and perhaps for playing an expanded role in import and export (foreign) food establishment inspections or certifying the equivalency of systems between the United States and exporting countries. The FDA would provide training to state inspectors, review inspectional procedures, and ensure that state inspections were equivalent to FDA inspections. The FDA could also defer to the states for inspection of animal feed mills. In most cases, feed mill inspectors are already from the states' departments of agriculture and are specifically trained and contracted to perform federally required GMP inspections. They also conduct state feed mill audits for label compliance, weights and measures, and sanitation.

FDA regional and district offices are spread across the U.S. mainland, but as the food industry shifts over time, they are not necessarily located in the same places as the industry (Fraser, 2009; Givens, 2009). Thus, the number of inspectors in each district office may not align with the number of establishments that need to be inspected. An individual state is in a better position to know what food establishments are within its borders (Osterholm, 2009). Therefore, a system whereby each state receives a pro rata share of inspectional resources based on the number of establishments requiring inspection might ensure more homogeneity with regard to num-

bers and quality of inspections. The FDA currently funds state inspections by contract; this pool of funds could be adjusted based on the inspection burden within the states and in lieu of changing the number of federal inspector positions. The agency should include in its budget a line item to fund these state contracts and partnerships to ensure their sustainability.

USE OF THIRD-PARTY AUDITS AS A SUBSTITUTE FOR INSPECTIONS

There has been a proliferation of both auditing and certifying bodies in the United States and elsewhere, and the data gathered by these third parties could be useful for enhancing the science behind the FDA's risk-based approach to food safety management. Third-party auditing evolved in the European Union when large retailers demanded certain characteristics from their suppliers, such as quality, safety, limited environmental impact, and animal welfare (see Chapter 4). In Europe, an association of retail chains, EuroGAP, was formed in 1999, changing its name in 2007 to GlobalGAP (GAP = Good Agricultural Practice) (Yudin and Schneider, 2008). Many European buyers will buy only from suppliers that can provide a certificate demonstrating compliance with rules such as those of GlobalGAP. Inspection of the suppliers is carried out by a certification body, a group of third-party auditors who are accredited by an accreditation body. Usually the accreditation body is a technical committee comprised of experts from the retail and supplier sectors (Albersmeier et al., 2009). Further discussion of the potential value of third-party auditing as a governing model for managing food safety can be found in Chapter 4.

Third-party auditing was not developed originally to supersede government oversight of food production and manufacture. In Europe, the producer of food must conform to both legal and third-party audit requirements. Private certification is characteristic of the European food industry, whereas public certification schemes still predominate in the United States, Canada, and Japan (Albersmeier et al., 2009). However, private certification is catching up in the United States. For example, the Global Food Safety Initiative (GFSI) was created in 2000 to set common benchmarks for different national and industry food safety programs, and GFSI standards are now used widely around the world, including in the United States. Likewise, the California Leafy Greens Marketing Agreement, operating with oversight from the California Department of Food and Agriculture, provides a mechanism for verifying that the U.S. produce industry (farmers, shippers, and processors) follows appropriate food safety practices in producing leafy greens.

In response to a new challenge, private standards can be implemented more quickly than public standards, which are enacted by a government or

an organization such as Codex (DeWaal and Plunkett, 2007; Henson and Humphrey, 2009). However, private standards may result in unnecessarily higher food prices. DeWaal and Plunkett (2007) conclude that a government accreditation requirement might be a better solution.

The FDA is taking some steps to assess the value of third-party auditing. In 2009, for example, the FDA released its *Guidance for Industry on Voluntary Third-Party Certification Programs for Foods and Feeds,*[4] describing the general attributes the agency believes third-party certification programs should possess whether they are administered by private entities or by federal, state, local, or foreign regulatory bodies (FDA, 2009c). However, the FDA goes further to state that it will recognize a certification program only if it has sufficient confidence in the certification body. Although this stance appears to be directed toward ensuring the safety of imported foods, it could also apply to domestic certification bodies in the future.

The committee deliberated about the legitimate role of information from third-party audits as a tool for the FDA to use in overseeing food safety. This question is also being examined at an international level, and an easy answer is unlikely (Henson and Humphrey, 2009). Although third-party certification may drive the industry to a higher standard that benefits everyone, the public acceptance of third-party auditors that are paid for by the industry needs to be evaluated. With appropriate standards in place, these audits could be of value for a risk-based approach. Therefore, before accepting third-party food safety audits, the FDA should develop standards and oversight procedures as necessary to ensure the credibility of the audit results. In particular, the FDA should set minimum standards for auditors and audits with a view to eventually having oversight by an accreditation and standards body. Further, if the type of information gathered during these audits could be of value for a risk-based approach, the FDA should seek ways to determine whether it can legally be mined from third-party audits/auditors.

KEY CONCLUSIONS AND RECOMMENDATIONS

Irrespective of the potential gains from allocating more funds to the FDA's inspection capacity, the committee concluded that a more basic and valuable exercise would be for the agency's inspection procedures to be reviewed for efficiency. The committee believes that, especially in light of resource limitations, the efficiency of the FDA's inspectional activities could be improved. The committee deliberated on ways to improve inspections with this perspective in mind.

[4] See http://www.fda.gov/RegulatoryInformation/Guidances/ucm125431.htm (accessed March 2, 2010).

The committee identified the following barriers to improved efficiency of FDA inspections: (1) the FDA's food programs do not have direct authority over the work of inspectors and inspectional procedures, resulting in substantial delays in policy implementation in the field; (2) inspectional procedures themselves may be inefficient; and (3) the FDA underutilizes other sources of information, such as state inspections. These barriers may result in the duplication of inspections, unnecessary targeting of resources, gaps in model coverage, and misunderstandings about priorities and highest risks, all with the potential to affect public health. (Recommendations for overcoming cultural and organizational barriers to the increased efficiency of inspections are presented in Chapter 11 in the context of other organizational changes.) Gains in efficiency would be realized if food safety inspection activities at the federal level were coordinated, and the committee supports the GAO recommendations to this end (GAO, 2004, 2005a,b; see Appendix B). In keeping with its statement of task, however, the committee did not analyze the inspectional activities of other federal agencies; it focused on formulating recommendations for overcoming the above barriers.

In addition to the need for a risk-based approach, the recommendations in this chapter reflect the conclusions presented in Chapter 7 with regard to the need to integrate all food safety activities at the federal, state, and local levels: (1) all food safety programs need to be standardized and harmonized; (2) state and local agencies are conducting many inspections, some of them under contract with the FDA, that need to be standardized and follow a risk-based approach; (3) once inspections (and other aspects of food safety programs) become standardized, the FDA will be able to capitalize on the work the states are already doing in many food safety areas, including inspection, to drive their risk-based models and make policy decisions; and (4) once food safety programs in states meet standards for food safety governance, the role of the FDA in standards setting, education, evaluation, oversight, and audit can be augmented.

Finally, the recommendations below apply to feed inspections with a caveat. Although GMPs should be extended for all medicated feed, there is currently insufficient information to justify separate GMPs for nonmedicated feed.

Recommendation 8-1: The FDA should work toward an inspection system in which the frequency and intensity of inspection of each facility are based on risk, with minimum standards for the frequency and intensity of inspection of all facilities. To support the establishment of such a system, an outside panel should review the potential legal and cultural roadblocks to streamlining inspections and revise the *Investigations Operations Manual* so as to enhance efficiency and protection of

the public health. As a prerequisite for a risk-based inspection system, the FDA should update its GMPs, including those for medicated animal feed, now and hereafter as necessary.

Based on the number of food safety inspections already conducted at the state and local levels and on the need for national integration of food safety activities, the committee makes the following recommendation.

Recommendation 8-2: As alternative regulatory models emerge, the FDA should evolve toward conducting fewer inspections, instead delegating inspections to the states and localities (including territories and tribes). The FDA should maintain a cadre of inspectors for several critical tasks, such as auditing inspections, providing specialty expertise, developing training and instructional materials for inspectors, identifying and evaluating new inspection techniques, and serving as a backup corps in situations of special need. In preparation for this move, the FDA should review and update curricula specific to general food inspections as well as to particular types of inspections (e.g., seafood HACCP). Agency employees with responsibility for auditing inspections by others should also be provided with specific training. An FDA-sponsored food safety certification program should be established whereby inspectors become certified as they meet agency standards. The agency should include in its budget a line item to fund state contracts and partnerships to help the states move toward and maintain full certification. Plans for implementation of the suggested changes should proceed in an evolutionary fashion, with intermediate goals and associated performance measures.

The committee also recommends that the FDA continue to consider the use of third-party certifications.

Recommendation 8-3: The FDA should fully consider the implications of accepting inspection data from an auditing program in which third-party auditors would inspect facilities for compliance with food safety regulatory requirements. If this approach is utilized, the FDA should set minimum standards for such auditors and audits, with oversight and implementation being assigned to an accreditation and standards body.

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9

Improving Food Safety and Risk Communication

According to the National Research Council (NRC) (NRC, 1989), risk communication is "an interactive process of exchange of information and opinion among individuals, groups, and institutions. It involves multiple messages about the nature of risk and other messages, not strictly about risk, that express concerns, opinions, or reactions to risk messages or to legal and institutional arrangements for risk management." Communication with stakeholders is an essential activity of any regulatory agency. In a food safety regulatory agency, the various stakeholders provide different perspectives on factors that enter into the decision-making process of a risk-based food safety management system. Indeed, this type of communication with stakeholders is integral to a risk-based approach and is an important aspect of many of the steps in such an approach as delineated in Chapter 3.

Risk communication can also be viewed more broadly as a policy tool available to the U.S. Food and Drug Administration (FDA) to achieve its food safety–related public health objectives. As such, risk communication encompasses a range of activities, from consulting with the public or professional organizations, to meeting with governmental partners, to designing and delivering recalls or warnings. Preceding chapters have addressed several aspects of risk communication in various contexts, focusing on such topics as identifying the roles of different partners (Chapter 4), sharing data (Chapter 5), and integrating federal activities with those of state and local governments (Chapter 7). This chapter complements those discussions by focusing on risk communication activities at the FDA across contexts, but with emphasis on those contexts in which the FDA provides

messages or training to inform and support food safety–related decisions and behaviors.

The Food Protection Plan (FPP) explicitly includes communication as one key step in responding to food safety problems, but it also mentions other FDA actions that entail communication (e.g., risk assessments for prevention, compliance guides, technical advice, training programs or materials for food safety workers and industry) (FDA, 2007). This responsibility is also implied in legislation that directs the FDA to enhance various specific communication functions.[1,2] Accordingly, the agency's website states that: "[t]he FDA is also responsible for helping the public get the accurate, science-based information they need to use medicines and foods to improve their health" (FDA, 2009a).

The FDA's food risk communication activities range from issuing recalls and outbreak notifications, to sharing information about food defense with other countries, to providing guidance and training materials for food safety organizations and individuals. The FDA communicates risks both indirectly, by regulating the labeling and advertising of some products, and directly, by developing and sharing information with all parties in the food system. While the agency's ultimate goal is to protect the public health, the specific objectives, audiences, and methods of its communications differ across tasks and contexts (FDA, 2009a). Communications during crises are a major FDA responsibility[3]; during a recall, for example, the agency is required to ensure efficient and effective communications, reaching people throughout the food system rapidly with actionable messages. In contrast, training and guidance about food safety involve long-term partnerships and collaborations with, for example, professional associations and educational institutions.

Dramatic changes in food production and distribution systems (see Chapter 2) and additional knowledge about the epidemiology and determinants of foodborne illness have resulted in a food safety enterprise that is increasingly complex. For example, worldwide feed production has nearly doubled since 1980—from 370 million tons in 1980 to 614 million tons in 2004 (IFIF, 2009), and the number of food facilities increased by 10 percent from 2003 to 2007 (GAO, 2008a). This complexity adds to the challenges of communicating food safety information to food suppliers, preparers, consumers, and other stakeholders. As populations grow, as food sources globalize, and as production increases in scale, the potential for rapidly

[1] *Food and Drug Administration Amendments Act of 2007*, Public Law 110-85, 110th Cong. (September 27, 2007).

[2] *FDA Food Safety Modernization Act of 2009*, 111th Cong., 1st sess., Congressional Record 510 IS. (March 3, 2009).

[3] *Food and Drug Administration Amendments Act of 2007*, Public Law 110-85, 110th Cong. (September 27, 2007).

evolving crises—and the need for effective crisis communication—escalates (GAO, 2004a, 2008b).

Food safety and risk communications are critical at numerous points in the food system, from training field workers and restaurant or institutional food service employees to alerting consumers who may have contaminated products in their kitchens (Taylor and David, 2009). This chapter begins with a general overview of the FDA's risk communication and education activities. In particular, it highlights the FDA's most recent progress in this area, such as the establishment of the Transparency Task Force and the Risk Communication Advisory Committee (RCAC). It examines the communication efforts that are needed during crisis situations, such as recalls. Communication with the food industry is emphasized as an area that warrants increased attention. The chapter also offers recommendations for enhancing food safety and risk communication activities with regard to consumers, public health officials, and other health professionals. Finally, the chapter underscores the importance of conducting social research to design messages and to evaluate risk communication efforts as an essential element of a risk-based approach.

FOOD RISK COMMUNICATION AND EDUCATION AT THE FDA

Risk communication and education is one way the FDA can help ensure food safety. To be effective, risk communication requires an understanding of the needs of those involved, two-way communication, and evaluation (NRC, 1989). As with other interventions, the use of communication and education as policy tools needs to be part of strategic planning in a risk-based approach (see Chapter 3). In addition, decisions to adopt specific communication or education interventions should be based on empirical evidence of effectiveness. In essence, developing a risk-based approach such as that recommended in Chapter 3 is the first step in developing effective risk communication and education activities as policy interventions. An appropriate approach to assessing the level of risk and identifying the possible prevention and mitigation points in food production, processing, distribution, and preparation will also identify the points at which risk communication can reduce risk. This knowledge will enable the FDA to respond consistently and appropriately to stakeholders' needs for information. In addition, such an approach should serve to identify those stakeholders that can collaborate most effectively with the FDA to reduce risk at different points in the system. As discussed in Chapter 3, the strategic planning process should identify the various stakeholders and how they will be consulted and engaged for their contributions. Included in the stakeholder list should be the subgroup of consumers, industry workers, and health professionals that is the focus of this chapter. The committee agrees with the general risk

communication steps and actions in the FPP, but it concludes that the necessary details of implementation are lacking. The committee was unable to obtain detailed information about the FDA's communication and education programs specifically related to foods; therefore, the information in this chapter was obtained from public meetings and the FDA website.

As noted, the FDA's risk communication responsibilities are specified in the Food and Drug Administration Amendments Act of 2007 (FDAAA). The act also directs the agency to establish and consult with the RCAC, which is composed of risk communication experts from academia and industry as well as representatives of consumer advocacy groups (FDA, 2009b).

One recent positive development has been the introduction of foodsafety.gov, a website managed by the U.S. Department of Health and Human Services (HHS) as a collaborative effort of the White House, HHS, the U.S. Department of Agriculture (USDA), the FDA, the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health. Its purpose is to consolidate food safety information produced by various federal agencies that have a role in the regulation of the U.S. food supply and to provide the public with current information about food safety. Containing very little technical jargon, the website is designed for consumers and food safety educators and also for vulnerable populations. Much of the website contains information about food safety alerts, prevention, food preparation, causes of food poisoning, and how state and federal governments respond to foodborne illness outbreaks. The website also links to the official websites of the FDA, USDA, and CDC. Written content is supplemented by simple charts, videos, audio podcasts, and social media tools that allow for two-way communication.

Numerous entities within the FDA are engaged in communication (see Table 9-1). The agency's risk communication activities are coordinated by an internal Communication Council. A risk communication director in the Immediate Office of the Assistant Commissioner for Planning leads the agency's strategic planning process and is in charge of coordinating both the internal Communication Council and the external RCAC.[4] The lack of past strategic planning for risk communication and education suggests that prior to these initiatives, risk communication and education efforts at the FDA lacked a cohesive strategy.

Work of the RCAC

The RCAC was established specifically as an FDA advisory body on communications with patients and consumers, recognizing that the agency

[4] Personal communication, Nancy M. Ostrove, FDA RCAC, Washington, DC/North Gaithersburg Hilton, February 28, 2008.

TABLE 9-1 Description of Communication-Related Activities at the U.S. Food and Drug Administration (FDA)

Office of the Commissioner	
Office of Foods	• Directs a program of public outreach and communication on food safety, nutrition, and other food-related issues to advance the FDA's public health and consumer protection goals.
Office of Legislation	• Works with members of Congress and staff on legislative proposals that grant new agency authority. • Provides Congress with requested information on FDA programs and policies.
Office of Chief of Staff, Office of Executive Secretariat	• Serves as the FDA's liaison to the U.S. Government Accountability Office and the U.S. Department of Health and Human Services (HHS) Office of the Inspector General on several highly visible studies. • Coordinates numerous high-level briefings for the commissioner and manages the FDA's review and clearance process for executive correspondence, memorandums of understanding, reports to Congress, consumer correspondence, and other items.
Office of External Affairs, Office of External Relations	• Arranges briefings between the commissioner and outside stakeholders on crucial FDA issues. • Manages high-level outreach to various stakeholder groups on all major FDA announcements. Develops a series of innovative "listening sessions" between the commissioner and major stakeholders. • Continues to refine and strengthen the FDA's newly designed home page and its web-based consumer information program, producing articles to support the FDA's public health mission and establishing new distribution channels for this material.
Office of External Affairs, Office of Public Affairs (OPA)	• Provides numerous announcements of agency actions, including food recalls and implementation of requirements under the Food and Drug Administration Amendments Act of 2007. • Conducts crisis communication activities, such as the response to the outbreak of *Salmonella* Saintpaul. • Provides public affairs presence at FDA public meetings, congressional hearings, and advisory committee meetings and responds to inquiries from members of the media.

continued

TABLE 9-1 Continued

Office of External Affairs, Office of Special Health Issues	• Is responsible for engaging, collaborating, and communicating with health professionals, patients, patient advocates, and other special-interest populations about FDA regulatory decisions and policies. • The "FDA Updates for Health Care Professionals" e-list provides recent announcements related in particular to human medical product safety, human medical product approvals, opportunities to comment on proposed rules, upcoming public meetings, and other information of interest to health professionals. • Has a new health professional webpage—MedWatch—to serve as a portal for FDA information, particularly safety-related information of interest to health professionals.
Office of Policy, Planning, and Budget, Office of Policy	• Handles high-priority, cross-cutting, and novel regulatory issues, and coordinates the issuance and publication of all FDA regulations, notices, and guidance documents.
Office of Policy, Planning, and Budget, Office of Planning	• Analyzes risk communication activities and assists agency components in planning to improve the effectiveness of those activities. • Coordinates the Risk Communication Advisory Committee (RCAC). • Sets up internal pilot projects for testing messages prior to issuance. Completed a national survey of physicians concerning their perceptions about emerging and uncertain risks of medical products, the results of which will guide communications directed toward that audience. • Leads the process to develop the FDA's Strategic Plan for Risk Communication, as well as a prioritized research agenda. • Coordinates the presentation of the strategic plan and research agenda to the RCAC for feedback.
Office of the Counselor to the Commissioner, Office of Crisis Management	• Provides coordination and strategic management of the FDA's response to numerous incidents concerning FDA-regulated commodities, including outbreaks, natural disasters, and actual or potential product defects that pose a risk to human or animal health (e.g., melamine-contaminated infant formula, salmonella in imported produce, flooding in the midwest). • Charged with meeting the HHS goal to improve the FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA-regulated products.
Advisory Committee Oversight and Management Staff	• Works to maintain and improve the transparency, integrity, and consistency of the FDA's advisory committee program. • Published important new draft guidance on when the FDA convenes advisory committee meetings. • Helped improve the FDA webpage on advisory committees, increasing the program's transparency and improving public access to important information.

TABLE 9-1 Continued

FDA Centers and Office of Regulatory Affairs (ORA)	
Center for Food Safety and Applied Nutrition	• Manages the 1-800-SAFEFOOD information line and e-mail inquiries from consumers, industry, and other constituents; this information line averages around 2,100 inquiries monthly. • Develops and implements comprehensive risk communication roll-out strategies to reach all stakeholder groups, domestic and international, including industry, consumers, state and local public health and regulatory agencies, the clinical community, and media, with FDA messages related to emergencies as well as new regulations and guidance and other initiatives. • Directs the development of long-term consumer education campaigns for multiple targeted audiences and messages related to food safety and nutrition best practices. • Maintains a comprehensive stakeholder directory. • Coordinates with other FDA entities and develops major media news releases and social media (Web 2.0) tools related to emergency response communications for foodborne outbreaks and major recalls. • Conducts social research to support communication efforts.
Center for Veterinary Medicine	• Protects human and animal health by regulating animal drugs and feeds for millions of companion animals, poultry, cattle, swine, and other animal species. • Communicates frequently with veterinarians, industry, the public, and other stakeholders about product recalls, new animal drug approvals, guidance for industry, and other animal health issues.
Office of Regulatory Affairs (ORA), Division of Federal State Relations	• Uses a number of mechanisms to provide accurate and timely information to state, local, and tribal partners. • Serves an advisory role to field public affairs specialists.
ORA, Public Affairs Specialists	• Located in ORA field offices, work within their local communities around the country to promote and protect the public health and work closely with OPA to deliver FDA messages. • In addition to serving the general public, work with traditionally underserved populations, such as women, seniors, and ethnic minority communities. • Reach a variety of audiences—including health professionals and students, government and industry representatives, and members of community groups and faith-based organizations—through outreach and educational programs, workshops, conferences, exhibits, and speeches. • Take the pulse of the public, reporting consumer concerns to agency management. This feedback guides future FDA programs so that messages are better targeted to consumer concerns, and agency decisions are responsive to developing public health policy.

needs to communicate more effectively with the public and based on recommendations in the Institute of Medicine (IOM)/NRC report *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (IOM/NRC, 2007). As noted, the FDAAA of 2007 chartered the RCAC, establishing a mandate for the committee to advise the FDA on its risk communication activities in general and on crisis communications during recalls. The RCAC consists of a core of 15 voting members selected by the commissioner for their expertise in such fields as social marketing and health literacy, and for their experience in risk communication and work with patients, consumers, and health professional organizations (FDA, 2009b). Since its inception, the RCAC has held nine public meetings, some of which have addressed food risk communication issues. Meeting agendas have included the review of a draft strategic plan for risk communication at the FDA, research on risk communication, and communication strategies during food recalls and outbreaks (FDA, 2009c,d).

As an example of its advisory role, the RCAC was consulted with regard to communication with the public during food recalls, which remains problematic. Specifically, the RCAC was asked about the appropriateness of a draft press release template for communicating with consumers during Class 1 recalls.[5]

The FDA receives formal and informal recommendations during the RCAC meetings. Informally, for example, the committee chair proposed the different types of expertise needed for effective risk communication. In addition, the chair suggested considering a model recommended by the Canadian Standards Association, and adopted by some government agencies, that requires two-way communication between risk managers and stakeholder representatives throughout the development and implementation of a program (CSA, 1997). Following a more formal process, the RCAC adopted the resolutions in Box 9-1 at its August 2008 meeting. After receiving RCAC recommendations, the FDA reports back to the committee in subsequent meetings on its progress, for example, with regard to risk communication funding in the FDA supplemental budget.[6]

One of the first actions of the RCAC in 2008 was to advise the FDA to engage in strategic planning of its risk communication activities (FDA, 2009d). With this impetus and with attention to aligning its specific strategies with the risk communication–related goals of the FPP (improve risk communications to the public, industry, and other stakeholders [FDA, 2007]), the FDA developed a draft Risk Communication Strategic Plan

[5] A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

[6] Personal communication, Nancy M. Ostrove, FDA RCAC, Washington, DC/North Gaithersburg Hilton, February 28, 2008.

BOX 9-1
Risk Communication Advisory Committee
Resolutions, August 2008

- The U.S. Food and Drug Administration (FDA) should consider risk communication as a strategic function.
- The FDA should engage in strategic planning of its risk communication activities.
- The FDA should find ways to do risk communication research efficiently, ensuring that communications are designed in a timely fashion to a scientific standard.
- The FDA should routinely present quantitative risk and benefit information, in formats consistent with its regulatory constraints.
- The FDA should develop a participatory design and testing process for FDA consumer communication. The process should include vulnerable groups with barriers to understanding and access.

SOURCE: FDA, 2009d.

(FDA, 2009e). The plan, which was aligned with the goals of the HHS Strategic Plan, presents the FDA's strategies for risk communication and proposes ways to improve the agency's science base, its capacity for action, and its policy processes (see Box 9-2). Also, communication is included in the FPP explicitly as one key step in responding to food safety problems. The three primary goals in the draft Risk Communication Strategic Plan are

(1) expand FDA capacity to generate, disseminate, and oversee risk communication;
(2) optimize FDA policies on communicating risks and benefits; and
(3) strengthen the science that supports effective risk communication (FDA, 2009e).

In this plan, the FDA states its view that risk communication is a two-way process integral to carrying out its mission effectively, that such communication must be adaptable to the various needs of the parties involved, and that it should be evaluated to ensure optimal effectiveness (FDA, 2009e).

BOX 9-2
Summary of U.S. Food and Drug Administration (FDA) Risk Communication Strategic Plan

Expand the FDA's *capacity* to generate, disseminate, and oversee effective risk communication.

Capacity Strategy 1:	Streamline and more effectively coordinate the development of communication messages and activities.
Capacity Strategy 2:	Plan for crisis communications.
Capacity Strategy 3:	Streamline processes for conducting communication research and testing, including evaluation.
Capacity Strategy 4:	Clarify roles and responsibilities of staff involved in drafting, reviewing, testing, and clearing messages.
Capacity Strategy 5:	Increase staff with decision and behavioral science expertise and involve them in communication design and message development.
Capacity Strategy 6:	Improve the effectiveness of the FDA's website and Web tools as primary mechanisms for communicating with different stakeholders.
Capacity Strategy 7:	Improve two-way communication and dissemination through enhanced partnering with government and nongovernment organizations.

The FDA's Transparency Task Force

On January 21, 2009, President Obama issued two memorandums to the heads of executive departments and agencies expressing a commitment to promoting transparency and openness in government (FDA, 2009f; GPO, 2009). These memorandums were followed by the Open Government Directive in December 2009 (OMB, 2009). Executive departments and agencies have been charged with harnessing new technologies to disclose information about operations and decisions online and to make this information readily available to the public. In addition, executive departments and agencies have been instructed to solicit public input and feedback to identify information of greatest use to the public (GPO, 2009).

Accordingly, the FDA has formed a Transparency Task Force (see

Optimize the FDA's *policies* on communicating risks and benefits.

Policy Strategy 1: Develop principles to guide consistent and easily understood FDA communications.

Policy Strategy 2: Identify consistent criteria for when and how to communicate emerging risk information.

Policy Strategy 3: Re-evaluate and optimize policies for engaging with partners to facilitate effective communication about regulated products.

Policy Strategy 4: Assess and improve FDA communication policies in areas of high public health impact.

Strengthen the *science* that supports effective risk communication

Science Strategy 1: Identify gaps in key areas of risk communication knowledge and implementation, and work toward filling those gaps.

Science Strategy 2: Evaluate the effectiveness of FDA's risk communication and related activities, and monitor those of other stakeholders.

Science Strategy 3: Translate and integrate knowledge gained through research/evaluation into practice.

SOURCE: FDA, 2009e.

Box 9-3), which includes the agency's principal deputy commissioner, center directors, associate commissioner for regulatory affairs, chief counsel, and chief scientist (FDA, 2009g). The task force is soliciting public opinion on various communication and transparency matters and has held two public meetings. The first public meeting, held on June 24, 2009 (FDA, 2009h), was meant to solicit input on how the agency can make useful and understandable information about its activities and decision making more transparent and readily available to the public. The second public meeting, on November 3, 2009, was held to receive comments on three specific issues: (1) early communication about emerging safety issues, (2) disclosure of information about product applications that are abandoned or withdrawn by the applicant before approval, and (3) communication of agency decisions about pending product applications (FDA, 2009i). In addi-

BOX 9-3
Transparency Task Force Action Items

- Seek public input on issues related to transparency.
- Recommend ways that the agency can better explain its operations, activities, processes, and decision making, compatible with the agency's goal of appropriately protecting confidential information.
- Identify information the U.S. Food and Drug Administration (FDA) should provide about specific agency operations, activities, processes, and decision making, including enforcement actions, recalls, and product approvals.
- Identify problems and barriers, both internal and external, to providing useful and understandable information about FDA activities and decision making to the public, taking into consideration health literacy and the needs of special populations.
- Identify appropriate tools and new technologies for informing the public.
- Recommend changes to FDA's current operations (e.g., internal policies and procedures, standards, information formats, guidance) to improve the agency's ability to provide such information to the public in a timely and effective manner.
- Recommend legislative or regulatory changes, if appropriate, to improve the FDA's ability to provide such information to the public.
- Submit a written report to the Commissioner on the Task Force's findings and recommendations.

SOURCE: FDA, 2009g.

tion to these meetings, the FDA has established a Transparency Blog, which also provides opportunities to learn about, and provide feedback on, what the agency is doing, specific topics prompted by the FDA, the basis for its decisions, and the processes used to make those decisions (FDA, 2009j). In response to comments and requests in these forums, the FDA has created a website explaining the basics of its activities.[7]

The task force was to submit a written report to the FDA commissioner approximately 6 months after being convened, and the commissioner was to report back and confer with the Secretary of HHS on the recommendations in the report. The FDA envisions that implementation of the task force's

[7] See http://www.fda.gov/AboutFDA/Basics (accessed October 8, 2010).

recommendations will make agency actions, decisions, and underlying processes more transparent to the public while still meeting the agency's goal of appropriately protecting confidential information. Further, implementation of the recommendations should reduce the need for public requests for agency information under the Freedom of Information Act (FDA, 2009g). To date, this transparency initiative has resulted in recommendations that the FDA plans to implement in three different phases: (1) development of a web-based resource that will provide information about commonly misunderstood agency activities; (2) formulation of an approach to making information and decision making more transparent; and (3) transparency specifically to regulated industry. As planned, in December 2009 the task force submitted a written report to the HHS Secretary detailing progress in implementing phase 1, the launching of the FDA basics website.[8]

Although the task force is an admirable effort and intuitively valuable, an evaluation of its activities would be premature since it has been in place for only a few months. The committee encourages its continuation and future evaluation of this new activity.

COMMUNICATING AT A TIME OF CRISIS: FOOD RECALLS AND OUTBREAKS

The number of food recalls issued annually has increased by an order of magnitude in the last two decades and is expected to continue increasing with improved detection technologies (GAO, 2004b). The most common tool the FDA now uses to mitigate emerging outbreaks is public warning.[9] During these recalls, the FDA currently sends an e-mail to all state public health departments and key stakeholders (e.g., the Food Allergy and Anaphylaxis Network in the case of allergens) to post on their websites, and it posts the same information on its own website and on foodsafety.gov. The FDA has also begun using social media and provides Twitter feed about recalls on request.[10] Section 1003 of the FDAAA contains provisions concerning enhancing the quality and speed of the FDA's communication with the public in recall situations.[11,12]

In its 6-month and 1-year FPP progress reports, the FDA reported the development of templates for recalls that it presented to the RCAC in 2008 (FDA, 2008a,b). These templates were tested within the agency's

[8] See http://www.fda.gov/AboutFDA/Basics (accessed October 8, 2010).

[9] Personal communication, Nancy M. Ostrove, FDA RCAC, Washington, DC/North Gaithersburg Hilton, February 28, 2008.

[10] Personal communication, Nancy M. Ostrove, FDA RCAC, Washington, DC/North Gaithersburg Hilton, February 28, 2008.

[11] FDAAA, Public Law 110-85, 110th Cong. (September 27, 2007).

[12] *Code of Federal Regulations Food and Drugs* § 7.42 Recall strategy (2003).

own heterogeneous workforce and used as surrogate groups representing public responses. The RCAC provided specific advice on the development of these templates during one of its meetings with the FDA, as noted above. The FDA has also considered partnerships with other organizations as a way of carrying out formative evaluations of communication strategies.

For food recalls, the FDA recognizes that people must be given answers to three key questions: (1) What is the product? (2) What is the concern? and (3) What do I need to do? In a national survey on awareness of and behavioral responses to food recalls, Hallman and colleagues (2009) found that the messaging used during the most recent food recalls had been ineffective in leading consumers to take action. Messages must be delivered quickly with clear criteria for identifying a recalled product and the symptoms caused by consumption of the product. They also need to provide motivational information on the appropriate course of action without frightening consumers, which the survey results suggest is lacking since few respondents had ever looked for recalled food products in their homes. The survey revealed that, while most Americans hear or read about food recalls, they fail to recognize recalled products and feel that food recalls are more relevant to other consumers. Consumers are unaware of the frequency of food recalls and exhibit widespread misconceptions about the division of responsibilities between federal agencies in such situations. Nearly 75 percent named the FDA as responsible for meat and poultry recalls (which are the responsibility of USDA); 48 percent failed to identify any agency as responsible for fruit and vegetable recalls, and just 32 percent identified the FDA as the responsible agency. Thus, despite awareness of recent food recalls, an illusion of invulnerability and a lack of knowledge about the food recall process appear to be widespread among American consumers. These findings signify the need for a clear, coordinated, and centralized communication strategy for food recalls.

This need for information applies to feed as well. Failures in communication during the melamine-associated pet food recall of 2007 spurred the passage of special sections (1002 and 1003) of the FDAAA directed at ensuring the safety of pet food and animal feed. These improvements to the feed safety system include "posting information about a recall in a single location on FDA's Web site" and establishing a Reportable Food Registry for feed in addition to food (Covington and Burling, LLP, 2007; FDA, 2008b,c).

Further, the FDA has been criticized for damaging the food industry by issuing overly general messages (e.g., do not eat raw spinach). It is important to recognize that during the course of a recall, government officials are challenged to be expeditious about communicating with the public while also being accurate and specific about the contaminated product. Protecting

the public health without inhibiting sales of safe food requires a delicate balance when the information needs to be provided quickly.

Another challenge in managing recalls is communicating their termination. FDA regulations provide that a recall will be terminated only when "it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product."[13] The regulations require the FDA to provide written notification of termination to the recalling firm, but they do not address the communication of such information to the public. Risk perception research shows that consumers generally do not know when recalls end and tend to play it safe by avoiding the general category of the recalled product for months thereafter (Cuite et al., 2007). The FDA's procedures regarding recall termination need to be reviewed so that economic losses can be minimized to the extent possible consistent with protecting the public health.

The FDA is working on a set of goals for understanding how to better use food distribution and communication networks to reach consumers. The agency is concerned about being able to reach consumers with timely updates as recall situations evolve.[14] If consumers receive a behavioral cue at an opportune moment—for example, when they are purchasing or preparing food—they can reduce their risk of foodborne illness (e.g., Nauta et al., 2008). Grocery store receipts (Hallman et al., 2009), televised and online recipe and cooking information (Powell, 2000; Mathiasen et al., 2004), newspaper recipe and menu sections, and vending machines are examples of contact points at which recall information could be communicated.

A cursory analysis of online government portals for food recall information shows that the new foodsafety.gov website is prominent, but so, too, are other federal government sites, such as the Joint Institute for Food Safety and Applied Nutrition's foodrisk.org and the USDA National Agricultural Library site foodsafety.nal.usda.gov. These latter sites may confuse consumers, however, because either they do not link to foodsafety.gov for food recalls, or they link to more than one site with information about recalls. The current design of foodsafety.gov includes an immediately visible recall window, as required in Section 1003 of the FDAAA, but other parts of the website link to other websites for core food safety information. The more that linking steps are required, the greater is the potential for communication failures. Consumers, educators, and state and local governments cannot at present find food recall information and report food safety prob-

[13] 21 C.F.R. 7.55(a).

[14] Personal communication, Nancy M. Ostrove, FDA Risk Communication Advisory Committee, National Transportation Safety Board Conference Center, Washington, DC, August 13, 2009.

lems and foodborne illnesses on a single authoritative website. Section 1003 states that the FDA website and recall database shall be easily accessed and understood by the public; without an empirical evaluation, it is difficult to demonstrate that these goals have been achieved.[15]

EDUCATING THE FOOD INDUSTRY

As stated above, risk and safety communications are critical at numerous points in the food system. Food producers, processors, and retailers play a vital part in the prevention of foodborne illness and require education tailored to their role in the food safety system. For example, effective training of industry personnel is a critical component of a preventive, risk-based food safety system and is necessary for successful implementation of Hazard Analysis and Critical Control Points (HACCP) (NACMCF, 1997). As the leading food safety oversight agency, the FDA must incorporate the risk and safety communication needs of the food industry and regulators into its risk communication strategy.

Food service workers at institutions, such as schools or nursing homes, that purchase and prepare food for large numbers of potentially sensitive subpopulations are an important control point for risk communication in the food safety system. In fact, the majority of foodborne illnesses in confirmed outbreaks in OutbreakNet for 2007[16] were associated with exposures outside the home, with 30 percent of illnesses attributed to restaurants or delis. Rising trends in eating out, food preparation and service employment, and a high proportion of young (Bureau of Labor Statistics, 2009), foreign-born (ROC-United, 2009; Bureau of Labor Statistics, 2010a), and Hispanic or Latino workers in food service (Bureau of Labor Statistics, 2010a; ROC-United, 2009, 2010) underscore the importance of targeting this sector for food safety training. Food preparation and service workers rely primarily on short-term on-the-job training to prepare for the work (Bureau of Labor Statistics, 2010b). While a lack of health care benefits and illness policies contribute to workers showing up for work when ill (ROC-United, 2009),

[15] Section 1003 reads: "(1) work with companies, relevant professional associations, and other organizations to collect and aggregate information pertaining to the recall; (2) use existing networks of communication, including electronic forms of information dissemination, to enhance the quality and speed of communication with the public; and (3) post information regarding recalled human and pet foods on the Internet Web site of the Food and Drug Administration in a single location, which shall include a searchable database of recalled human foods and a searchable database of recalled pet foods, that is easily accessed and understood by the public" (FDAAA, Section 1003, Public Law 110-85. 110th Cong. [September 27, 2007]).

[16] OutbreakNet. Foodborne Outbreak Online Database. See http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx (accessed October 8, 2010).

studies of food service employees suggest that targeted training in the positive outcomes of specific behaviors (e.g., hand washing making it less likely that people will get sick), in combination with reducing barriers to such behaviors (e.g., convenient facilities, available time), can contribute to needed improvements in food safety behaviors (Howells et al., 2008; Pilling et al., 2008, 2009; see also Green and Selman, 2005).

Numerous sources of information and training materials currently exist for the food industry. The Center for Food Safety and Applied Nutrition (CFSAN) posts training materials and notices on its website under the Retail Food Protection's Industry and Regulatory Assistance and Training Resources page, as well as under Food Defense (FDA, 2009k,l). In addition, industry associations provide comprehensive and standardized training materials for the food industry. For example, ServSafe is well recognized as the leading training program for food retailers (ServSafe, 2009). Grocery Manufacturers of America has developed a HACCP guide for the food industry that is frequently modified by others to suit their needs (GMA, 2009). Other groups, such as the National Environmental Health Association, also provide training materials for the food industry (NEHA, 2008).

The feed industry relies heavily on trade associations such as the American Feed Industry Association, the National Grain and Feed Association, and specific food animal associations (e.g., the National Pork Producers Council, National Turkey Federation, U.S. Poultry and Egg Association) for information and training. Further, many land grant universities have developed feed safety bulletins and other educational materials and have those materials available on their websites. Not unlike conferences addressing specialty crops, nearly every conference targeting livestock production includes topics on safe feed/safe food. While all of these mechanisms are excellent sources for the industry, however, some may be expensive for small processors and retailers (Behnke, 2009).

The Cooperative Extension System provides a broad range of educational programs and serves as a resource for food safety training and information for the food industry. Regulatory agencies frequently refer food producers, particularly small establishments, to Cooperative Extension Services for training and information on food safety and the implementation of new regulations. Cooperative Extension Services often advertise their programs through their websites and by mailing risk communication and training notifications to the food industry. They frequently set their training schedules months in advance but get little, if any, advance notice of the implementation of new regulations. As a result, they can be overwhelmed when new regulations are issued. In addition, funding shortfalls compound the problem as state and federal agencies cut their budgets. Therefore, while Cooperative Extension Services are a good resource for meeting the food industry's educational needs, their ability to serve the large number of food

processors and retailers in the United States is limited. Also, few Land Grant institutions have spent the time and effort to develop significant expertise in feed production and safety, although, based on the experience of committee members, this situation is slowly beginning to change (Behnke, 2009).

One particular subgroup of the food industry that may not have the resources to update its workforce on the latest policy developments and may need more targeted attention is small producers, processors, and retailers. Hirsch and Cutter (2006) used several methods to examine the training and support available to small and very small meat and poultry establishments. They also conducted a mail survey and later organized a workshop to learn from small and very small meat and poultry producers in the Northeast about their sources of information and the value and quality of training available to them. The results point to the inadequacies of, and barriers to, training and the need for standardization (Hirsch and Cutter, 2006).

The committee is unaware of similar studies for the portion of the food industry regulated by the FDA. Yet while the study by Hirsch and Cutter focuses on USDA-regulated establishments, it clearly demonstrates the need for a comprehensive, standardized education and training program for the food industry, and the industry training needs it identifies could impact producers of FDA-regulated products as well. The committee concluded that a similar study should be conducted to identify training needs in the FDA-regulated portion of the food industry.

OTHER TARGETED POPULATIONS

In addition to information for industry, the FDA creates and collates on its website important information for targeted populations, such as consumers, industry, and health professionals. This section addresses the importance of enhancing communications with these populations.

Consumers

While the food industry—from the farm to the retailer—plays an essential part in mitigating the risks from foods, consumers also play a role in reducing their risks from food through appropriate food purchases and handling (Nauta et al., 2008). Understanding what consumers know, value, and do is an essential first step in providing them with relevant information in a form they can understand and use; risk communication research can bridge the gap between what experts say and consumers hear, or need to hear, about handling food safely (Fischhoff and Downs, 1997; Morgan et al., 2001; Bruhn, 2005; Fischhoff, 2009). If consumers are to make informed food consumption decisions, they also need information with which to weigh benefits and risks—for example, to understand when the

nutritional benefits of foods may outweigh the risks from potential trace contaminants (IOM, 2007).

While in some cases consumers may be unaware of food risks, in others they may be unnecessarily worried because they lack specifics on what they can do to protect themselves effectively. Although estimates of the percentage of Americans that have confidence in the safety of the food supply vary considerably because of methodological differences across surveys, in general confidence appears lower today than it has been since 2001 (Gallup, 2010). Public opinions about, and confidence in, food safety are highly responsive to specific food safety incidents (Cuite et al., 2007; Blendon et al., 2009), although, as with other risks (Weinstein, 1989; Rothman et al., 1996), consumers generally tend to be optimistic and, as noted above, to believe that foodborne illnesses and food recalls are more relevant to the general public than to themselves (Miles and Scaife, 2003; Hallman et al., 2009). Kinsey and colleagues (2009) analyzed the influence of media attention on consumer confidence and concluded that media coverage has a significantly negative effect on consumer confidence in the safety of the food system. Overall, favorable attitudes toward the FDA declined from 1997/1998 to 2010 (from 75 percent to 58 percent) (The Pew Research Center, 2010). This general trend toward lower confidence in the FDA, however, may be due not only to food safety incidents and coverage by the media but also to increasing general distrust in the U.S. government (and in the FDA in particular) since the late 1990s (The Pew Research Center, 2010). Kinsey and collaborators' most recent data[17] show that confidence in food safety has neither decreased further nor increased much in the last year.

According to FDA research (Levy et al., 2008), several safe food practices have increased in the United States over the last decade. Consumer knowledge about foodborne pathogens, high-risk foods, vulnerable populations, and safe food-handling practices has also increased in recent years, although this knowledge is sometimes incomplete or wrong (FSIS, 2002). On the other hand, despite increased self-reported use of safe food-handling practices, food preparers do not always follow these practices (Redmond and Griffith, 2003; Anderson et al., 2004; Howells et al., 2008; Abbot et al., 2009). The International Food Information Council found that for some practices, such as washing hands, the majority of those surveyed reported using them as a precaution. For other practices, the percentages of use reported were lower—for example, 50 and 25 percent, respectively, for using a different or freshly cleaned cutting board for each type of food and for using a food thermometer to check the doneness of meat and poultry

[17] Personal communication, Jean Kinsey, Director, The Food Industry Center, University of Minnesota, May 21, 2010.

items (IFIC, 2009). Other research shows that younger people in particular are increasingly ignorant of safe food-handling practices and foodborne illness (Byrd-Bredbenner et al., 2007a,b); young adults (aged 18–25) are the age group most likely to engage in risky food handling (Byrd-Bredbenner et al., 2007a,b).

Although these findings about precautionary behaviors are disappointing, they may reflect consumers' difficulty in understanding what to do. Once consumers become aware of the risk associated with particular food-handling and consumption behaviors (e.g., consuming certain raw foods), they may become concerned; however, they are unlikely to take protective action unless they see the risk as personal, know what to do to reduce the risk, and are confident that they can do it (Prochaska and Velicer, 1997; Prochaska et al., 2002; Brewer et al., 2004, 2007; Weinstein et al., 2007; Cuite et al., 2008). Social pressures and practices can also influence consumer behaviors (Cialdini and Goldstein, 2004; Cialdini, 2005, 2007; Abroms and Maibach, 2008).

Risk communications that build on empirical evidence of, and interactive exchanges about, consumer understanding and food risks and benefits can help consumers make informed decisions (Morgan et al., 2001; Bruhn, 2005; Fischhoff, 2009). In the United States, people currently learn about food safety from a variety of sources, ranging from social networks and television to specific government programs (Cuite et al., 2008; Hallman et al., 2009). Use of these sources varies by consumer circumstances. For example, in a 2008 study (Kwon et al., 2008), Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) recipients surveyed reported receiving food safety information from WIC (78.7 percent), family (63.1 percent), and television (60.7 percent). In a 2003 survey conducted in Lubbock, Texas (Whatley et al., 2005), family and friends were cited overwhelmingly as sources of food safety information. With respect to young adults, home economics classes are becoming increasingly rare (Beard, 1991); instead, young adults learn about food safety primarily from their parents, with very few (5 percent) reporting never learning about it (Byrd-Bredbenner et al., 2007a,b).

Certain groups—infants and children, pregnant women, and older persons—are deemed biologically and clinically more susceptible to food safety risks. This susceptibility stems in part from altered or adversely affected immune systems or chemical kinetics, the sensitivity of developing organ systems to toxicological insult, or the effects of age-related diseases, treatments, and declining physiological function (Kendall et al., 2006; Hayashi, 2009).

In addition, the United States is becoming increasingly diverse both culturally and ethnically, adding complexity to the food safety messages provided to the public. This increased diversity will likely have an impor-

tant impact on the risk of food safety incidents for several reasons. First, ethnic and cultural food preferences may affect the distribution of domestic food consumption, altering risks to consumers. For example, diets high or low in processed meats or raw vegetables may affect the general risks of foodborne illness associated with these food categories. Second, various groups may differ in socioeconomic status or access to different types of foods (French, 2003; Zenk et al., 2009), again altering food safety risks. Also, various ethnic groups may have special dietary traditions and recipes associated with altered risk because of either food content or special methods of preparation. For example, *Yersiniosis* infections associated with unsafe preparation of chitterlings in Georgia have been documented and addressed through communications (Georgia Division of Public Health, 1998). Likewise, the consumption of Mexican-style soft cheese resulted in *Listeriosis* infections among pregnant Hispanic women (MMWR, 2001). There have also been documented problems with contaminated food products in retail ethnic food establishments (Rudder, 2006). The special food safety issues associated with diverse ethnic and cultural food acquisition, preparation, and dietary practices have been only partially evaluated and deserve additional attention.

Health Professionals

From the FDA's perspective, both the public and clinical health professional communities are important audiences for food safety education and risk communication. This is especially true for specific subgroups, such as doctors, educators, media specialists, and others who either work with food safety or mediate risk communications with the public or other stakeholders. In addition to guidance for producers to minimize food contamination,[18,19] the FDA's website includes information for health professionals and educators on the latest advisories regarding pathogens and diagnoses of foodborne illness.[20] It also offers information designed to assist the states in laboratory analysis and inspectional procedures.[21] While state and local public health agencies conduct important food safety–related work, such as surveillance and testing, they often require information from other states

[18] See http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm (accessed October 8, 2010).

[19] See http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/default.htm (accessed October 8, 2010).

[20] See http://www.fda.gov/Food/ResourcesForYou/HealthCareProfessionals/default.htm (accessed October 8, 2010).

[21] See http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/default.htm (accessed October 8, 2010).

and the federal government to carry out this work, generating an important set of multidirectional communication needs (see Chapter 5). In addition, food safety–related programs and surveillance findings from state and local public health agencies—as well as those from federal agencies such as the FDA, USDA, and CDC—must be communicated clearly to the public.

Communicating with the clinical health community is also critical to maintaining food safety. Severe food-related adverse clinical events are almost always detected in the clinical care system. Such patients need to be identified, treated, and reported to public health agencies, again necessitating effective communication channels. In addition to this detection and surveillance role, the clinical care system plays a critical preventive role in food safety. Health professionals manage many patients with conditions that place them at increased risk of harm from tainted or contaminated foods, as well as patients who use special diets to control various chronic illnesses. In both of these cases, the FDA and other federal agencies have an important role in communicating about food-related risks to primary care, specialty, and dietetic professionals who specify diets for such patients.

MECHANISMS FOR EFFECTIVE INFORMATION EXCHANGE AND TRANSPARENCY

The FDA has available a number of mechanisms to enhance its food risk communication and education efforts. They include stakeholder involvement through formal partnerships, ad hoc public forums and consultations, and innovative interactive web tools.

An example of a formal partnership is the Partnership for Food Safety Education (PFSE), a nonprofit collaboration of industry, government, and consumer groups. PFSE launched its food safety initiative, Fight BAC!, under the Clinton Administration, but is no longer funded solely by the government. Its goal is to educate consumers about safe food-handling practices (PFSE, 2006). Another example of such a partnership is the International Food Protection Training Institute, which has the FDA as a partner and was established to deliver career-spanning training for state and local food protection professionals.

The FDA also has many partnerships with academic, domestic, and international organizations and governments through formal agreements (FDA, 2009m). As of 2004, there were more than 50 interagency agreements governing food safety (GAO, 2004a); in 2005, 71 such agreements were identified (GAO, 2005). The U.S. Government Accountability Office recommends that the FDA use these agreements to reduce spending on duplicate efforts and to share resources so as to stretch limited funds. Memorandums of understanding (MOUs) also exist between the FDA and universities for collaboration in the areas of education, research, and out-

reach. There are currently 12 such MOUs in effect, most of them between the FDA and one university.

In addition to those formal partnerships to facilitate communication, other means of collaborating would enhance the FDA's risk communication activities. Tabletop discussions,[22] public forums, and consultations with scientists and advocacy groups on critical decisions would enable the agency to anticipate new needs and reactions to new activities and adapt appropriately. The media, advocacy groups, and scientists should be essential partners in the agency's efforts to communicate with the public. However, the FDA's activities have been less than transparent to many parties over the last decade. Advocacy groups and others have been surprised by FDA actions that have at times been taken without consultation or communication with stakeholders, nor have they been full participants at media briefings.[23] One concern raised during an RCAC public meeting was the difficulty of obtaining timely information from the FDA. During the same meeting, according to journalist Kathryn Foxhall, the FDA was identified as among the most stringent agencies in applying permission-to-speak systems, which were implemented across the federal government more than a dozen years ago. All communications with reporters go through a public relations officer and may be subject to additional clearances. This process has been characterized as effectively destroying the relationship between the media and the agency. In Ms. Foxhall's words, "Agencies track, monitor, control, and chill our conversations with staff."[24] One way of learning about diverse needs is to talk to those in the mass media with special interests in food safety on a regular basis. Lacking good relationships with the press, the FDA is unlikely to gain the scientific and authoritative profile it needs to communicate effectively with the public.

As noted above, mechanisms for two-way communication with the public can lead to improved foodborne illness surveillance. Interactive websites can be used to collect information from the public as well as to present information, and they are increasingly used in government to gather both general and program- or product-specific feedback and suggestions. Communications with less conventional sources of information on food safety may be possible as part of an effective FDA-based communication program. For example, allowing members of the public to report putative outbreaks through a health professional (e.g., their primary physician) could serve as an early warning system for local, state, and federal agencies. Similar

[22] A tabletop discussion is a focused practice activity that places the participants in a simulated situation requiring them to function in the capacity that would be expected of them in a real event.

[23] Personal communication, Tony Corbo, Food and Water Watch, September 2009.

[24] Personal communication, Katherine Foxhall, FDA RCAC, Washington, DC/North Gaithersburg Hilton, February 28, 2008.

mechanisms, such as the Vaccine Adverse Event Reporting System (Chen et al., 1994) or the Consumer Complaint Monitoring System in USDA's Food Safety and Inspection Service (Dubrawski et al., 2006), have already been implemented in other venues. Such data cannot be taken at face value, but methods are being developed to take advantage of the information they provide (Dubrawski et al., 2006). Mechanisms for ongoing surveillance in health systems can be built into electronic health records (EHRs) so that suspected foodborne illnesses are reported. For example, it may be possible for EHRs to generate surveillance messages automatically based on specific clinical text, as well as to generate educational messages relevant to food safety for patients and clinicians when certain clinical situations arise. Communications with drug manufacturers could be another important source of surveillance through automated monitoring of prescriptions or sales of medications, such as antidiarrheal drugs. All of these approaches would require thorough research and demonstration, and in some cases legislative change, but their potential for enhancing food risk communications warrants the effort.

RESEARCH, EVALUATION, AND CONTINUOUS IMPROVEMENT

Given the importance of communications with stakeholders as one of the interventions in the FDA's tool kit of interventions, decisions about how to best provide these communications should be based on data collected (see also Chapters 3 and 5). Through research, the FDA estimates consumers' awareness, understanding, and reported behaviors related to food contaminants, such as methyl mercury, *Salmonella*, pathogenic *Escherichia coli*, and *Listeria monocytogenes*. These results are used to inform and evaluate the FDA's policies and rules as well as its public information and educational outreach on safe food handling and preparation. The FDA's typical research methods are both quantitative (surveys, experiments) and qualitative (focus groups, interviews, mental modeling).

Research can also help target messages that are more effective at reaching different cultural and ethnic groups, people with varying levels of education or language skills, and other subpopulations. Media segmentation and multimodal strategies may help reach more people than conventional methods. New social media marketing and viral marketing approaches may enhance the value of the FDA's communication efforts (Gosselin and Poitras, 2008). The Consumer Studies Team at CFSAN helps set program priorities and informs communications within CFSAN and across the FDA and other agencies (e.g., the Federal Trade Commission, the U.S. Environmental Protection Agency, USDA, and CDC). As of February 2008, the team included eight social scientists from a variety of disciplines conduct-

ing both survey and experimental research.[25] The team members typically design all of their own research protocols, perform their own data analyses, and use an extramural contractor for field service.

Recognizing that the FDA is not a research institution, there is nevertheless a need to reorient its activities so that empirical evidence from research constitutes the basis for its interventions (see Chapter 6). While the deficiencies of the FDA's risk communication research have been noted (e.g., IOM, 2007), the creation and recent activities of the RCAC and the internal Communications Committee are promising developments that may enhance the agency's research efforts in this critical area. In its May 6–7, 2010, meeting with the RCAC, which focused on research, the FDA reported that a research priority list was being developed with previous input from the RCAC.

An effective food safety system requires dedicated funding for behavioral and social science research on food safety risk communication and education, as well as a capacity to conduct this research. As noted in Chapter 3, academic programs generally do not offer adequate training and education in risk analysis disciplines, including risk communication. In particular, there is value in evaluating the role of past communication techniques in crisis situations, such as during the outbreaks related to peppers and peanuts (Cuite et al., 2005). Retrospective review using both formative and summative approaches can make subsequent communication programs more effective. Moreover, social and behavioral science research on the food safety knowledge and patient advice practices of public health professions should drive the FDA's educational activities targeted to those groups. Surveillance of food industry knowledge and practices can also identify the educational needs of those stakeholders. The committee did not receive sufficient information from the FDA to evaluate the research capacity in social and behavioral sciences pertaining to risk communication in the food safety area.

One potential avenue for educating consumers and promoting safe food handling, for which further research on effectiveness is needed, is labeling of food products with respect to safety. In the United States, some laws or regulations mandate safety information on food labels. For example, raw or partially cooked meat and poultry products must contain information on cooking, storage, and handling. Also, U.S. law requires that eight food allergens be identified in plain English on all food labels, although it does not require any advisories. Otherwise, food producers and retailers are under no obligation to use food labels that contain food safety advice, and they are often reluctant to do so. There are likely many reasons for this, including the large amount of information that might be placed in the lim-

[25] Personal communication, Steven Bradbard, FDA RCAC, Washington DC/North Gaithersburg Hilton, February 28, 2008.

ited space on labels (e.g., nutritional content, source content, traceability of sources, eco-friendly procedures, techniques of manufacture, suggested recipes) and the difficulty of communicating risk in such a small space, including warnings about special high-risk groups (e.g., *Listeriosis* among pregnant women) (Caswell, 2006). It is also likely that food manufacturers do not want to deter food purchasers by implying that their product is categorically unsafe.

Current food safety–related label messages that appear to be simple and straightforward are actually unregulated by the FDA and may be subject to varied interpretation; an example is "sell by" or "best if used by" on date labels. In focus groups, messages such as the product contains "antilisterial" agents were not well received (Lenhart et al., 2008) and perhaps not fully understood. Similar issues may exist in labeling for potential food allergens, where different messages ("may contain," "shared equipment," "same plant") may be correct but do not convey information that is helpful in interpreting risk and promoting appropriate behavior (Pieretti et al., 2009). It is likely that underlying some of these problems of effective labeling is the challenge of communicating risk and appropriate responses in a way that effectively guides healthful attitudes and behaviors. The FDA should develop and sustain a label research program to inform the design of safety labels that effectively communicate and enhance safe food-handling behaviors among consumers. When a suitable body of evidence is available, regulations for mandatory safety messages on food products should be considered.

A Slow Process for Research Approval and Funding

Information sharing is a critical policy tool (OTA, 1995) that, to be effective, can require audience-based assessments and product evaluations (e.g., Schriver, 1989, 1996; Roth et al., 1990). Implementation of the FDA's social science research agenda can be slowed by many factors, some of which are common to any research agenda, such as the sensitive nature of new research and emerging topics, collaboration with others, funding cycles and budgets, and standard operating procedures for review and clearance at the level of the center, agency, and department. Another factor recognized by the RCAC to be a barrier to the FDA's ability to conduct communication-related research in a timely and scientifically sound manner is the current interpretation of the Paperwork Reduction Act (PRA) of 1990.[26] The act stipulates that agencies must seek public comment (through 60-day notices in the *Federal Register*) on proposed research involving the

[26] *Paperwork Reduction and Federal Information Resources Management Act of 1990*, 101st Cong.

collection of information and receive clearance from the Office of Management and Budget (OMB) if ten or more subjects are involved in such research. The agency publishes its response to public comments in a 30-day *Federal Register* notice, which reopens the docket for an additional public comment period. When this comment period closes, the agency again reviews comments, provides OMB with written responses, and addresses any remaining OMB concerns. Negotiations between OMB and the FDA, possibly including changes in the research plan and/or the instruments, may take as long as 7 or 8 months before OMB approval. Exceptions to standard PRA requirements are made for focus groups and interviews, rapid response surveys, and 30-day emergency OMB approval. In an effort to find a solution to these delays, the RCAC recommended that the FDA identify the public welfare implications of *not* testing its communications. The RCAC also recommended that the FDA submit a proposal to OMB for a protocol for evaluating food safety communication research that would balance the public welfare needs associated with the FDA's mandate and the requirements of PRA (FDA, 2009e).

Concurrently with this review by OMB, the Research Involving Human Subjects Committee (RIHSC) (the FDA's Institutional Review Board [IRB]) is tasked with reviewing all studies using human subjects. Every FDA center has an RIHSC liaison who reviews materials submitted in support of such research. Most social science research involving adults is considered exempt from full review unless it uses high-risk populations and/or studies highly sensitive topics. Nevertheless, even partial reviews, required under 45 Code of Federal Regulations (CFR) 46.101, can delay research projects.

Nationally, social and behavioral research conducted in pursuit of better communication, education, or policies continues to be impeded, and in some cases discouraged, by unnecessarily restrictive and intrusive human subjects review procedures developed for biomedical research (Schrag, 2009). In a 2006 study of the effectiveness of IRBs, "removing or reducing scrutiny of many fields within the social sciences and humanities that pose minimal risk" is a key recommendation (Gunsalus et al., 2007, p. 3). While OMB review may be the more onerous of the reviews to which FDA consumer studies are subjected, there is evidence that IRB reviews hamper and discourage such research as well. As an example, the FDA often uses its own workforce as surrogate groups representing public responses, which is a less than ideal subject sample. Given that such research does not collect sensitive personal information, is not overly intrusive, and likely contributes to more effective communications and warnings and therefore to public protection, consideration should be given to reducing or eliminating human subjects–related review requirements under 45 CFR 46.101 for social science research—in particular, research on perceptions and communications that meets appropriate confidentiality standards. A

recent study at the University of Michigan characterizes "the tenor of the national conversation regarding the system for protecting human subjects from harm" as follows: "Regulations and policies are often narrowly and conservatively interpreted; terms and definitions are not clearly defined; the system is burdened with documentation requirements; and there is a paucity of empirical evidence to guide ethical decision making" (Pennell et al., 2008, p. vii). The need for OMB and IRB reviews may also be discouraging the FDA from conducting surveys or other data collection efforts that are more representative than focus groups.

Risk Communication Capacity

Effective risk communication programs require understanding public responses to messages, targeting the correct audiences, developing technologies and partnerships to reach targeted groups, and being familiar with information networks (NIH, 2008). As is the case for any federal agency with a public health mandate, the FDA cannot communicate successfully without interaction and advice, and it needs to build its internal capacity to design and evaluate risk communications. Capacity for effective communication is a function of organizational structure as well as human and technological resources. While the Consumer Studies Team at the FDA focuses on consumer studies, its emphasis with regard to food-related research is primarily on nutrition labeling, and its ability to conduct research is currently limited.[27]

With a small social science research group, significant research clearance requirements, and resource barriers to conducting empirical evaluations and research studies, the FDA has faced an uphill battle in developing its food safety education and risk communication efforts. Recent regulatory and organizational changes have improved the prospects for addressing these barriers, but much remains to be done to make the FDA a trusted and authoritative resource for food safety information so it can meet its food safety communication responsibilities effectively.

KEY CONCLUSIONS AND RECOMMENDATIONS

The RCAC, established in 2008, and the 2009 risk communication strategic planning are positive initiatives that will help the FDA improve its risk communication efforts. Although the FDA is on a path toward developing critical risk communication capacity, effective implementation of its risk communication strategic plan will require integrating such communication

[27] Personal communication, Donald Zink, Senior Science Advisor, FDA/CFSAN, September 25, 2009.

into an overarching risk-based management strategy. For example, elements of the strategic plan, such as determining criteria for communicating risk information in areas of high public health impact, require a clearly articulated approach that is embraced throughout the agency. In an era of instantaneous communications and multiple media, transparency in communications about food safety issues is essential.

Many partners, including regulatory agencies, provide food safety education to the public in various formats; that is, there is no single, authoritative voice on food safety in the United States. This is of concern especially for communications in times of crises, such as national outbreaks, which demand a coordinated and centrally controlled plan. While the FDA, with other federal agencies, has established foodsafety.gov, a website intended to better provide food safety information to the public, enhancements to this gateway are needed. Likewise, many partners (e.g., trade organizations, Cooperative Extension Services at universities) are engaged in training industry in food safety, but coordination, research, and evaluation of these efforts are essential and appear to be lacking. Standardized food safety training and education for public health officials in state and local (including territorial and tribal) governments do not exist and are currently not being investigated or evaluated. While the FDA has many communication-related partnering arrangements in place, there is room for creative progress to take advantage of new information and communication technologies.

For the FDA to improve its food safety messages, scientific evaluation of risk communication as part of an overall social science research portfolio is essential. The results of such research make it possible to understand consumers' knowledge, perceptions, and behaviors, including those of populations with heightened vulnerability to food hazards. Whether the research is extramural or intramural, obtaining approval and funding for a human subjects study currently requires a long, stringent process. Because risk communication studies are often time sensitive, this lengthy approval process deters investigators from conducting valuable research on food safety messages. Surveillance of those who may contribute to providing protection from foodborne illness, such as public health professionals and industry personnel, can also help in the FDA's selection of communication interventions.

The committee recommends that the FDA continue to respond to the advice of the RCAC and offers the following recommendations to enhance the FDA's risk communication and education functions.

Recommendation 9-1: In its effort to integrate risk communication into the recommended risk-based food safety management system, the FDA should play a leadership role in coordinating the education of the food industry, the public, clinical health professionals, and public

health officials at all government levels. The FDA could carry out its leadership role in educating industry personnel, health professionals, and public health officials by seeking authority to mandate the setting of training standards, preparing training materials, certifying trainers, and providing technical support for the interpretation of policies and for the implementation of the risk-based approach.

Recommendation 9-2: In collaboration with other federal agencies, the FDA should continue efforts to develop a single source of authoritative information on food safety practices, foodborne illness and risks, and crisis communications. The FDA, with other federal agencies, should develop a coordinated plan for communicating in one voice with all affected parties during crises so that stakeholders receive timely, clear, and accurate information from a single recognizable source.

To enhance these communication efforts, reducing barriers to and conducting more consumer research will be essential. To this end, the committee makes the following recommendation.

Recommendation 9-3: The FDA should improve its understanding of the knowledge and behavior of industry, health professions personnel, and consumers with respect to food safety, paying specific attention to knowledge about demographic groups that are particularly susceptible to food risks.

In making critical decisions about risk communication to implement recommendations 9-1, 9-2, and 9-3, the FDA should explore new mechanisms (e.g., tabletop discussions, public forums, consultations) for expanding its use of strategic partnerships and collaborations.

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10

Modernizing Legislation to Enhance the U.S. Food Safety System

In the 1906 Pure Food and Drugs Act, for the first time Congress prohibited interstate commerce in "adulterated" food, which included, among other things, food "contain[ing] any added poisonous or other added deleterious ingredient which may render such article injurious to health" and food "consist[ing] in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance."[1] The government could enforce these and all other provisions of the 1906 act through the collection and examination of specimens, criminal prosecution, the seizure and condemnation of violative articles, and the sampling and exclusion of imported goods.[2]

In 1938, Congress repealed the 1906 act and replaced it with the Federal Food, Drug, and Cosmetic Act (FDCA), which, as amended, is still in effect today.[3] While preserving, with a few minor changes, the 1906 adulteration provisions quoted above,[4] the 1938 act enhanced the U.S. Food and Drug Administration's (FDA's) food safety authority in various significant ways, including (1) a provision defining a food as adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health"; (2) a section empowering the FDA to establish an emergency permit system for food contaminated with microorganisms; and (3) a section providing for the establishment of tolerances for unavoid-

[1] *Federal Food and Drugs Act of 1906*, Sec. 7.
[2] *Federal Food and Drugs Act of 1906*, Sec. 2, 3, 10, 11.
[3] *Federal Food, Drug, and Cosmetic Act (FDCA)*, 21 U.S.C. §§ 301 et seq., 1938.
[4] FDCA 402(a)(1), (3).

able poisonous and deleterious substances.[5] In addition, for food and all other regulated products, the 1938 FDCA added injunction proceedings and mandatory establishment inspection to the enforcement tools included in the 1906 act.[6]

Since 1938, Congress has occasionally amended the FDCA to further enhance the FDA's power to accomplish its food safety mission. Notable examples of these amendments include the Food Additives Amendments of 1958, creating a premarket approval system for food additives; the Color Additives Amendments of 1960, creating a premarket approval system for color additives; and the Animal Drugs Amendments of 1968, creating a unified scheme for all aspects of animal drug regulation, including ensuring the safety of animal drug residues in food.[7] More recently, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)[8] strengthened the food safety provisions of the FDCA by, among other things, (1) authorizing the FDA to administratively detain food for which there is "credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals,"[9] (2) mandating the registration of food facilities,[10] (3) giving the FDA access to industry records related to food that "presents a threat of serious adverse health consequences or death to humans or animals,"[11] (4) empowering the FDA to require the maintenance of records needed by the agency "to identify the immediate previous sources and the immediate subsequent recipients of food,"[12] and (5) requiring prior notice of imported food shipments. Finally, in 2007 Congress added a new section to the FDCA (the Food and Drug Administration Amendments Act of 2007) requiring the FDA to establish a Reportable Food Registry for the reporting of instances in which there is a "reasonable probability that the use of, or exposure to, [a] food will cause serious adverse health consequences or death to humans or animals."[13]

Nevertheless, in some other fundamental respects, the law under which

[5] FDCA 402(a)(4), 404, 406.

[6] FDCA 302, 704.

[7] *Food Additives Amendment*, 72 Stat. 1784 (1958); *Color Additive Amendments*, 74 Stat. 397 (1960); *Animal Drug Amendments*, 82 Stat. 342 (1968).

[8] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)*, HR 3448, 107th Cong, 2nd sess. (FDCA 801(m)).

[9] FDCA 304(h).

[10] FDCA 415.

[11] FDCA 414(a).

[12] FDCA 414(b).

[13] FDCA 417.

the FDA must ensure the safety of 80 percent of Americans' food supply[14] remains unchanged since 1938, despite the dramatic changes in food production and distribution patterns that have taken place since (see Chapter 2). For example, the provisions of the FDCA that the agency invokes most often in attempting to prevent and address the pathogenic infection of food read exactly the same as they did 72 years ago.[15]

The FDA needs to have the power to fulfill its food safety mission in the face of an increasingly complex and global food supply. In this chapter, the committee recommends some important legislative changes to this end. As shown by the length of the food safety bills currently under consideration in Congress, this chapter cannot address every area in which statutory amendments may be warranted; instead, it highlights those the committee deems most critical. For example, this chapter does not address authorities, such as embargo power[16] and civil monetary penalties, that might be helpful but less essential to ensure public health than the ones discussed below. Furthermore, this chapter does not consider how much money Congress should appropriate for the FDA's food safety activities or what funding mechanisms the agency should use. Although the committee supports increasing funding for the FDA to the extent necessary to implement the recommendations contained in this report, it is also firmly convinced that simply putting more money into the food safety system as it is currently constituted, without essential reforms, would be insufficient from a public health perspective and an inefficient expenditure of resources.

Finally, the legislative recommendations in this chapter are not intended to suggest that the FDA does not already have the authority in question under current law. Various existing statutory provisions give the agency broad discretion and flexibility that might encompass the powers discussed herein. There are instances in which a specific authority has not been explicitly given to the FDA, so that legal interpretations might result in differences in opinion that would raise controversy among stakeholders. In these cases, the committee concluded that it would be helpful to provide such authorities to the FDA explicitly. For example, the committee recommends giving the FDA explicit authority to mandate that food facilities establish preventive process controls, maintain records, and provide the agency with access to these records during inspections. Yet even without such explicit statutory authority, the FDA has promulgated Hazard Analysis and Criti-

[14] The term "food," as defined in the FDCA, includes "all articles used for food or drink for man or other animals" and thus encompasses what is commonly known animal "feed." Throughout this chapter, therefore, as throughout the rest of the report, the word "food" includes animal feed unless otherwise noted.

[15] See FDCA 402(a)(1), (3), (4) (*Adulterated Food*); 404 (*Emergency Permit Control*).

[16] As discussed later in the chapter, the committee does recommend that the FDA be given the power to issue cease distribution orders as part of a broader mandatory recall authority.

cal Control Points (HACCP) regulations that impose such requirements on seafood and juice processors. The agency issued both of these rules pursuant to section 701(a) of the FDCA (21 U.S.C. 371(a)), which gives the FDA broad "authority to promulgate regulations for the efficient enforcement of this Act." For the juice HACCP rule, the agency also relied in part on section 361 of the Public Health Service Act (42 U.S.C. 264), under which the FDA commissioner has been delegated power to "make and enforce such regulations as in [her] judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession" (HHS/FDA, 1995, 2001).[17]

The seafood and juice HACCP rules have not been challenged in court as unreasonable interpretations of the statutes, and the rules might well survive such challenges if they arose. Nonetheless, the FDA should be able to impose preventive controls based on hazard analysis and risk, as defined in Chapter 3, on all food facilities—and to exercise the other powers enumerated below—free of any doubt that it has the authority do so. The agency is prone to hesitate before pursuing measures based on broad delegations of authority rather than detailed statutory provisions, and agency actions taken pursuant to such broad delegations are more vulnerable to court challenge. Hence, the committee believes it is important to revise the FDCA to expressly provide the FDA with explicit authorities in the areas of facility registration, preventive controls, performance standards, risk-based inspection, access to records, traceability, mandatory recall, reporting of adulteration, and banning of all food imports from a country if a review of its food safety system indicates that the public health is at risk.

FACILITY REGISTRATION

The FDA cannot have an adequate food safety program unless it knows exactly where food is being produced, processed, packed, and held. Section 415 of the FDCA, "Registration of Food Facilities," currently requires food facilities, both domestic and foreign, to register with the FDA. Although the act requires registrants to notify the agency of changes in the submitted information, it does not mandate regular reregistration in the absence of such changes. Moreover, it does not provide for the suspension of the registration of a facility that has committed violations that threaten the public health. The act needs to be amended to include mandatory periodic reregistration and, with adequate procedural protections, FDA authority to suspend registrations.

The FDCA's definition of a "facility" subject to the registration require-

[17] 42 U.S.C. 264 sec. 361.

ment is limited to "any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food."[18] Many food importers, however, never physically possess the food they import and thus fall outside this definition. To enhance the FDA's ability to trace and apply the act to imported foods, the definition of "facility" should be amended to embrace entities in the business of importing foods from foreign countries even if these entities do not "manufacture, process, pack, or hold" the foods (see Appendix E).

Section 415 of the act also explicitly exempts farms, restaurants, and other retail food establishments from the definition of "facility" and thus from the current registration requirement. The committee believes that, to enhance the agency's ability to trace food along its entire production and distribution chain, all domestic farms, restaurants, and other food service and retail food establishments ought to be required to register with the FDA. This is not to say that such establishments should be subject to the same panoply of requirements as, for example, food factories and warehouses. Congress might sensibly decide to exempt farms, restaurants, and other food service and retail food establishments from requirements other than registration imposed on all "food facilities." Therefore, the goal of universal registration should probably not be achieved by simply amending the definition of "facility" in section 415(b)(1) to delete the exception for farms, restaurants, and retail establishments.

PREVENTIVE CONTROLS

As demonstrated by its promulgation of the seafood and juice HACCP rules, the FDA has found authority under current law to impose preventive process control regimes on food facilities. Nonetheless, the FDCA needs to be amended not only to make this authority explicit, but also to mandate that all registered food facilities have such controls in place. Every food facility ought to be required to conduct a hazard evaluation, identify potential hazards, implement preventive controls, monitor the controls, establish corrective actions, and maintain comprehensive records of the system's implementation. Each facility should also be required to prepare a food safety plan that sets forth the hazard evaluation results, the identified preventive controls, and the facility's program for monitoring the preventive controls, validating them, taking corrective action, and keeping records. In addition, the act needs to specify that the food safety plan and the implementation records must be made available to FDA inspectors. Finally, the act should state that if a facility fails to satisfy these requirements for preventive controls based on hazard analysis and risk, any food produced,

[18] FDCA 415(b)(1).

processed, packed, or held in that facility is considered adulterated under section 402 of the act.

The committee discussed the possibility of recommending mandatory testing for pathogens. However, it concluded that the FDA should address this complex issue on a case-by-case basis, pursuant to the overall risk-based food safety management approach proposed in this report.

PERFORMANCE STANDARDS

The FDCA needs to be amended to require the FDA to periodically issue enforceable, risk- and science-based performance standards for pathogens and other contaminants significant to public health. The agency should be required to use a risk-ranking approach to prioritize the development and issuance of those standards.

RISK-BASED INSPECTION

A process for making decisions about what, when, and how to inspect is essential for an efficient food safety system. In Chapter 3, the committee recommends that the FDA use a risk-based approach to make decisions and allocate resources. In Chapter 8, the committee specifically calls for a review and update of FDA inspection processes so they are consistent with a risk-based approach. Although the FDA is already thinking through its decision-making process for the conduct of inspectional activities, the committee concluded that this is one key area that requires a congressional mandate.

The FDCA needs to be amended to require the FDA to adopt a risk-based approach to both the frequency and intensity of inspections. The committee also believes, however, that the law should establish minimum standards for the frequency and intensity of inspection of all food facilities, regardless of their risk ranking. Moreover, the committee believes it is important to maintain some element of randomness in the scheduling and targeting of inspections.

ACCESS TO RECORDS

The FDCA as currently written expressly authorizes the FDA to demand access to only four categories of records relating to food: (1) those showing

the movement of food in interstate commerce kept by shippers/carriers and by recipients of interstate shipments,[19] (2) those kept pursuant to FDA regulations by shippers/carriers regarding sanitary transportation practices,[20] (3) those relating to infant formula,[21] and (4) those needed to determine whether a food is adulterated and presents a threat of serious adverse health consequences or death.[22] The agency has access to documents under the fourth provision, added by the Bioterrorism Act of 2002, only if it has a "reasonable belief" that the food is adulterated and presents a threat of serious health consequences or death.[23]

In contrast, with respect to prescription drugs, nonprescription drugs intended for human use, and restricted devices, the FDCA provides the FDA with broad access to records bearing on whether the products are adulterated, misbranded, or otherwise in violation of the act. The committee believes that Congress needs to give the FDA similarly broad access to records in food facilities. As explained above, the effective enforcement of a food safety system based on preventive controls depends on the FDA's having access to each facility's food safety plan and implementation records. But in light of the fact that other categories of documents may also bear on food safety, the FDA's access should not be limited to preventive control documents.

TRACEABILITY

Section 414(b) of the FDCA, added by the Bioterrorism Act of 2002, authorizes the FDA to issue regulations requiring food facilities, excluding farms and restaurants, to establish and maintain "records . . . needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food . . . in order to address credible threats of serious adverse health consequences or death to humans or animals."[23] Such regulations cannot require that facilities maintain those records for longer than 2 years. The agency issued such regulations in 2004.[24] These regulations, in accordance with the statute, exempt farms and restaurants from all the requirements, and they also exempt entities that sell directly to consumers from the requirement to identify subsequent recipients. The FDA has access to these records under the same standard applicable to all records sought under

[19] FDCA 703(a).
[20] FDCA 703(b).
[21] FDCA 704(a)(3).
[22] FDCA 414(a). This category was added by the *Bioterrorism Act of 2002*.
[23] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)*.
[24] 21 CFR 1.326-1.368.

the Bioterrorism Act; the agency must have a "reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals."[25] The committee believes that the FDCA needs to be amended to require farms to maintain records identifying immediate subsequent recipients, other than individual consumers, and restaurants to maintain records identifying immediate previous sources.

MANDATORY RECALL

When confronting a food safety emergency, the FDA can often depend on state governments to use their embargo authority to stop the distribution and sale of the adulterated food. Moreover, section 304(h)(1)(A) of the FDCA gives the FDA itself the power to administratively detain any article of food if an officer or qualified employee of the agency "has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals."[26] However, the FDA does not currently have explicit authority to mandate a recall of the products it regulates, with the exception of infant formula, medical devices, and biological products.

In communications with the committee, the FDA maintained that it should be given the power to order a company to recall an adulterated food when necessary to protect the public health. The bills currently under consideration in Congress give the FDA the power, subject to specified procedures, to issue a cease distribution order and a subsequent recall order when there is a reasonable probability that a food will cause serious adverse health consequences or death.[27]

In most instances, the FDA does not need mandatory recall authority to fulfill its food safety mission. The agency has developed a sophisticated and highly successful "voluntary recall" process with respect to food as well as all other products it regulates (Title 21 CFR—"Food and Drugs," Subpart J, "Establishment, Maintenance, and Availability of Records," 2004; Degnan, 2006, pp. 107–113). Food companies almost always cooperate with FDA-requested recalls, and even when companies resist, the agency

[25] 21 CFR 1.361.

[26] A detention order may be issued by an "officer or qualified employee" of the FDA, but such order must be approved by the commissioner or by an official designated by the commissioner who ranks no lower than district director (FDCA 304(h)(1)). A claimant for a detained article may appeal the detention order, and the commissioner must, after providing an opportunity for an informal hearing, confirm or terminate the order within 5 days of when the appeal is filed (FDCA 304(h)(4)(A)).

[27] HR759, *Food and Drug Administration Globalization Act of 2009*; S510 IS, *FDA Food Safety Modernization Act of 2009*.

can usually induce cooperation through the threat of negative publicity. Indeed, the voluntary recall process is normally so efficacious that the FDA rarely uses its mandatory authority even in those areas in which it possesses such authority. For example, although the FDA has had mandatory recall authority over medical devices since 1990, the committee learned that the agency has invoked this power only ten times, and never since 1994.[28]

Nonetheless, the committee concludes that there may be rare circumstances, involving uncooperative food distributors, in which the FDA needs the power to formally order a party to cease distribution of an article of food and recall it. Congress thus needs to amend the statute to provide the FDA with such authority with respect to foods that are adulterated under section 402 of the FDCA and may cause serious health consequences or death. To ensure that the existence of mandatory recall authority does not undermine the carefully honed and highly effective voluntary system already in place, Congress should require the FDA to always provide the party in question an opportunity to cease distribution and recall an article voluntarily (according to terms prescribed by the agency) before it issues an order. If the party refuses to proceed voluntarily, the FDA should then have the power to order the party to cease distribution immediately, but the party should, except in instances of imminent danger, be given an opportunity for an expeditious informal hearing before the FDA modifies the order to mandate recall.

REPORTING OF ADULTERATION

In 2007, Congress amended the FDCA to require all registered food facilities to report to the FDA, through an electronic portal into a Reportable Food Registry, any "article of food . . . for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals."[29] While the committee supports the concept of this registry, it is concerned that the mandatory reporting requirement may lead to a reduction in testing by food facilities reluctant to report any problems they may find. Section 417(d)(2) exempts from the reporting requirement any party that detects the adulteration prior to the transfer of the food to another party and corrects the adulteration or destroys the food. The committee believes this safe harbor ought to be extended to parties that detect adulteration even after transfer of the food to an immediately subsequent party as long

[28] Personal communication, Joanna Weitershausen, Center for Devices and Radiological Health, FDA, September 30, 2009.

[29] FDCA 417.

as the responsible party corrects the adulteration (or causes it to be corrected) or destroys the food (or causes it to be destroyed).

AUTHORITY TO BAN ALL FOOD IMPORTS FROM A COUNTRY

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) administers the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act (FSIS/USDA, 2009a). Pursuant to these statutes and implementing regulations, FSIS permits imports of meat, poultry, and egg products only from countries it has certified as having inspection systems that ensure that exported food products meet American food safety standards.[30] FSIS makes the determination that a country's food regulatory system provides food safety protections equivalent to those provided by U.S. domestic regulatory programs (and thus that the country is eligible to export meat, poultry, or egg products) based on document reviews, on-site audits, and port-of-entry reinspection (FSIS/USDA, 2009b).

The FDCA does not require the FDA to make a similar country-by-country equivalence determination, and the committee does not believe that such an approach would be practicable for the agency, which has jurisdiction over a much more global and diverse imported food supply relative to FSIS. Nonetheless, in administering a risk-based food safety system, the FDA might decide to review the regulatory systems of some or all of the nations that export food to the United States. In addition, the agency might conclude, based on a comprehensive risk assessment, that a particular country's food safety regulatory system is so inadequate that all food imports from that country should be banned. The FDCA needs to be amended to empower the FDA to ban all food imports from a country if the agency concludes, in light of a review of that country's food safety regulatory system, that such a measure is necessary to protect the public health. The committee also concluded that, rather than dramatically increasing inspectors in foreign countries, the FDA should use a risk-based approach to prioritize inspections at the border (see Chapter 3).

KEY CONCLUSIONS AND RECOMMENDATIONS

The FDA bears responsibility for ensuring the safety of 80 percent of the nation's food supply. Despite the dramatic developments in food production and distribution that have occurred since the 1938 enactment of the FDCA, the main statutory provisions under which the agency carries out its food safety mission remain largely unchanged. These provisions are broad

[30] See Title 9 CFR 327.2 (meat), 381.196 (poultry), 590.910 (egg products).

delegations of power rather than detailed grants of authority. The agency is often reluctant to take action without an explicit mandate to do so, and those actions it does take in the absence of express statutory authorization are vulnerable to court challenge. Therefore, the committee believes the FDCA needs to be revised to detail the FDA's authorities in the areas of facility registration, preventive controls, performance standards, risk-based inspection, access to records, traceability, mandatory recall, reporting of adulteration, and banning of all food imports from a country if a review of its food safety system indicates that the public health is at risk.

Recommendation 10-1: Congress should consider amending the FDCA to provide explicitly and in detail the authorities the FDA needs to fulfill its food safety mission. The following are the most critical areas in which Congress should enact amendments: mandatory reregistration of food facilities and FDA authority to suspend registrations for violations that threaten the public health, mandatory preventive controls for all food facilities, FDA authority to issue enforceable performance standards, mandatory adoption by the FDA of a risk-based approach to inspection frequency and intensity, expansion of the FDA's access to records, FDA authority to mandate recalls, and FDA authority to identify countries with inadequate food safety systems and to ban all imports from such countries.

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11

Achieving the Vision of an Efficient Risk-Based Food Safety System

Preceding chapters have presented a variety of recommendations aimed at improving the U.S. Food and Drug Administration's (FDA's) food safety–related activities. Box 11-1 lists some of the areas in which the committee found that significant improvements are warranted. In formulating its recommendations, the committee emphasized the need for the FDA to move toward a risk-based approach to food safety. Recognizing that many enhancements (e.g., leadership commitment, staff retention, strategic planning) can be realized without structural changes, the committee initially formulated its recommendations in the context of the FDA's current food safety management structure. Subsequently, however, the committee concluded that while some recommendations pertain only to the FDA's functions and operations, success in implementing many others will be achieved only through cooperation with partners that play important roles in maintaining food safety. As the study progressed and the committee's ideas matured, it became clear that the effectiveness of the FDA's food safety programs will not be fully realized without organizational changes both in the structure of the agency itself and across the multiple government agencies and departments with food safety responsibilities.

Such changes will not occur without strong leadership with a clear vision for reform and the capacity (i.e., resources) and authority to implement the changes effectively. Leadership should direct change and be authorized to redirect resources and bring in new personnel with the appropriate expertise. The agency leaders with responsibility for implementing the changes must also have the appropriate support at high levels of governmental oversight. At the same time, not just high-level management but also

BOX 11-1
Selected Proposed Improvements in the U.S. Food and Drug Administration's (FDA's) Food Safety Management Highlighted Throughout This Report

- Apply the recommended risk-based approach to the management of all domestic and imported foods and hazards, whether derived from food or animal feed or from intentional (i.e., with the intent to harm) or inadvertent contamination (Chapter 3).
- Address the lack of resources (e.g., data infrastructure, human capacity) and organization for the implementation of a risk-based food safety management system. Access to appropriate resources (personnel, data, models) in support of this effort is central to the success of the FDA's future food safety risk management activities (Chapter 3).
- Identify metrics with which to measure the effectiveness of intervention strategies and the food safety system as a whole (Chapter 3).
- Define the roles of the various parties sharing responsibility for food safety, and develop a road map with defined criteria for food safety governance, that is, the level and intensity of policy interventions and plans to evaluate them (Chapter 4).
- Develop a strategic plan to identify data needs for a risk-based approach, and establish mechanisms to coordinate, capture, and integrate the data (Chapter 5). This includes data collected by state and local (including tribal and territorial) governments (Chapter 7), field personnel (Chapter 5), and the food industry (Chapter 5).
- Remove barriers to the practical utilization of data to support a risk-based system, including problems with data sharing and gaps in analytical expertise within the FDA (Chapter 5).

the entire team tasked with facilitating agency changes must have the necessary vision, understanding, and experience to implement those changes. Further, since many FDA food safety activities are inextricably linked to those of other agencies with food safety jurisdiction (federal, state, and local) (see Table 2-1 in Chapter 2), coordination and collaboration with these agencies will be essential. As discussed in Chapter 3, moreover, change cannot occur without careful prior planning and substantial investments in physical, human, and financial resources. Finally, the need for strong leadership implies that appropriate legislative authority must be given to the agency (see Chapter 10).

- Conduct strategic planning and coordination of the FDA's food safety research portfolio, keeping in mind the need to partner with other groups in carrying out the agency's research function, including the value of funding mechanisms to facilitate cooperative research between the FDA and external entities (Chapter 6).
- Integrate state and local food safety programs with the ultimate goal of making these food surveillance, inspectional, and analytical systems full partners in the national food safety program (Chapter 7).
- Address the existence of barriers to improving the efficiency of inspections, such as the fact that the FDA's food programs do not have direct authority over the work of inspectors, resulting in substantial delays in policy implementation in the field, the inefficiency of inspection procedures, and underutilization of other sources of information, such as state inspections (Chapter 8).
- Continue development of a single source of authoritative government information on food safety, safe food practices, foodborne illnesses and risks, and crisis communications (Chapter 9).
- Create a coordinated and centrally controlled plan for communicating with one voice with all affected parties during food safety crises, including coordination of recalls, so that all constituents (producers, distributors, retailers, and consumers) receive timely and reliable information (Chapter 9).
- Modernize the legislative framework to give the FDA the necessary legal authority to perform its role in ensuring and enhancing the safety of FDA-regulated foods (Chapter 10).

For more than a decade, various organizations, consumer groups, and individuals have recommended organizational changes in the U.S. food safety system, with the goal of increasing its efficiency and enhancing the public health (IOM/NRC, 1998; GAO, 2004, 2005a, 2007, 2008; Gombas, 2009; Halloran, 2009; IOM, 2009; Plunkett, 2009; Scott, 2009; Waldrop, 2009).[1] Furthermore, governments in other countries

[1] Gaps in Food Safety Illustrated by the Peanut Products Outbreak, Testimony before the Senate Committee on Agriculture, Nutrition, and Forestry, Washington, DC, February 5, 2009.

have reorganized and adapted their food safety systems to reflect current circumstances (GAO, 2005b). More recently, in congressional testimony on federal oversight of food safety and the FDA's Food Protection Plan (FPP), Lisa Shames, the U.S. Government Accountability Office's director of natural resources and environment (GAO, 2008), stated that:

> it is important to note that FDA is one of 15 federal agencies that collectively administer at least 30 laws related to food safety. This fragmentation is a key reason we designated federal oversight of food safety as a high-risk area. Two agencies have primary responsibility—FDA is responsible for the safety of virtually all foods except for meat, poultry, and processed egg products, which are the responsibility of the United States Department of Agriculture (USDA). In addition, among other agencies, the National Marine Fisheries Service in the Department of Commerce conducts voluntary, fee-for-service inspections of seafood safety and quality; the Environmental Protection Agency regulates the use of pesticides and maximum allowable residue levels on food commodities and animal feed; and the Department of Homeland Security is responsible for coordinating agencies' food security activities. This federal regulatory system for food safety, like many other federal programs and policies, evolved piecemeal, typically in response to particular health threats or economic crises. (GAO, 2008, p. 3)

As of this writing, change is already under way, as evidenced by the creation of the White House Food Safety Working Group (FSWG) in March 2009. The FSWG was formed by the Obama Administration to address the critical need for cooperation across the spectrum of federal food safety agencies (FSWG, 2009a). Chaired by the Secretaries of the U.S. Department of Health and Human Services and USDA, the FSWG "will coordinate with other agencies and senior officials to advise the President on improving coordination throughout the government, examining and upgrading food safety laws, and enforcing laws that will keep the American people safe" (FSWG, 2009a). According to Agriculture Secretary Thomas J. Vilsack:

> The Working Group will be an important tool for gathering ideas as to how we can strengthen the food safety system to be more accountable and accessible to the public it protects, flexible enough to quickly resolve new safety challenges that emerge, and able to meet the robust needs of our rapidly changing world. (HHS, 2009)

In an effort to foster transparency and openness, the FSWG has invited public participation and is focusing on five basic principles similar to those in the FDA's FPP:

(1) Respond rapidly to outbreaks and facilitate recovery.

(2) Expand risk-based inspection and enforcement.
(3) Focus on prevention.
(4) Target resources effectively.
(5) Strengthen surveillance and risk analysis. (FSWG, 2009b)

The FSWG proposes to strengthen federal coordination by clarifying responsibilities, improving accountability, and modernizing current statutes. Thus its establishment is, at the time of this writing, a critical first step toward a comprehensive overhaul of the U.S. food safety management system, with the FDA as a key player (FSWG, 2009b).

The committee strongly supports the direction being taken by the FSWG. It is concerned, however, that these efforts remain piecemeal. A review of the FSWG website reveals little activity since the group's inception, and its membership is unclear. To be effective, the FSWG must include experts with the depth of background in food safety needed to understand the multitude of issues facing those agencies charged with food safety oversight. Increased transparency and stakeholder participation would strengthen and enhance the role of the FSWG as the leader in planning and implementing the comprehensive overhaul needed to optimize the U.S. food safety management system. The remainder of this chapter addresses issues relevant to reorganization and resource allocation within the FDA and approaches to the unification of food safety activities across the multiple agencies and departments with food safety responsibilities.

ISSUES RELEVANT TO REORGANIZATION AND RESOURCE ALLOCATION

Barriers to Change Within the FDA

As outlined in Chapter 2, FDA responsibilities relative to the nation's food supply lie within multiple centers and units. As it currently stands, there are deep-seated and fundamental differences in the cultures within the various FDA units. Historical differences in mission, financing, legal authorities and responsibilities, and institutional traditions have led to disparate perspectives on food safety issues among these units (Bell, 2009; Osterholm, 2009). A good example is the differing visions for the Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Regulatory Affairs (ORA). Past studies (Glavin, 2008) have also noted the conflicts inherent in the FDA's dual roles of law enforcement and protection of the public health. Policy setting for FDA food and feed regulation has historically resided with CFSAN (formerly the Bureau of Foods) and the Center for Veterinary Medicine (CVM), respectively, which are headed by a director. On the other hand, enforcement of policies and regulations is

carried out by ORA, which is headed by an associate commissioner. Much of ORA's organizational culture is focused on its law enforcement role. CFSAN and CVM employees, on the other hand, are not law enforcement officers (Givens, 2009). Thus, ORA investigators can request data while they conduct an inspection, and these data may be helpful in guiding regulatory decisions that affect the public health. On the other hand, if these data reveal policy violations, they can also become the basis for regulatory action against a food facility. This possibility could contribute to hesitancy on the part of industry to share potentially important data with the FDA (see Chapter 5).

Historically, ORA district offices sought approval from CFSAN (or the Bureau of Foods) for legal action when sufficient evidence existed, in the opinion of CFSAN scientists/administrators, to support such action. Over time, more authority was ceded to the ORA regions/districts to take action on specific findings without center approval or concurrence. Establishing field research centers and strengthening support for ORA laboratories as part of ORA's "revitalization strategies" were perceived by some as usurping what was traditionally a function of CFSAN scientists (Swann, 1993; Glavin, 2008). The relationship between the two centers has reportedly varied over time with changes in personnel and personal relationships among leaders within the offices of the director at CFSAN and the associate commissioner for regulatory affairs, as well as at lower echelons within each organization.

A related problem that derives from this division of roles at the FDA is that inspectors under the jurisdiction of ORA have responsibilities for more than one type of FDA-regulated product. As a result, the agency has imprecise data on the proportion of field resources dedicated to food safety (Givens, 2009; Solomon, 2009). This situation appears to be due to the policy that individual inspectors are not assigned to specific types of facilities (foods, drugs, devices, cosmetics) but handle a variety of establishments in their jurisdictions (Givens, 2009). Although maintaining a workforce with diverse training in foods, drugs, devices, and cosmetics purportedly provides the agency with flexibility, the committee argues that it results in an inspection force that may not have sufficient expertise in food safety (see Chapter 8) (Givens, 2009; Wagner, 2009).

In summary, the separation of the public health and enforcement roles within the FDA and the lack of clarity about their overlap have resulted in a situation in which CFSAN and CVM, the agency's food and feed policy arms, have little direct authority over the FDA's activities in the field. This lack of direct authority hampers the FDA's ability to prioritize such activities as inspections, the collection of data necessary to drive a risk-based food safety management system, and even the implementation of new or updated CFSAN policies. These are essential activities that are central to the

FDA's success in managing food safety with a risk-based approach; implementing many of the recommendations in this report will not be feasible if these problems persist.

Efficient Use of Resources

Among other factors, the organizational structure at the FDA contributes to a setting in which the utilization of available resources is often less than ideal. This report has pointed to various areas in which such operational inefficiencies exist at the FDA; two particularly important areas are discussed below.

One area of concern for the committee that has also been highlighted by others (GUIRR/NAS, 2009) is the lack of coordination of the nation's food safety and defense research portfolios. Within the FDA, in the absence of a strong organizational focus with a well-defined strategic plan, food safety–related research has evolved into a poorly integrated network of research centers, institutes, and laboratories (see Chapter 6). The ORA laboratories play into this issue; their work is focused on enforcement, but with appropriate agency restructuring, they could well be a critical source of data to support risk-based food safety management. As part of any organizational restructuring, changes to the agency's research portfolio (and laboratory functions) will be necessary, including reallocation of irrelevant or poorly performing initiatives and identification of future resources needed to support risk-based efforts.

Data infrastructure issues are a second area of critical importance with respect to resource allocation and internal reorganization. Underlying virtually all of the recommendations made in this report is the fundamental need for reliable data to guide the decision-making process. Reliable data must be appropriate (fit-for-purpose), complete, available, and representative of all sectors and stakeholders (Bell, 2009; Osterholm, 2009; Plunkett, 2009; Scott, 2009). As described in Chapter 5, there are many technical, cultural, and perhaps even legal barriers to meeting such data needs, including inadequate information technology (IT) infrastructure, cultures that discourage the sharing of data, and delays or lack of collaboration in sharing data due to misunderstandings about legal constraints. Also, the lack of high-quality personnel to carry out the collection, analysis, and management of data has been highlighted in this report as a barrier to good data infrastructure and management (Chapter 5). At the most basic level, the FDA must give top priority to the development of robust IT systems that can accommodate the data available from multiple partners; such systems must be designed to collect the right data in the right format to facilitate risk-based decision making. In any internal FDA reorganization, an applied statistician and an IT/data manager with experience in developing and maintaining

large databases must be included in the top management group, and their respective divisions must have access to the necessary resources and work collaboratively to create a modern data management system.

Current Approaches to Internal FDA Reorganization

As this report is being written, the FDA has initiated internal reorganization plans that would integrate the food safety functions of, CFSAN and CVM. The committee is encouraged by, and strongly supportive, of the creation of the Office of Foods with authority over CFSAN and CVM (see Chapter 2). However, this consolidation will not resolve concerns associated with the separation of the enforcement and public health roles of ORA and the centers, respectively. In fact, based on the problems discussed above, the committee concluded that if the FDA is to accomplish its food safety mission efficiently, its food programs should have complete authority over field activities related to the foods it regulates. The committee is also concerned about how the plans currently being developed will deal with structuring the agency's research mission and with addressing the IT and data management deficiencies highlighted in this report.

UNIFICATION OF FOOD SAFETY ACTIVITES ACROSS MULTIPLE AGENCIES AND DEPARTMENTS

In keeping with its statement of task, the committee did not conduct an in-depth review of the whole food safety system and responsible government agencies. Nor has the committee considered or evaluated the pros and cons of all potential organizational changes that might address the current challenges reviewed in this report. The committee does believe, however, that certain key organizational changes described below would enhance the ability of the FDA, and the federal government in general, to ensure food safety.

The committee concludes that focusing attention on risk-based priorities, workforce development, and the integration of activities currently scattered among many poorly coordinated agencies would result in a marked increase in efficiency throughout the system. While the resource and organizational issues to be addressed may appear to be daunting in the short term, it is highly likely that well-designed components of an integrated food safety system would, in the long run, save money and improve the public health.

Similar sentiments have been expressed by government officials in other countries that have recently reorganized their food safety systems (see Appendix C). Although evaluations of the outcomes of these reorganizations are still in progress, officials in each country believe that the final bal-

ance will be a positive one. In addition to improvements in efficiency, such as less overlap in inspections and more consistent and timely enforcement of laws and regulations, some countries cite areas that should result in savings, such as reduced duplication of inspections and lower costs associated with administrative personnel (GAO, 2005b).

There are well-documented difficulties inherent in any internal restructuring of government agencies, difficulties that are magnified when such efforts involve reorganizing across agencies and departments that have traditionally operated independently. The committee is aware that any reorganization efforts directed at the food safety system will require careful planning and may require stepwise implementation. Regardless of the final structure of the food safety system, it must include data management and analytical functions that will ensure that the data needs of a risk-based food safety system are met. The approaches described below reflect what could be an evolutionary process in which the first step—creation of a centralized risk-based analysis and data management center—leads toward accomplishing the more challenging goal of a unified food safety agency.

Creation of a Centralized Risk-Based Analysis and Data Management Center

A risk-based food safety system requires the analytical capacity to assess food safety risks and policy interventions and the ability to access data from a broad array of sources. To meet these needs, the committee envisions the establishment of a centralized center with risk-based analysis and data management functions. The need for data to support a scientific basis for decision making has been articulated by the White House FSWG as well as a variety of other public and private groups (Taylor and Hoffman, 2001; GAO, 2004, 2005a; Taylor and Batz, 2008). The proposed center would serve as an information hub or broker that would streamline data collection from a variety of sources to support a risk-based approach. Such data might include epidemiological and farm-to fork surveillance data collected at the national level; inspectional, laboratory, and epidemiological data collected at the state and local levels; supporting food safety data, such as industry surveillance and academic research findings; and other relevant data related to food safety and food defense.

Establishment of a centralized food safety data management function would be an important step toward the implementation of a risk-based approach to food safety management. However, the act of collating and organizing data does not necessarily mean that the right data have been collected or that the data will be used appropriately. Therefore, this center also needs to house the analytic capacity, including the appropriate scientific and technical expertise, to identify (in consultation with the relevant agen-

cies) specific data needs, ensure that data are collected in an appropriate manner, and analyze the data with the clear goal of supporting risk-based food safety decision making.

The committee envisions several advantages to the establishment of such a centralized risk-based analysis and data management center. On the analytical side, having such a center responsible for all food safety data, irrespective of agency, would go a long way toward developing the much-needed capacity that is currently lacking. The center's independence from a specific regulatory agency would not preempt any agency's prerogative to develop its own approach to food safety management, but would eliminate the need for each agency to develop its own comprehensive expertise in risk and decision analysis. This in turn would reduce interagency competition for available scientific resources (including personnel), reduce redundancy, harmonize analytical methods, and increase efficiency. Specifically, because the agencies involved would not have competing analytic groups, the center concept would ensure a consistent technical approach to surveillance, data analysis, and modeling. On the data management side, the centralized nature of this body would help overcome some of the current barriers to data acquisition and transfer, keeping in mind that additional actions needed to overcome the data sharing barriers identified in Chapter 5 would have to be considered during the center's establishment. The ability of such a center to promote communication, collaboration, and sharing of data among government agencies is central to its value.

Positioning the risk-based analysis and data management center as a free-standing (independent) entity that is not directly answerable to any one regulatory agency would also result in a scientifically credible source of unbiased data and analytic capacity. This model is consistent with the need for separation of the risk management and assessment functions, which is central to the assurance that risk-based decision making is objective and not influenced to support a predetermined policy or political agenda (NRC, 1983, 1996). Further, within such a structure, it may be easier to recruit and retain scientists and maintain the interactive and multidisciplinary scientific base essential to the functioning of such an organization. Although it is important to stress that this center should be independent from political influence, it is also essential that the strategic plan for the center be developed to address the needs of the regulatory food safety agencies. The term "independent" in this context means free from political influence but accountable to the public health needs and mission of the regulatory agencies. In Europe, quasi-governmental research institutes (such as the National Institute for Public Health and the Environment in the Netherlands or the European Food Safety Authority) serve the dual purposes of functioning as a hub for national data collection and providing the independent scientific and analytical expertise necessary to support policy decision

making. The proposed center could be established as an entity in its own right or as a step toward the ultimate establishment of a single, unified food safety agency.

Creation of a Single, Unified Food Safety Agency

For well over a decade, many responsible suggestions have been made that the major elements of the U.S. food safety system would be more effective and efficient if many of the core activities of multiple agencies were consolidated into a single food agency (IOM/NRC, 1998; National Commission on the Public Service, 2003; GAO, 2005b; IOM, 2009). The committee concluded that, to effect the risk-based approach and actions proposed in this report, a unified food safety agency will ultimately be essential. Such an agency would have overall authority for all aspects of the risk-based food safety system outlined in Chapter 3, from planning and data collection to policy and regulatory development, including oversight of all food safety inspections. Its functions would be supported by the centralized risk-based analysis and data management center described above; in fact, the unified entity would be responsible for this center.

Establishment of a single food safety agency would certainly be challenging. It would require reorganization of various federal agencies and buy-in from several congressional committees to facilitate changes to many food safety–related laws and regulations (IOM/NRC, 1998; GAO, 2004). Given the jurisdictional and political ramifications, an immediate and total reorganization of this magnitude probably is not feasible. Nonetheless, it is the consensus of this committee that core federal food safety responsibilities should ultimately reside within a single entity having a unified administrative structure, a clear mandate, a dedicated budget, and above all, full responsibility for oversight of the entirety of the safety of the nation's food supply.

KEY CONCLUSIONS AND RECOMMENDATIONS

The committee is confident that the recommendations offered in this report constitute a series of actions that would enhance the FDA's food programs and their ability to ensure food safety now and in the future. The committee is encouraged by changes already occurring in the FDA's food programs, such as the establishment of the Office of Foods in 2009. However, the committee has not been persuaded that the consolidation of responsibility represented by the establishment of this office will resolve issues associated with the current separation of the FDA's food safety–related enforcement and public health roles and the lack of authority of CFSAN and CVM over inspection and enforcement. In addition, food safety in the

United States today is managed by multiple government agencies, hampering the efficiency and effectiveness of the overall food safety system.

Efficiency in working toward the common goal of ensuring food safety and the public health will be greatly enhanced if the recommendations in this report are implemented in the context of the organizational changes outlined in this chapter. The committee realizes that there are many potential avenues to the evolution and implementation of those organizational changes and that there are serious barriers to overcome. Hence, the importance of in-depth analysis and planning of the implementation process cannot be overemphasized. With regard to the overall organization and functioning of the FDA, the committee makes the following recommendations.

Recommendation 11-1: The committee recommends that the FDA's Office of Foods have complete authority over and responsibility for all field activities for FDA-regulated foods, including inspection, sampling, and testing of foods. Implementing this recommendation would resolve issues associated with the separation between the agency's enforcement functions and larger public health roles and responsibilities, and ensure a well-trained field workforce with specialized expertise in food safety and risk-based principles of food safety management.

Recommendation 11-2: There is a compelling need to elevate and unify the nation's food safety enterprise so that the FDA and relevant sister agencies can better ensure a safe food supply. The committee recognizes that organizational change to enhance the effectiveness and efficiency of the nation's food safety system as a whole is an evolutionary process that would require careful analysis, planning, and execution. With this in mind, the committee recommends that the federal government move toward the establishment of a single food safety agency to unify the efforts of all agencies and departments with major responsibility for the safety of the U.S. food supply.

Recommendation 11-3: Regardless of the evolution of the food safety system, an integrated, unimpeded, and centralized approach to risk-based analysis and data management is required to enhance the FDA's and the broader federal government's ability to ensure a safe food supply. To achieve this goal, and as a potential intermediate step toward the creation of a single food safety agency, the committee recommends the establishment of a centralized risk-based analysis and data management center. This center should be provided with the staff and supporting resources necessary to conduct rapid and sophisticated assessments of short- and long-term food safety risks and of policy interventions, and to ensure that the comprehensive data needs of the recommended

risk-based food safety management system are met. This center should be as free from external political forces and influence as possible and accountable to the public health needs and mission of the regulatory agencies.

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Appendix A

Workshop Agendas

Review of U.S. Food and Drug Administration's (FDA's) Role in Ensuring Safe Food

The Keck Center of the National Academies
Room 100
500 Fifth Street, NW
Washington, DC 20001
January 29, 2009

AGENDA

Open Session—Meeting with Sponsor—11:00 a.m. to 2:30 p.m.

11:00 a.m. **Welcome and Introductions**
Robert Wallace, Committee Chair

11:15 a.m. **FDA's Perspective on the Statement of Task**
David Acheson, Associate Commissioner for Foods

1:00 p.m. **FDA's Perspective on the Statement of Task (continued)**
David Acheson, Associate Commissioner for Foods

Perspectives on FDA's Role in Ensuring Safe Food

Venable LLP Conference Center
8th floor Capitol Room
575 7th Street, NW
Washington, DC 20004
March 24–25, 2009

AGENDA

March 24

8:45 a.m. **Welcome and Purpose of Workshop**
Robert Wallace, Committee Chair

Session 1: FDA Organization and Responsibilities
Moderator: Robert Wallace

8:50 a.m. **FDA's Organization and Responsibilities**
Leslye Fraser, Office of Regulations, Policy, and Social Sciences, FDA/Center for Food Safety and Applied Nutrition (CFSAN)

9:30 a.m. **FDA's Legal Authority**
Lars Noah, University of Florida

9:50 a.m. **FDA's Resources**
Joseph Levitt, Hogan & Hartson

10:10 a.m. **Break**

10:30 a.m. **Role of Foodborne Disease Surveillance and Food Attribution in Food Safety**
Dale Morse, Office of Science, New York State Department of Health
Mike Osterholm, Center for Infectious Disease Research and Policy, University of Minnesota
David Warnock, Division of Foodborne, Bacterial and Mycotic Diseases, Centers for Disease Control and Prevention

Session 2: Approaches to Food Safety Prevention, Inspection, and Research
Moderator: Lee-Ann Jaykus

11:30 a.m. **FDA's Approach to Risk-Based Inspections**
Steven Solomon, FDA/ORA
Roberta Wagner, Office of Compliance, FDA/CFSAN
Steven Kendall, FDA/ORA

12:30 p.m. **Lunch**

1:30 p.m. **FDA's Risk-Based Prevention**
Donald Kraemer, Office of Food Safety, FDA/CFSAN

2:00 p.m. **Research Priorities**
Steven Musser, Office of Regulatory Science, FDA/CFSAN

2:30 p.m. **Panel Discussion with Session 2 Speakers**

3:15 p.m. **Break**

Session 3: Perspectives from Stakeholders
Moderator: Martha R. Roberts

3:35 p.m. **Consumer Perspectives**
David Plunkett, Center for Science in the Public Interest
Jean Halloran, Consumers Union
Christopher Waldrop, Consumer Federation of America

4:20 p.m. **Industry Perspectives**
Jenny Scott, Grocery Manufacturers Association
David Gombas, United Fresh Produce Association
Jon Bell, National Fisheries Institute

5:05 p.m. **Public Comments (3-5 min each)**

5:30 p.m. **Adjourn**

March 25

The National Academy of Sciences Building
Room 150
2101 Constitution Avenue, NW
Washington, DC 20418

1:00 p.m. **Effective Risk-Based Approaches for Food Safety**
Bob Buchanan, University of Maryland

FDA's Role in Ensuring Safe Food

The Keck Center of the National Academies
Room K201
500 Fifth Street, NW
Washington, DC 20001
May 28, 2009

AGENDA

Open Session—8:00 a.m.–5:30 p.m.

8:00 a.m. **Welcome and Purpose of Workshop**
Robert Wallace, Committee Chair

Session 1: Coordination of Food Defense Activities
Moderator: Robert Wallace

8:10 a.m. **Food Defense Initiatives at FDA**
LeeAnne Jackson, Office of Food Defense, Communication, and Emergency Response, FDA/CFSAN

8:30 a.m. **Questions from Committee Members**

Session 2: FDA's Risk-Based Activities
Moderator: Lewis Grossman

9:00 a.m. **Discussion Panel: FDA and State Inspections of Food**
FDA District Office Directors

10:00 a.m. **Break**

10:15 a.m. **Anthropogenic and Natural Chemical Contaminants in Food—Detection and Control**
Philip M. Bolger, Office of Food Safety, FDA/CFSAN

10:45 a.m. **Feed and Pet Food Safety at the Center for Veterinary Medicine**
Martine Hartogensis, Office of Surveillance and Compliance, FDA/Center for Veterinary Medicine

11:15 a.m. **Questions from Committee Members**

12:15 p.m. **Lunch**

Session 3: U.S. Department of Agriculture's (USDA's) Approach to Ensuring Food Safety
Moderator: Joseph Rodricks

1:15 p.m. **General Overview of Food Safety at Food Safety and Insepction Service (FSIS)**
Dan Engeljohn, Office of Policy and Program Development, USDA/FSIS

1:50 p.m. **Proposed Risk-Based Inspection System at FSIS**
Carol Maczka, Office of Data Integration and Food Protection, USDA/FSIS

2:15 p.m. **Questions from Committee Members**

Session 4: Safety of Imported Foods
Moderator: Tim Jones

2:45 p.m. **USDA Model to Ensure Safety of Imported Foods**
Phil Derfler, Office of Policy and Program Development, USDA/FSIS

3:05 p.m. **Break**

3:25 p.m. **European Union Model and Third-Party Certifications for Food Safety**
Wolf Maier, European Commission

3:45 p.m. **Ensuring Food Safety of Food Imports**
Caroline Smith DeWaal, Center for Science in the Public Interest

4:05 p.m. **Ensuring Food Safety at the Border**
Cathy Sauceda, U.S. Department of Homeland Security/ Customs and Border Protection

4:25 p.m. **Perspective from the Industry**
Steve Mavity, Bumble Bee Foods, LLC

4:45 p.m. **Questions from Committee Members**

5:30 p.m. **Meeting Adjourned**

Appendix B

Past Recommendations About the U.S. Food and Drug Administration's Food Safety Program

TABLE B-1 Past Recommendations about U.S. Food and Drug Administration (FDA) Food Safety Program

Topic	Recommendations	Source
General Authorities	We recommended that FDA and U.S. Department of Agriculture (USDA) study their agencies' existing statutes and identify what additional authorities they may need relating to security measures. On the basis of the results of these studies, the agencies should seek additional authority from the Congress.	GAO, 2003
Authority for Mandatory Recalls and Related Recommendations	Consumers Union (CU) has called . . . for Congress to grant the agency broad mandatory recall authority in light of the recent outbreak of salmonella in tomatoes.	Consumers Union, 2008a
	The Commissioner of FDA should develop a sound methodology for district staff to verify that companies have quickly and effectively carried out recalls.	GAO, 2005a
	To ensure that USDA and FDA have information and authority so they can act quickly to remove potentially unsafe food from the marketplace and can better protect consumers, Congress may wish to consider legislation that would require a company to notify the responsible agency when it becomes aware that a food it has distributed is unsafe.	GAO, 2005a

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	To ensure that USDA and FDA have information and authority so they can act quickly to remove potentially unsafe food from the marketplace and can better protect consumers, Congress may wish to consider legislation that would give USDA and FDA authority to issue a mandatory recall order and establish recall requirements.	GAO, 2005a
	To ensure that companies promptly and effectively recall foods that may cause serious illness or death, the Secretary of Agriculture and the Commissioner of FDA should revise agency guidance to recalling companies to include specific time frames for notifying their customers, removing recalled food from the marketplace, and providing the agencies with the names and locations of customers that received the food.	GAO, 2005a
	To ensure that companies promptly and effectively recall foods that may cause serious illness or death, the Secretary of Agriculture and the Commissioner of FDA should use agency data systems to routinely generate reports for recall program managers so that they may monitor ongoing recalls and oversee recall timeliness and effectiveness.	GAO, 2005a
	To ensure that companies promptly and effectively recall foods that may cause serious illness or death, the Secretary of Agriculture and the Commissioner of FDA should track in their data systems the dates that the agencies start and finish verification checks.	GAO, 2005a
	To ensure that companies promptly and effectively recall foods that may cause serious illness or death, the Secretary of Agriculture and the Commissioner of FDA should track in their recall data systems the dates that companies (1) start and finish notifying their customers, (2) provide the agency with the lists of customers that received the food, and (3) start and finish recovering the recalled food.	GAO, 2005a

TABLE B-1 Continued

Topic	Recommendations	Source
	To ensure that companies promptly and effectively recall foods that may cause serious illness or death, the Secretary of Agriculture and the Commissioner of FDA should work jointly to determine what, if any, additional approaches are needed for alerting consumers about recalls.	GAO, 2005a
Authority to Impose Penalties	FDA needs the authority to enforce meaningful penalties to deter behavior like the Peanut Corporation of America's. The maximum penalties for such wrongdoing should be increased from the current cap of $10,000 to $1 million.	Consumers Union, 2009a
	To ensure that USDA and FDA have information and authority so they can act quickly to remove potentially unsafe food from the marketplace and can better protect consumers, Congress may wish to consider legislation that would give USDA and FDA authority to . . . impose monetary penalties or seek fines or imprisonment for failing to follow food recall requirements.	GAO, 2005a
Authority to Inspect	CU urges Congress to overhaul the nation's food safety laws and to mandate annual inspections of food processing facilities.	Consumers Union, 2009b
	CU has called for the FDA to increase inspections of food processing plants.	Consumers Union, 2008a
Authority to Require Company Records and to Develop Traceability Methods	To ensure that companies promptly and effectively recall foods that may cause serious illness or death, the Secretary of Agriculture and the Commissioner of FDA should revise agency guidance to recalling companies to include specific time frames for notifying their customers, removing recalled food from the marketplace, and providing the agencies with the names and locations of customers that received the food.	GAO, 2005a
	To enhance FDA's oversight of fresh produce safety, the Commissioner of FDA should seek authority from the Congress to provide FDA enhanced access to firm records during food-related emergencies.	GAO, 2008a

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	We recommend that FDA seek statutory authority, if necessary, to strengthen existing records requirements regarding lot-specific information.	OIG, 2009
	We recommend that FDA consider seeking additional statutory authority to improve traceability.	OIG, 2009
	We recommend that FDA seek statutory authority to conduct activities to ensure that facilities are complying with its records requirements.	OIG, 2009
	Congress, with input from experts, should establish traceability requirements that permit federal, state, and local officials to rapidly obtain from food companies reliable information on the source of commodities, ingredients, and finished products.	Taylor and David, 2009
Develop Traceability Methods	We urge FDA to move quickly to improve product traceability, and in particular to focus on the most problematic produce—the produce that has caused the most illnesses—first.	Consumers Union, 2008b
	In addition, trace-back systems that include package identifiers allowing each product to be traced back to the field in which it originated are needed to further protect consumers from contaminated food.	Consumers Union, 2008a
	We recommend that FDA work with the food industry to develop additional guidance to strengthen traceability.	OIG, 2009
Education of Consumers/ Communication	A more consistent and focused effort in determining and communicating public health risks from contaminated seafood should also be developed.	IOM, 1991
	One-fifth of the fish and shellfish eaten in the United States is derived from recreational or subsistence fishing, and these products are not subject to health-based control; there is need to improve protection for consumers of these products by regulation of harvest and by education concerning risks associated with their consumption.	IOM, 1991

TABLE B-1 Continued

Topic	Recommendations	Source
	There is a lack of understanding of the nature of seafood hazards in the food service sectors and by the consuming public and health professionals; a vigorous campaign for information dissemination and education in these matters is needed, particularly for high-risk consumers and high-risk products such as raw shellfish.	IOM, 1991
	The FDA should implement targeted educational programs to inform the public about the risks of consuming raw milk and raw milk products.	IOM/NRC, 2003
	Consolidated advice is needed that brings together different benefit and risk considerations, and is tailored to individual circumstances, to better inform consumer choices.	IOM, 2007
	Partnerships should be formed between federal agencies and community organizations. This effort should include targeting and involvement of intermediaries, such as physicians, and use of interactive Internet communications, which have the potential to increase the usefulness and accuracy of seafood consumption communications.	IOM, 2007
	Dietary advice to the general population from federal agencies should emphasize that seafood is a component of a healthy diet, particularly as it can displace other protein sources higher in saturated fat.	IOM, 2007
	Although advice from federal agencies should also support inclusion of seafood in the diets of pregnant females or those who may become pregnant, any consumption advice should stay within federal advisories for specific seafood types and state advisories for locally caught fish.	IOM, 2007
	Consumer messages should be tested to determine if there are spillover effects for segments of the population not targeted by the message.	IOM, 2007
	Research is needed to develop and evaluate more effective communication tools for use when conveying the health benefits and risks of seafood consumption as well as current and emerging information to the public.	IOM, 2007

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	Among federal agencies there is a need to design and distribute better consumer advice to understand and acknowledge the context in which the information will be used by consumers.	IOM, 2007
	Appropriate federal agencies (National Oceanic and Atmospheric Administration [NOAA], U.S. Environmental Protection Agency [EPA], and FDA) should increase monitoring of methylmercury and persistent organic pollutants in seafood and make the resulting information readily available to the general public. Along with this information, these agencies should develop better recommendations to the public about levels of pollutants that may present a risk to specific population subgroups.	IOM, 2007
	To ensure that companies promptly and effectively recall foods that may cause serious illness or death, the Secretary of Agriculture and the Commissioner of FDA should work jointly to determine what, if any, additional approaches are needed for alerting consumers about recalls.	GAO, 2005a
	We recommend that [FDA] conduct education and outreach activities to inform the food industry about its records requirements.	OIG, 2009
Establish a Single Food Safety Agency	CU has also called for consolidation of the 15 agencies that oversee our food safety system.	Consumers Union, 2008a
	To implement a science-based system, Congress should establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.	IOM/NRC, 1998
	To address the growing threat of foodborne illnesses, Congress should *unify the USDA's Food Safety and Inspection Service and the food safety activities of FDA within U.S. Department of Health and Human Services (HHS)* and ensure provision of adequate resources for high-quality inspection, enforcement, and research.	IOM, 2009

TABLE B-1 Continued

Topic	Recommendations	Source
	To develop a uniform, risk-based inspection system, we recommend that the Congress hold oversight hearings to evaluate options for revamping the federal food safety and quality system, including (1) creating a single food safety agency responsible for administering a uniform set of food safety laws, (2) creating a uniform set of food safety laws that are administered by the current federal food safety agencies, or (3) establishing a blue-ribbon panel to develop a model for inspection and food safety enforcement based on the public health risks posed by the products and processes.	GAO, 1992
	To provide more efficient, consistent, and effective federal oversight of the nation's food supply, Congress may wish to consider establishing a single, independent food safety agency at the Cabinet level.	GAO, 2004a
	If the Congress does not opt for an entire reorganization of the food safety system, it may wish to consider modifying existing laws to designate one current agency as the lead agency for all food safety inspection matters.	GAO, 2004a
	We recommended that the Congress consider enacting comprehensive, uniform, and risk-based food safety legislation to streamline inspection and enforcement efforts, and consolidate food safety functions by establishing a single, independent food safety agency or by designating one current agency as the lead agency for all food safety inspection matters.	GAO, 2005b
	We have recommended that the Congress consider statutory and organizational reforms, and we continue to believe that the benefits of establishing a single national system for the regulation of our food supply outweigh the costs. In making these recommendations, we fully recognize the time and effort needed to develop a reorganization plan and to transfer authorities, as necessary, under such a reorganization.	GAO, 2005b

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	Congress should give the Secretary of HHS a legislative mandate to lead the development of an integrated, national food safety system that incorporates and enhances the food safety capacity of state and local agencies.	Taylor and David, 2009
	HHS and the states should declare as a matter of policy that the establishment and enforcement of nationally uniform food safety standards is a common goal and joint responsibility of federal, state, and local governments, with the federal government bearing primary responsibility for establishing science-based standards for preventing foodborne illness and states and localities preserving full legal power to adopt and directly enforce federal standards and establish their own.	Taylor and David, 2009
Feed	The committee recommends that the government's risk management strategy for dioxin-like compounds (DLCs) give high-priority attention to reducing the contamination of animal forage and feed and interrupting the recycling of DLCs that result from the use of animal fat in animal feed.	NRC, 2003
	We recommended that . . . FDA strengthen enforcement of the feed ban and its management of inspection data.	GAO, 2003
Funding	CU has called for more funding for the FDA to perform yearly inspections.	Consumers Union, 2008a
	The assessment and collection of fees from domestic and foreign food plants would also supplement appropriated funds, and the fees could fund routine, up-front inspection work.	Consumers Union, 2009a
	Congress and the administration should require development of a comprehensive national food safety plan. Funds appropriated for food safety programs (including research and education programs) should be allocated in accordance with science-based assessments of risk and potential benefit.	IOM/NRC, 1998

TABLE B-1 Continued

Topic	Recommendations	Source
	Congress should declare that the federal government has a responsibility to support the capacity building needed to strengthen the performance of state and local agencies in the national food safety system and has a shared responsibility with the states to adequately fund food safety programs and capacity building, in accordance with the integration plan and benchmarks. To help carry out the federal responsibility for state and local capacity building, Congress should authorize and establish an appropriation line item for FDA to provide federal funding to the states in the form of a food safety block grant, with a specified share flowing to local agencies. In addition, Congress should establish a matching grant program to foster improvement and innovation beyond base capacity building. State and local governments should maintain stable funding streams sufficient to meet their responsibility for funding of food safety programs, in keeping with agreed criteria and benchmarks for food safety capacity and performance.	Taylor and David, 2009

continued

TABLE B-1 Continued

Topic	Recommendations	Source
Implement Preventative Approaches	On behalf of the Center for Science in the Public Interest (CSPI) and our 900,000 members, we are submitting a petition to the FDA urging the agency to issue standards and regulations to help ensure the safe production of fresh fruits and vegetables. These regulations are clearly needed, as demonstrated by recent multi-state outbreaks in produce, including the *E. coli* O157:H7 outbreak from spinach that sickened over 200 people and killed at least four and the more recent *Salmonella* outbreak caused by tomatoes that has sickened nearly as many. Many other outbreaks have been traced to produce, and these will continue to occur until FDA adopts enforceable standards for this important sector. CSPI urges the FDA to develop mandatory regulations and auditing programs for produce growers and processors to reduce the likelihood of microbial contamination. These regulations are authorized under the Federal Food, Drug, and Cosmetic Act, section 402(a) and the Public Health Service Act, section 361. We also hope that FDA will expedite development and publication of produce regulations.	CSPI, 2006
	The best way to minimize or prevent contamination [in produce] is through implementation of hazard identification and process control systems. These systems should be mandated, starting with the highest risk products first—those that have been repeatedly linked to illness outbreaks. To that end, regulations should be developed that require processors and others in the fresh-cut produce supply chain to have written plans that identify hazards associated with their product and the steps, interventions, and programs taken to address those hazards. . . . [I]t is critical that these mandatory programs be developed and implemented by FDA.	CSPI, 2007a
	CU has called for . . . the agency to develop operating plans for food processing facilities that insure safety, and for domestic and foreign food producers to be required to be certified as in compliance with these safety plans and with U.S. food safety standards.	Consumers Union, 2008a

TABLE B-1 Continued

Topic	Recommendations	Source
	To enhance FDA's oversight of fresh produce safety, the Commissioner of FDA should seek authority from the Congress to make explicit FDA's authority to adopt preventive controls for high-risk foods.	GAO, 2008a
	To enhance FDA's oversight of fresh produce safety, the Commissioner of FDA should: 1) see that the agency update its good agricultural practices guidance for fresh produce to incorporate new knowledge about safe growing practices, 2) see that the agency update its current good manufacturing practice regulations for food to incorporate new knowledge about the food industry and safe manufacturing, processing, and holding practices.	GAO, 2008a
	Chronic illness resulting from seafood consumption is associated primarily with environmental contamination; thus, control depends on improved understanding of the occurrence and distribution of the chemical agents involved, the exclusion of contaminated seafood from the market, and increased action to prevent additional pollution of the waters.	IOM, 1991
	With currently available data, it is possible to identify the source of much of the acute illness associated with seafood consumption, though the dimensions of the problems are not always known; these data, in turn, can form the basis for national control programs.	IOM, 1991
	The Center needs to carefully devise management procedures for emergency events so that these events will not disrupt other activities. Although emergency events cannot be eliminated, management should attempt to develop systems and regulations that lessen their frequency and seriousness.	CRC/SB, 1999

continued

TABLE B-1 Continued

Topic	Recommendations	Source
Improve Surveillance and Outbreak Response	Appropriate federal agencies (NOAA, EPA, and FDA) should increase monitoring of methylmercury and persistent organic pollutants in seafood and make the resulting information readily available to the general public.	IOM, 2007
	An improved national surveillance system should be developed to provide more reliable and comprehensive information on seafoodborne disease incidence. Data will then permit risk identification and risk assessment as a basis for effective regulation of seafoods (current data on disease occurrence in seafood consumption are too fragmentary to allow reliable risk assessment of microbiological and natural toxin hazards).	IOM, 1991
	We recommend specific initiatives to improve the Food Safety Information Structure (FSII) 1) Create a food safety epidemiology user group, to address: • improving surveillance and analysis to meet stakeholder needs, and • increasing timeliness and depth of information access.	Taylor and Batz, 2008
	Congress should direct the Secretary of HHS to create, in consultation with the Food Safety Leadership Council and in collaboration with the states, a National Foodborne Illness Data Program that builds on existing efforts of the U.S. Centers for Disease Control and Prevention (CDC), states and localities, and Council to Improve Foodborne Outbreak Response (CIFOR), but with the goal of significantly expanding the contribution of food safety epidemiology and other data collection to understanding and preventing foodborne illness.	Taylor and David, 2009
	HHS, working through CDC and FDA and in collaboration with the Food Safety Leadership Council, should support and build on CIFOR's continuing efforts to define and foster implementation of best practices for foodborne outbreak response.	Taylor and David, 2009

TABLE B-1 Continued

Topic	Recommendations	Source
Information Technology (IT) at FDA	The FDA should enhance the program to monitor performance metrics and put the appropriate IT infrastructure in place to track the evolution of those metrics.	FDA, 2007
	Based on the evidence of important foundational work to date in IT and yet the continued existence of critical IT capability gaps, there should be significant investment in IT at the FDA to accelerate progress toward an information processing and communications capability that can support all regulatory science.	FDA, 2007
	FDA IT must develop the intramural capability to support all regulatory science activities and should catalyze the development of multi-sectoral shared health information exchanges to support industry innovation and fulfillment of regulatory responsibilities.	FDA, 2007
	The FDA should identify and implement high-return enhancements of FDA IT infrastructure.	FDA, 2007
	FDA IT must develop the intramural capability to support all regulatory science activities and should catalyze the development of multi-sectoral shared health information exchanges to support industry innovation and fulfillment of regulatory responsibilities.	FDA, 2007

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	We recommend that the federal government via legislation (or executive order) enact a national policy that would: • foster coordinated approaches to collecting food safety information among federal state and local agencies, • consider the whole food safety system in information collection activities, and • maximize access to and active sharing of food safety information among government agencies and with the private sector. Priority areas of this new national policy should include: • improving collection of and accessibility to public information, including CDC outbreak data, Foodborne Disease Outbreak Surveillance Network (FoodNet) data, electronic Laboratory Exchange Network (eLEXNET), and public inspection, enforcement, and recall information, • strengthening protocols for information sharing during outbreaks; • expanding commissioning of state and local officials by FDA; • amending or interpret the Information Quality Act; • making USDA research information systems, such as the Agricultural Research Information System, fully public; and • working toward standardizing and harmonizing sampling and laboratory procedures.	Taylor and Batz, 2008

TABLE B-1 Continued

Topic	Recommendations	Source
	We recommend specific initiatives to improve the FSII: Create a "network of networks" to improve interconnectivity of the food safety web • collaborative relationships between websites and information owners, and • standardized summary pages and organized structure for browsing. Create a database for tracking research and information collection • build on USDA/National Agricultural Library/ Food Safety Research Information Office database to include more research projects and to include additional information collection activities. Increase access to information and publications resulting from publicly funded food safety research • researchers, publishers, and funders should develop and utilize online data repositories, • "open access" to publicly funded research and move to free-and-open model of publication, and • increase back-catalog of online journals. Increase access to industry-generated food safety information • identify specific problem-areas or information needs that industry data could address, and • develop guidelines or "business rules" to govern information collection and sharing	Taylor and Batz, 2008
	Center for Food Safety and Applied Nutrition (CFSAN) should, if they are not already doing so, develop tools to measure the effectiveness of the technology transfer process, and apply these tools on a routine basis.	CRC/SB, 1999

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	To help ensure the success of FDA's modernization efforts, we recommend that the Commissioner of FDA require the Chief Information Officer to take expeditious actions to: • set milestones and a completion date for developing a comprehensive IT strategic plan, including results-oriented goals, strategies, milestones, performance measures, and an analysis of interdependencies among projects and activities, and use this plan to guide and coordinate its modernization projects and activities; • develop a documented enterprise architecture program management plan that includes a detailed work breakdown of the tasks, activities, and time frames associated with developing the architecture, as well as the funding and staff resources needed; • complete the criteria for setting priorities for the segment architecture and prioritize the segments; • accelerate development of the segment and enterprise architecture, including "as is," "to be," and transition plans, and in the meantime develop plans to manage the increased risk to modernization projects of proceeding without an architecture to guide and constrain their development; and • develop a skills inventory, needs assessment, and gap analysis, and develop initiatives to address skills gaps as part of a strategic approach to IT human capital planning.	GAO, 2009
Organization	We recommend that FDA reform legislation [to] consolidate and reorganize the food safety functions of the agency into one office—rather than the four FDA offices within which it is currently placed—in order to increase the agency's accountability both to Congress and to consumers.	Consumers Union, 2009a
	Rebuild CFSAN, Center for Veterinary Medicine (CVM) scientific base and their related inspection and enforcement functions to a level that is commensurate with their regulatory responsibilities.	FDA, 2007

TABLE B-1 Continued

Topic	Recommendations	Source
	We recommend that the Secretaries of Agriculture, Commerce, and HHS enter into agreements that require the agency most frequently visiting a food-processing plant to act as the lead federal inspection agency. The lead agency would perform the inspection tasks, if any, required by the other agencies and request plants to make changes to comply with all federal food safety laws and regulations. However, when necessary, the lead agency would refer continuing violations to the responsible regulatory agency to pursue corrective action in the courts. In addition, the agency with regulatory responsibility would retain primary responsibility and inspect plants when warranted, such as to respond to consumer complaints or to follow up on referrals made by other agencies.	GAO, 1992
	To help ensure effective coordination between federal agencies with food safety and quality responsibilities, we recommend that the Secretaries of Agriculture, Commerce, and HHS evaluate and revise as necessary all current coordination agreements related to food safety and quality. Specifically, the Secretaries should direct the agency heads to revise the agreements, as necessary, to (1) define the responsibilities of each agency, (2) require the referral of firms with unsanitary food-processing conditions or unsafe food products to all agencies with regulatory oversight or grading responsibilities, (3) specify how and when referrals should be made, and (4) identify the individual or office to which referrals should be made. In addition, the Secretaries should direct the agency heads to periodically, but no less than annually, review their respective coordination agreements and update them when necessary.	GAO, 1992

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	To more efficiently and effectively monitor the safety of imported seafood, the Secretary of HHS should direct the Commissioner of FDA to work toward developing a memorandum of understanding with NOAA that leverages NOAA's Seafood Inspection Program's resources. The memorandum of understanding should address mutually agreeable protocols and training programs that are necessary to begin using NOAA employees to provide various services. Those services could include inspections of foreign firms, importer inspections, port-of-entry examinations and sample collections, and laboratory analyses.	GAO, 2004b
	GAO recognizes that, short of reorganization, other improvements can be made to help reduce overlap and duplication and to leverage existing resources. For example, the FDA could use existing authority to commission USDA inspections of dual jurisdiction establishments.	GAO, 2005b
	If cost effective, we recommend that FDA, as authorized under the Bioterrorism Act, commission USDA inspectors to carry out inspections of FDA regulated foods at food establishments that are under their joint jurisdiction. We also recommend that USDA and FDA examine the feasibility and cost effectiveness of establishing a joint training program for their food inspectors.	GAO, 2005b
	To better use FDA's limited inspection resources and leverage USDA's resources and if appropriate and cost effective, the Commissioner of the FDA, as authorized under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, should enter into an agreement to commission USDA inspectors to carry out FDA's inspection responsibilities for food establishments that are under the jurisdiction of both agencies.	GAO, 2005c

TABLE B-1 Continued

Topic	Recommendations	Source
	To strengthen management controls and maximize the effectiveness of interagency agreements that are designed to reduce overlap, increase coordination, and leverage resources, the Secretary of Agriculture, the Commissioner of the FDA, the Administrator of the EPA, and the Under Secretary of Commerce for Oceans and Atmosphere should identify and inventory all active interagency food safety-related agreements.	GAO, 2005c
	To strengthen management controls and maximize the effectiveness of interagency agreements that are designed to reduce overlap, increase coordination, and leverage resources, the Secretary of Agriculture, the Commissioner of the FDA, the Administrator of the EPA, and the Under Secretary of Commerce for Oceans and Atmosphere should evaluate the need for these agreements and, where necessary, update the agreements to reflect recent legislative changes, new technological advances, and current needs.	GAO, 2005c
	To better use FDA's limited inspection resources and leverage National Marine Fisheries Service's (NMFS's) resources, the Commissioner of the FDA and the Under Secretary of Commerce for Oceans and Atmosphere should ensure the implementation of the interagency agreement that calls for FDA to recognize the results of NMFS inspections when determining the frequency of its seafood inspections.	GAO, 2005c
	FDA has opportunities to better leverage its resources.	GAO, 2008b
	Tools such as a commission or chief operating officer can help agencies to address management challenges.	GAO, 2008b
	The development of an interagency structure with a single focus on seafood safety could contribute significantly toward increasing communication within the federal regulatory system, but the responsibility for primary control should be with the state.	IOM, 1991

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	A more pronounced and consistently defined federal role in the risk characterizations leading to seafood health advisories should be developed.	IOM, 1991
	Effort should be made to improve coordination of federal guidance with that provided through partnerships at the state and local level.	IOM, 2007
	The FDA is responsible for the safety of most of the nation's food supply. To accomplish this formidable task, and still have the resources to tackle their other duties we believe that the inspection of low-risk food firms should be restructured. This restructuring is necessary because of the vital ongoing need to inspect low-risk food firms coupled with FDA' s need to devote more resources to their higher priorities.	OIG, 1991
	FDA should enhance its internal capacities to conduct effective oversight.	OIG, 2000
	We recommend that the federal government create two mechanisms to implement this new national policy: • FSII Council — Intergovernmental body composed of heads of federal food safety agencies and representatives of state and local food safety agencies — Coordinate and implement actions needed to fulfill FSII policy responsibilities • FSII Stakeholder Forum — Administrated by FSII Council, but led by third party, such as the National Academy of Sciences — No fixed membership, but a tool for convening the food safety community — Principle vehicle for dialogue and collaboration to enact improvements to FSII	Taylor and Batz, 2008

TABLE B-1 Continued

Topic	Recommendations	Source
	The CFSAN Review Committee (CRC) encourages the Center to move with dispatch to develop a strategic plan that provides clarity of mission and goals, and needed measures of accountability. Use of outside expertise to facilitate development and execution of the plan is advised. The plan must be devised so as to assure that: 1) CFSAN's regulatory programs are based on sound science and a risk assessment approach. 2) Management procedures are clearly stated and provide for accountability. 3) Determination of the appropriateness of various research activities can be easily determined. This strategic plan will benefit the Center in several ways. Most importantly, it will provide clear guidance for organization, management decisions and operational practices. Publicizing such a plan will also enhance the Center's credibility, particularly if progress in attaining the stated goals is evident. Additionally, this plan will, if developed with participation of the CFSAN staff, serve as the "blueprint" for the culture change the Center must bring about.	CRC/SB, 1999
	The subcommittee applauds the Office of Regulatory Affairs (ORA's) efforts in planning, futuring and visioning. Clearly ORA recognizes its need to change and is trying through a transparent and inclusive process to make and act on strategic choices that have far-reaching consequences. We wish to express our full support both for the vision and for the initial outline of implementation plans. However, these choices represent today's assessment and are based on assumptions about a future that is more and more difficult to predict. This describes a "strategy paradox" that is a reality today as organizations plan forward. The subcommittee encourages ORA to include more external experts to help them continue to assess driving forces and assumptions as they move forward to implement the Revitalization business cases and beyond. The subcommittee also encourages ORA to recognize the need to develop greater flexibility and to recruit skillful people to address future uncertainty and ambiguity, which is both an important strategy in itself and a emerging core competency.	FDA, 2008

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	To a certain extent, ORA has conducted a self-examination and finds itself knowing that it needs to change; creating plans and strategies for change; yet, also caught up in an antiquated system/processes along with an unsympathetic public and congress that breeds a parochialism and stymies innovation, imagination, and change. ORA is taking on a leadership role in their efforts to become more strategic and contemporary but must have the support, internally and externally, to achieve revitalization. Furthermore, the ORA Subcommittee believes that the ORA planning must not be fragmented or separate from the larger FDA efforts to change and build critical scientific foundation.	FDA, 2008
	The ORA review, like the larger FDA Science Board Review has especially focused on capacity and to some extent it is difficult to judge organizational efficiency in the context of the significant under-resourcing which exists. Yet it is clear from discussions with ORA management and staff that even if the resource gap were immediately addressed, ORA would not be performing optimally. ORA must be enabled as well as resourced to develop further the requisite skills, experienced leadership and scientific foundation for success. To achieve these ORA must be allowed to incorporate the best technologies by which to accomplish its mission, and must be culturally receptive to the aggressive change management initiative that is called for in their Revitalization Report. In addition, there is a special need to better quantify capacity. The subcommittee recommends that ORA evaluate capacity index systems that can better quantify personnel needs to build their scientific capacity. These systems are based on logic models that define critical outcomes and results, then uses these end points to inform strategic hires.	FDA, 2008

TABLE B-1 Continued

Topic	Recommendations	Source
	Congress should direct HHS to unify the management of FDA's food safety functions under a single official with direct access to the Secretary of HHS whose full-time job is food safety and who would have clear authority, responsibility, and accountability for leading HHS food safety activities.	Taylor and David, 2009
Prioritize Research	To enhance FDA's oversight of fresh produce safety, the Commissioner of FDA should see that the agency develop a plan for identifying research priorities and facilitating research related to fresh produce.	GAO, 2008a
	We recommend specific initiatives to improve the FSII: Conduct targeted analyses to identify knowledge and information gaps • utilize database of research to analyze trends, and • use "systematic reviews" to deeply examine specific knowledge areas. Initiate dialogue to prioritize information needs • engage community to identify research priorities.	Taylor and Batz, 2008
	CFSAN should carefully review research programs at field laboratories and deactivate those programs that are too feeble to be effective, or are improperly focused. Cost savings that accrue from a paring of these activities should be used to augment research programs in well-established CFSAN laboratories.	CRC/SB, 1999
	Research on antibiotic resistance of microorganisms is of major importance and should be carefully integrated in a cross-center effort. This subject is also of central importance to CVM and other centers.	CRC/SB, 1999

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	The FDA should develop an agency-wide plan for method development research. A strategic approach using defined criteria for priority setting should be adopted. This process should involve all relevant governmental centers both within and outside the FDA. All aspects of food safety should be addressed. A strategy should also be developed to prioritize the development of methods for detecting new agents of public health concern. Direct ties to overall program priorities and research plans should be in place.	CRC/SB, 1999
Review Inspection Approaches	CSPI has petitioned for FDA to adopt written food safety control plans for produce growers and consider the implementation of a third-party certification system for U.S. growers and processors to ensure that these plans and facilities are reviewed at least once per year.	CSPI, 2008
	We recommend that the Secretaries of Agriculture, Commerce, and HHS enter into agreements that require the agency most frequently visiting a food-processing plant to act as the lead federal inspection agency. The lead agency would perform the inspection tasks, if any, required by the other agencies and request plants to make changes to comply with all federal food safety laws and regulations. However, when necessary, the lead agency would refer continuing violations to the responsible regulatory agency to pursue corrective action in the courts. In addition, the agency with regulatory responsibility would retain primary responsibility and inspect plants when warranted, such as to respond to consumer complaints or to follow up on referrals made by other agencies.	GAO, 1992

TABLE B-1 Continued

Topic	Recommendations	Source
	To help ensure effective coordination between federal agencies with food safety and quality responsibilities, we recommend that the Secretaries of Agriculture, Commerce, and HHS evaluate and revise as necessary all current coordination agreements related to food safety and quality. Specifically, the Secretaries should direct the agency heads to revise the agreements, as necessary, to (1) define the responsibilities of each agency, (2) require the referral of firms with unsanitary food-processing conditions or unsafe food products to all agencies with regulatory oversight or grading responsibilities, (3) specify how and when referrals should be made, and (4) identify the individual or office to which referrals should be made. In addition, the Secretaries should direct the agency heads to periodically, but no less than annually, review their respective coordination agreements and update them when necessary.	GAO, 1992
	We also recommend that the FDA Commissioner and the Secretaries of the Departments of Agriculture and Commerce incorporate referral procedures into inspector manuals or handbooks to assist agency personnel in making referrals properly and in a timely manner.	GAO, 1992
	We recommend that the FDA Commissioner (1) develop a formal system to track referrals received from other agencies, (2) establish minimum times for follow-up action on referrals, and (3) periodically advise the referring agencies of the status of active referrals.	GAO, 1992
	The Commissioner of FDA should revise guidance to agency staff to include risk-based time frames for completing verification checks promptly.	GAO, 2005a
	To better use FDA's limited inspection resources and leverage NMFS's resources, the Commissioner of the FDA and the Under Secretary of Commerce for Oceans and Atmosphere should ensure the implementation of the interagency agreement that calls for FDA to recognize the results of NMFS inspections when determining the frequency of its seafood inspections.	GAO, 2005c

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	We recommend that FDA explore the potential for certifying third-party inspectors; consider accrediting private laboratories to test seafood; and develop a memorandum of understanding with NOAA to use NOAA's Seafood Inspection Program resources to complete inspections on FDA's behalf.	GAO, 2008b
	Inspection at the processing level is important to maintain safety of seafoods, but there is little evidence that increased inspection activities at this level would effectively reduce the incidence of seafoodborne disease.	IOM, 1991
	Federal agencies should develop a set of monitoring and inspection practices focusing more strongly on environmental conditions and on contaminant levels in the edible portion of seafood at the point of capture.	IOM, 1991

TABLE B-1 Continued

Topic	Recommendations	Source
	The FDA is responsible for the safety of most of the nation's food supply. To accomplish this formidable task, and still have the resources to tackle their other duties we believe that the inspection of low-risk food firms should be restructured. This restructuring is necessary because of the vital ongoing need to inspect low-risk food firms coupled with FDA' s need to devote more resources to their higher priorities. The FDA, working with the States, should develop and seek legislative authority for a system to inspect low-risk food firms based on the following principles: • There is a need for a complete and uniform system for inspecting low-risk food firms. • The FDA's role should be in oversight, developing standards, and providing technical assistance to the States. • And the States should have the responsibility for inspecting low-risk food firms. At a minimum, the system should include the following recommendations. • The FDA should design a uniform system that ensures both a systematic identification of all food firms and collection of inspection results. • The FDA should develop requirements for low-risk food safety inspections, and certify which States meet these requirements. • Certified States should conduct inspections of low-risk food firms. • The FDA should seek legislation to provide inspectors with the inspection tools necessary. • The FDA should collect an inspection user fee from all food firms. This user fee will fund all low-risk food safety inspection activities of both FDA and the States that meet FDA's certification requirements.	OIG, 1991
	FDA should reevaluate its reliance on the partnership agreements as a mechanism for conducting inspections.	OIG, 2000

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	FDA should work with states to achieve basic equivalency in food safety standards and laws, and in inspection programs and practices.	OIG, 2000
	FDA should devote high priority to improving its on-site audit mechanism for evaluating the effectiveness of state inspections.	OIG, 2000
	FDA should require that states routinely provide FDA with standardized information on the inspections they conduct.	OIG, 2000
	FDA should draw on multiple external sources of information in assessing state inspection performance.	OIG, 2000
	FDA should provide substantive and timely feedback to states on their inspection performance.	OIG, 2000
	FDA should increase public disclosure of its oversight of state food firm inspections.	OIG, 2000
	HHS/FDA, working in collaboration with state and local agencies, should develop and implement a plan for integrating and modernizing federal and state food manufacturing regulatory programs for facilities under FDA's jurisdiction.	Taylor and David, 2009
	HHS/FDA should make the full implementation of the Retail Food Regulatory Program Standards and the Manufactured Food Regulatory Program Standards a central component of its plan for building an integrated national food safety system and inspection program and should provide needed resources and incentives for state and local governments to participate.	Taylor and David, 2009
Risk-Based/ Science-Based Legislation	To provide more efficient, consistent, and effective federal oversight of the nation's food supply, Congress may wish to consider enacting comprehensive, uniform, and risk-based food safety legislation.	GAO, 2004a

TABLE B-1 Continued

Topic	Recommendations	Source
	To achieve a food safety system based on science, current statutes governing food safety regulation and management must be revised.	IOM/NRC, 1998
	Congress should change federal statutes so that inspection, enforcement, and research efforts can be based on scientifically supportable assessments of risks to public health.	
	Most current health risks associated with seafood safety originate in the environment and should be dealt with by control of harvest or at the point of capture. With minor exceptions, risks cannot be identified by an organoleptic inspection system.	IOM, 1991
Safety of Imports	CU has called for . . . the agency to develop operating plans for food processing facilities that insure safety, and for domestic and foreign food producers to be required to be certified as in compliance with these safety plans and with U.S. food safety standards.	Consumers Union, 2008a
	CSPI believes that a mandatory certification program is the best way to ensure the safety of imported food.	CSPI, 2008
	To strengthen FDA's current imported seafood program and ensure the safety of seafood consumed in the United States, the Commissioner of FDA should make it a priority to establish equivalence or other similar types of agreements with seafood-exporting countries, starting first with countries that have high-quality food safety systems.	GAO, 2004b
	While we recognize that third-party certification may in fact have a place in a robust food safety system, we urge FDA to remember that certification is not a guarantee of safety or a panacea for the problems that plague the agency. Certification programs may in fact be well-suited to certain commodities, and not all at useful for others. CSPI believes that both produce and imported FDA products may be appropriate for certification programs, provided that those programs are well-regulated and wisely implemented.	CSPI, 2008

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	To strengthen FDA's current imported seafood program and ensure the safety of seafood consumed in the United States, the Commissioner of FDA should develop and implement a system to track the time involved in documenting, reviewing, and processing regulatory and enforcement actions, such as issuing warning letters and detaining unsafe products, so that FDA can identify the reasons for the delays and take actions to address them.	GAO, 2004b
	To strengthen FDA's current imported seafood program and ensure the safety of seafood consumed in the United States, the Commissioner of FDA should give priority to taking enforcement actions when violations that pose the most serious public health risk occur.	GAO, 2004b
	To strengthen FDA's current imported seafood program and ensure the safety of seafood consumed in the United States, the Commissioner of FDA should consider the costs and benefits of implementing an accreditation program for private laboratories.	GAO, 2004b
	To strengthen FDA's current imported seafood program and ensure the safety of seafood consumed in the United States, the Commissioner of FDA should explore the potential of implementing a certification program for third-party inspectors, which would involve reviewing FDA's legal authorities and considering the costs and benefits, including developing and implementing the standards, controls, and oversight necessary to provide FDA with reasonable assurance that third-party inspectors are qualified and independent.	GAO, 2004b
	The Secretary of Agriculture and the Commissioner of the FDA should work together to consider the findings of USDA's foreign country equivalency evaluations when determining which countries to visit.	GAO, 2005c
	We recommended that FDA make it a priority to establish equivalence agreements with other countries.	GAO, 2008b

TABLE B-1 Continued

Topic	Recommendations	Source
	Because well over half the nation's seafood supply is imported and environmental contamination is globally pervasive, it is important that the safety of imported seafood be ensured through equivalent control measures in exporting countries.	IOM, 1991
	Consideration should be given to the development of agreements with foreign authorities and individual producers to ensure that imported products are treated in a manner consistent with and equivalent to domestic products.	IOM, 1991
	As more countries require the equivalency of domestic and imported products, it is apparent that the time has come for the international community to begin a process that would minimize the differences existing among national regulatory guidelines and approaches.	IOM, 1991
	The FDA should develop strategies to ensure the safety of imported seafood and produce by focusing on pathogen intervention strategies prior to shipment and on international harmonization of standards.	IOM/NRC, 2003
	We urge the FDA to 1) reconsider the advance notice time periods in the interim final rule to assure that the agency obtains information sooner about food imports so that suspect food imports can be adequately inspected, 2) require that a new prior notice must be submitted when there is any change in anticipated arrival information, particularly the port and time of arrival, and 3) assign FDA inspection personnel at all arrival ports, particularly those where high risk shipments may arrive.	CSPI, 2003
	CFSAN should be a world leader in establishing standards and procedures (reliable sampling procedures; rapid, accurate, and economical tests) for assuring the safety of foods crossing international boundaries. Safety when leaving the country of origin should be emphasized.	CRC/SB, 1999

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	We recommended that USDA and FDA, among other things, develop a coordinated strategy to identify resources needed to increase inspections of imported goods.	GAO, 2003
Safety of Imports —Pet Food	The ever-expanding recall of pet food containing contaminated ingredients from China demonstrates the immediate need for greater controls on imported foods, especially grain products originating from China. In light of the wheat and rice gluten problems, CSPI calls on the FDA to ban all grain imports from China until they can be certified by U.S. inspectors as free of illegal chemical or microbial contamination, including but not limited to pesticides, rat poison, and melamine. In addition, FDA should evaluate if the ban should extend to other foods or ingredients coming into the U.S. from China or any other country.	CSPI, 2007b
Science at the FDA	The FDA should institute a new scientific organization.	FDA, 2007
	The FDA must develop a program to manage "new science" that will provide a standardized approach to enable the FDA to address all emerging sciences and technologies.	FDA, 2007
	The FDA should create a distinctive research culture, take concrete steps to hire more high-quality scientific talent, and create better career ladders.	FDA, 2007
	FDA should develop and support a strong ongoing professional development program to ensure that staff maintains its scientific competence.	FDA, 2007
	The FDA must develop the capability to innovate in information science and technology to better support its regulatory mandate and more specifically to support regulatory activities for new science.	FDA, 2007
	Strengthen and organize the IT workforce to ensure that it can support the rapid evolution of the FDA information science and technology infrastructure.	FDA, 2007
	The FDA resource gap must be corrected to enable the Agency to fulfill its regulatory mandate.	FDA, 2007

TABLE B-1 Continued

Topic	Recommendations	Source
	An effective and efficient food safety system must be based on science.	IOM/NRC, 1998
	The FDA should expand research on risks associated with many specific practices in the fresh produce sector, and on the potential for and significance of internalization of pathogens into fresh produce.	IOM/NRC, 2003
	The FDA should work with industry to conduct research to assess the pathogen reduction efficacy of cheese manufacturing conditions and to develop science-based performance standards for reduction of targeted pathogens in finished cheese products.	IOM/NRC, 2003
	Postdoctoral and student intern programs are needed to expose researchers and management to new views and to provide the Center with an effective means for evaluating potential new hires.	CRC/SB, 1999
	Increasing the number of support personnel per scientist should be a high priority objective of management. The present number of support staff is woefully inadequate and not cost effective. The consequences are inefficient research and decreased employee morale.	CRC/SB, 1999
	Procedures for reviewing the performance of research personnel need to be carefully evaluated and redesigned. These reviews should occur on a regularly scheduled basis and should focus on matters of research productivity, quality, impact relevance to the CFSAN mission, and ability of the researcher to interact effectively with associates. These reviews, if properly conducted, can be a powerful tool for improving employee morale and effectiveness. This matter should be a high priority consideration by CFSAN management.	CRC/SB, 1999

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	The program for professional development should be greatly improved and expanded. This includes assuring that scientists regularly attend internal and external short courses in their areas of responsibility, attend at least one national or international scientific conference per year, have access to a sabbatical program, and are encouraged to accept adjunct faculty positions at universities. The successful adoption of these initiatives should strengthen CFSAN's research programs, improve employee morale, and improve the Center's ability to develop reasonable, effective regulations and to respond rapidly and effectively to public health emergencies.	CRC/SB, 1999
	CFSAN should strive to move from its current full-time equivalent-based budgeting practice to one that is program based. Without such a change, true costs, effectiveness and accountability of research programs cannot be meaningfully assessed.	CRC/SB, 1999
	CFSAN should prioritize its instrument purchases with great care.	CRC/SB, 1999
	CFSAN's laboratories should be certified.	CRC/SB, 1999
	Participation of CFSAN personnel in CODEX programs and other similar international programs is essential and should be continued.	CRC/SB, 1999
	Management should determine which aspects of research in chemical toxicology should be in CFSAN and which aspects can be provided by other governmental groups. Those aspects that support CFSAN's unique regulatory responsibilities should be strengthened in-house as well as through partnerships with other organizations. For example, CFSAN should consider partnering with, and in some cases depending on, state-of-the-art toxicology laboratories, such as FDA's National Center for Toxicological Research.	CRC/SB, 1999

TABLE B-1 Continued

Topic	Recommendations	Source
	CFSAN's microbial risk assessment program should be helping to establish improved Hazard Analysis and Critical Control Points protocols. CFSAN's in-house capability in microbial risk assessment should be enhanced with additional personnel and resources to help propel CFSAN toward a leadership role in this field. Partnering with other world experts, in the United States and other countries, should be considered to facilitate development of common methodologies and enable broader coverage. In addition to developing methodologies, a greater number of risk assessments should be performed annually to facilitate control of microbiological hazards. Methodologies for determining "acceptable" levels of risk for use in regulating microbial contaminants are also needed. Current partnerships with CDC and use of international data bases should continue to be emphasized, as should evaluation of risks from microbial contaminants in actual food matrices.	CRC/SB, 1999
	To use risk assessment appropriately in regulation, CFSAN should develop a public health-oriented approach to establish regulatory priorities for hazardous chemical and microbial agents. The priorities established should encompass the full food chain from pre-harvest to consumer. Because CFSAN alone does not have the mandate or resources to conduct a comprehensive assessment of public health, it should collaborate with other agencies.	CRC/SB, 1999
	The CRC endorses CFSAN's research activities to determine safe practices for new or modified food processes, but recommends that management regularly: (a) evaluate these projects for conformance to CFSAN priorities, progress and impact, and (b) determine for each project how the objectives can be achieved most effectively and efficiently, i.e., should the studies be conducted in-house, in collaboration with other groups, or by contract with other parties?	CRC/SB, 1999

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	CFSAN laboratory practices should conform to the principles of the Association of Analytical Communities Food Laboratory Accreditation Working Group. Consideration should also be given to achieving full International Organization for Standardization 25 accreditation for CFSAN laboratories.	CRC/SB, 1999
	A long-term strategic plan for dealing with critical issues related to food and nutrition should be developed. This plan should be based on public health needs as revealed by the National Nutrition Monitoring Programs.	CRC/SB, 1999
	The subcommittee also encourages ORA along with the entire FDA to further develop the discipline of regulatory science. The subcommittee meetings and discussions reinforced the uniqueness and importance of regulatory science as an intellectual field, and the subcommittee believes that ORA, together with the FDA Centers, must reinforce this regulatory science identity by championing risk ~~b~~ased programs, risk assessments, evidence ~~b~~ased policy and regulation, and knowledge management among other disciplines in order to successfully work in a world of greater uncertainty. These skills and activities need to be paralleled by the development of stronger analytical skills in decision ~~m~~aking. We understand that this discipline is still in a formative stage but encourage ORA to help lead the further maturation and use of regulatory science across FDA.	FDA, 2008
Science at the FDA —Contaminants	More complete data are needed on the distribution of contaminant levels among types of fish.	IOM, 2007
	More quantitative characterization is needed of the dose-response relationships between chemical contaminants and adverse health effects, in the ranges of exposure represented in the general U.S. population.	

TABLE B-1 Continued

Topic	Recommendations	Source
	The committee recommends more research on useful biomarkers of contaminant exposures and more precise quantitative characterization of the dose-response relationships between chemical contaminants and adverse health effects, in the ranges of exposure represented in the general U.S. population, in order to reduce uncertainties associated with recommendations for acceptable ranges of intake.	IOM, 2007
	Develop cost-effective analytical methods and reevaluate the use of toxicity equivalents in assessing DLC exposure.	NRC, 2003
	To move effectively toward reducing human exposure to DLCs through food, the federal government should begin by pursuing the following strategic courses of action: (1) establish an integrated risk management strategy and action plan, (2) foster collaboration between the government and the private sector to reduce DLCs in the food supply, and (3) invest in the data required for effective risk management.	NRC, 2003
	Increase research efforts on the effects of dietary DLCs on fetuses and breastfeeding infants.	NRC, 2003
	Develop predictive modeling tools and apply them in studies to assess the effects of potential interventions on reducing DLCs in the food supply.	NRC, 2003
	CFSAN should carefully monitor the activities of the private sector, other governmental agencies, and academia in developing rapid methods for specific pathogens, toxins and chemicals and enter into collaborative arrangements when these are feasible and effective. Management should also identify and prioritize the individual microorganism or toxin for which rapid methods are most needed and communicate these priorities to potential developers in the private sector to help avoid duplication of effort.	CRC/SB, 1999
Science at the FDA —Contaminants in Feed	Increase research efforts aimed at removing DLCs from animal forage and feed.	NRC, 2003

continued

TABLE B-1 Continued

Topic	Recommendations	Source
Science at the FDA—Food Animals	The committee recommends that CVM continue procedural reform to expedite the drug approval review process and broaden its perspective on efficacy and risk assessment to encompass review of data on products already approved and used elsewhere in the world.	NRC, 1999
	The committee recommends that, to improve drug availability [for food animals], worldwide harmonization of requirements for drug development and review be considered and further enhanced among the federal agencies that are responsible for ensuring the safety of the food supply.	NRC, 1999
	The committee recommends that CVM base drug use guidelines on maximal safe dosage regimens for specific food animals, consider greater emphasis on the pharmacokinetics of drug elimination from tissues that are consumed in large quantity, and set drug withdrawal times accordingly.	NRC, 1999
	The committee recommends establishment of integrated national databases to support a rational, visible, science-driven decision-making process and policy development for regulatory approval and use of antibiotics in food animals, which would ensure the effectiveness of these drugs and the safety of foods of animal origin.	NRC, 1999
	The committee recommends that further development and use of antibiotics in both human medicine and food-animal practices have oversight by an interdisciplinary panel of experts composed of representatives of the veterinary and animal health industry, the human medicine community, consumer advocacy, the animal production industry, research, epidemiology, and the regulatory agencies.	NRC, 1999
	The committee recommends increased funding for basic research that explores and discovers new or novel antibiotics and mechanisms of their action, including the development of more rapid and wide-screen diagnostics to improve the tracking of emerging antibiotic resistance and zoonotic disease.	NRC, 1999

TABLE B-1 Continued

Topic	Recommendations	Source
Science at the FDA—Seafood	New tools apart from traditional safety assessments should be developed, such as consumer-based benefit-risk analyses. A better way is needed to characterize the risks combined with benefit analysis.	IOM, 2007
	A consumer-directed decision path needs to be properly designed, tested, and evaluated. The resulting product must undergo methodological review and update on a continuing basis. Responsible agencies will need to work with specialists in risk communication and evaluation, and tailor advice to specific groups as appropriate.	IOM, 2007
	Research is needed on systematic surveillance studies of targeted subpopulations.	IOM, 2007
	Sufficiently large analytic samples of the most common seafood types need to be obtained and examined.	IOM, 2007
	Additional data is needed to assess benefits and risks associated with seafood consumption within the same population or population subgroup.	IOM, 2007
	Future epidemiological studies should assess intake of specific species of seafood and/or biomarkers, in order to differentiate the health effects of eicosapentaenoic acid/docosahexaenoic acid from the health effects of contaminants such as methylmercury.	IOM, 2007
	More complete data are needed on the distribution of contaminant levels among types of fish.	IOM, 2007
	More quantitative characterization is needed of the dose-response relationships between chemical contaminants and adverse health effects, in the ranges of exposure represented in the general U.S. population.	IOM, 2007

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	The committee recommends more research on useful biomarkers of contaminant exposures and more precise quantitative characterization of the dose-response relationships between chemical contaminants and adverse health effects, in the ranges of exposure represented in the general U.S. population, in order to reduce uncertainties associated with recommendations for acceptable ranges of intake.	IOM, 2007
	Research is needed to develop and evaluate more effective communication tools for use when conveying the health benefits and risks of seafood consumption as well as current and emerging information to the public.	IOM, 2007
	Among federal agencies there is a need to design and distribute better consumer advice to understand and acknowledge the context in which the information will be used by consumers.	IOM, 2007
Sharing Information/ Interagency Collaboration	The FDA should strengthen its collaboration across Centers and with other government agencies. It should appoint a Director of External Collaborations to administer a competitive external grants program.	FDA, 2007
	To more efficiently and effectively monitor the safety of imported seafood, the Secretary of HHS should direct the Commissioner of FDA to work toward developing a memorandum of understanding with NOAA that leverages NOAA's Seafood Inspection Program's resources. The memorandum of understanding should address mutually agreeable protocols and training programs that are necessary to begin using NOAA employees to provide various services. Those services could include inspections of foreign firms, importer inspections, port-of-entry examinations and sample collections, and laboratory analyses.	GAO, 2004b

TABLE B-1 Continued

Topic	Recommendations	Source
	The Secretary of Agriculture and the Commissioner of FDA should work together to ensure the implementation of the interagency agreement that calls for, among other things, sharing inspection- and enforcement-related information at food-processing facilities that are under the jurisdiction of both agencies.	GAO, 2005c
	To foster transparency and accountability, the Commissioner of FDA should provide specific information to the Congress and to the public on the strategies and resources for implementing the Food Protection Plan.	GAO, 2008a
	To enhance FDA's oversight of fresh produce safety, the Commissioner of FDA should see that the agency identify approaches for obtaining testing and other information from industry members to inform its research agenda.	IOM, 1991
	The development of an interagency structure with a single focus on seafood safety could contribute significantly toward increasing communication within the federal regulatory system, but the responsibility for primary control should be with the state.	IOM, 1991
	A more concise, comprehensive, and generally available single source for all FDA guidelines relating to seafood safety should be developed and updated on a regular basis. This information should be disseminated to industry and integrated into state regulatory processes through more routine and uniform training programs.	IOM, 1991
	Congress should provide the agency responsible for food safety at the federal level with the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety.	IOM/NRC, 1998

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	Partnerships should be formed between federal agencies and community organizations. This effort should include targeting and involvement of intermediaries, such as physicians, and use of interactive Internet communications, which have the potential to increase the usefulness and accuracy of seafood consumption communications.	IOM, 2007
	Effort should be made to improve coordination of federal guidance with that provided through partnerships at the state and local level.	IOM, 2007
	The CRC endorses research collaboration among various groups with interests in food safety practices and regulations, provided these collaborations have been determined to be the most effective and efficient approaches available. Factors that should be considered when contemplating collaboration include availability of appropriate personnel, equipment, and facilities; cost effectiveness of various alternative options, and likely long-term effectiveness of the partnership.	CRC/SB, 1999
	Research should not duplicate that which is being conducted elsewhere, and partners should be sought whenever appropriate and possible. For example, the CRC noted that research on soy products and their effects is currently underway at Iowa State University, University of Illinois, Loma Linda University and other institutions. Thus, work at these institutions should not be duplicated by CFSAN.	CRC/SB, 1999
	By the nature of its mission ORA's work is increasingly more reliant on partners and collaborations, including various stakeholders within and outside of the FDA. The extensive collaboration among federal, state inspection and increasingly foreign regulatory agencies is already impressive. The subcommittee encourages ORA to continue expend the time, energy, and resources necessary to build and secure greater collaboration locally, statewide, across other federal agencies outside FDA and globally.	FDA, 2008

TABLE B-1 Continued

Topic	Recommendations	Source
	Congress should establish and fund an intergovernmental Food Safety Leadership Council to foster federal-state-local collaboration in the design and implementation of an integrated national food safety system.	Taylor and David, 2009
	The Secretary, in consultation with the Food Safety Leadership Council and in collaboration with appropriate professional organizations, should conduct a survey of the current food safety capacities of state and local agencies—including staffing and skill levels, laboratory capacities, information systems, legal authorities, and organizational arrangements—and, on the basis of the survey, identify and prioritize capacity building and other state and local needs that must be met to fulfill their roles in the national food safety system.	Taylor and David, 2009
	Congress should direct HHS to develop, based on the capacity survey and consultations with the Food Safety Leadership Council, a 5-year plan for better integrating federal, state, and local food safety efforts and improving state and local capacity for that purpose. The integration plan should be based on mutually agreed criteria and benchmarks for such matters as timeliness of outbreak investigations, frequency of retail inspection, food safety staffing and skill levels, laboratory capacity, and information systems.	
	State and local governments should better integrate their own surveillance, outbreak response, and food safety regulatory and inspection activities, and each state should establish a focal point for better linking and integrating the state's food safety activities with the national system.	Taylor and David, 2009
	State and local governments should collaborate on the development and widespread adoption of a model state and local food safety law that addresses all aspects of state and local roles in food safety, modernizes food safety regulatory laws to adopt a more preventive and risk-based approach, clarifies the roles of state and local agencies in a more integrated system, and legally empowers state and local agencies to work more collaboratively among themselves and with the federal government.	

continued

TABLE B-1 Continued

Topic	Recommendations	Source
	HHS, working through CDC and FDA and in collaboration with states and localities, should establish a network of regional, federally-funded foodborne outbreak response centers to ensure an integrated "systems" approach to outbreak response and follow-up investigations. The centers would be staffed fulltime with a multi-disciplinary team of federal, state, and local epidemiologists, environmental health experts, regulatory officials, and food safety communicators (all federally funded) for purposes of: (1) supporting state and local agencies in their day-to-day foodborne illness surveillance and response activities; (2) improving the thoroughness and timeliness of outbreak detection, response, and follow-up investigation to inform future prevention; and (3) establishing the relationships, expertise, continuity, and surge capacity needed to ensure well-coordinated and effective response to major outbreaks.	Taylor and David, 2009
	HHS, in consultation with the Food Safety Leadership Council and working with states and localities, should establish protocols for managing multi-state outbreaks, including clear definition of federal, state, and local roles; mechanisms for collaboration; and criteria for triggering federal-level management of outbreaks.	Taylor and David, 2009
Training	The Secretary of Agriculture and the Commissioner of FDA should work together to examine the feasibility of establishing a joint training program for food inspectors.	GAO, 2005c
	All personnel should be fully cognizant of the goals of their program. Each project should undergo a formal review annually and be evaluated for progress, current priority status, and likelihood that continuation will lead to success.	CRC/SB, 1999
	We also recommended that both agencies provide training for all field personnel to enhance their awareness and ability to discuss security measures with plant personnel.	GAO, 2003

TABLE B-1 Continued

Topic	Recommendations	Source
	HHS, in collaboration with the Food Safety Leadership Council, should establish a Food Safety Leadership and Training Institute focused on building among food safety professionals at all levels a common vision for the nation's food safety system and the leadership skills, network of relationships, and trust needed for an integrated system to succeed.	Taylor and David, 2009

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Appendix C

Food Safety Systems in the United States and Other Countries

TABLE C-1 United States: Food and Drug Administration

1	Country population	307,446,061 (U.S. Census Bureau, 2009)
2	Name of organization	U.S. Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services
3	Year created	Although it was not known by its present name until 1930, the FDA's modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act, a law a quarter century in the making that prohibited interstate commerce in adulterated and misbranded food and drugs (FDA, 2009a).
4	Legislation	The FDA is 1 of 15 agencies that collectively administer at least 30 laws related to food safety (GAO, 2008a). Its responsibilities are outlined primarily in the Federal Food, Drug, and Cosmetic Act of 1938 and its amendments, as well as (1) the Federal Food and Drugs Act of 1906, (2) the Federal Meat Inspection Act, (3) the Federal Trade Commission Act, (4) the Filled Milk Act, (5) the Import Milk Act, (6) the Reorganization Plan 1 of 1953, (7) the Poultry Products Inspection Act, (8) the Fair Packaging and Labeling Act, (9) the Controlled Substances Act, (10) the Egg Products Inspection Act, (11) the Sanitary Food Transportation Act, (12) the Bioterrorism Act of 2002, and (13) the Federal Anti-Tampering Act (FDA, 2009b,c,d).

continued

TABLE C-1 Continued

5	Budget	The FDA requests a total budget of $3.2 billion under the President's fiscal year (FY) 2010 budget. This increase reflects an additional $259.3 million for Protecting America's Food Supply; added to the $662 million for FY 2009, the proposed total for food safety at the FDA is $921.3 million in FY 2010. Within this initiative, the FDA proposes to collect a total of $94.4 million in new user fees to register food facilities and increase food inspections, issue food and feed export certifications, and reinspect food facilities that fail to meet its safety standards (FDA, 2009e).
6	Number of employees for food	The estimated full-time equivalents (FTEs) for FY 2010 are • 947 FTEs in the Center for Food Safety and Applied Nutrition (CFSAN), • 456 FTEs in the Center for Veterinary Medicine (CVM), • 4,365 FTEs in the Office of Regulatory Affairs (ORA) (Of those 4,365, there is no specific number of FTEs dedicated to food safety [FDA, 2009f]. The FY 2010 budget stipulates 678 FTEs dedicated to Protecting America's Food Supply [FDA, 2009e]), and • 1,062 FTEs inspecting food (Givens, 2009).
7	Definition of "food"	The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article (21 U.S.C. 321, 1938, Federal Food, Drug, and Cosmetic Act, Section 201, Chapter II, "Definitions").
8	Items regulated	The agency as a whole regulates biologics, cosmetics, drugs, foods, medical devices, radiation-emitting electronic products, and veterinary products (FDA, 2009g). Recently, tobacco products were added to this list. As for food products, the FDA regulates all foods exchanged through interstate commerce or imported, with the exception of meat, poultry, and egg products, all of which are in the domain of the U.S. Department of Agriculture (USDA).

TABLE C-1 Continued

9	Organization	The FDA has three offices dedicated to food safety: CFSAN, which is responsible for the regulation of human food products; CVM, which is responsible for the regulation of animal food (feed) products; and ORA, which is the lead office for all FDA product-regulating offices: • CFSAN's food responsibilities include the safety of foods, both domestic and imported, encompassing food and color additives; biotechnologically developed foods; regulations governing seafood and juice Hazard Analysis and Critical Control Points (HACCP), dietary supplements, infant formula, and food labels; industry and consumer education and outreach; postmarket surveillance; international food standards and safety harmonization efforts; and regulatory and research programs to address health risks associated with foodborne, chemical, and biological contaminants. • CVM regulates the manufacture and distribution of food additives and drugs to be given to animals, including animals from which human foods are derived and pet (or companion) animals. CVM is responsible for regulating drugs, devices, and food additives given to or used on more than 100 million companion animals, plus millions of poultry, cattle, swine, and minor animal species. • ORA supports the five FDA product centers by inspecting regulated products and manufacturers, conducting sample analysis on regulated products, and reviewing imported products offered for entry into the United States. ORA also develops FDA-wide policy on compliance and enforcement and executes the FDA's Import Strategy and Food Protection Plans. ORA has offices across the United States and works with state, local, territorial, and tribal officials and sometimes funds grants and cooperative agreements with these officials (FDA, 2009b).
10	Regulation of on-farm activity	The FDA has had minimal involvement in on-farm regulation. However, it appears that the FDA has the authority to regulate at least some on-farm activities related to other food products under the Federal Food, Drug, and Cosmetic Act[a] and the Public Health Service Act.[b] In 2004, the FDA issued a proposed rule governing safety procedures for shell eggs, which would be its first comprehensive on-farm regulation. Legislative proposals, including HR912, HR3624, HR5620, HR5904, HR6581, S2077, and S3385, also address the FDA's role on farms (Burrows, 2008; Becker, 2009).

continued

TABLE C-1 Continued

11	Risk-based policies, models, use of Hazard Analysis and Critical Control Points (HACCP), etc.	HACCP is in place for juice and seafood. The FDA has some programs that it calls "risk-based." See Chapters 1, 2, 3, and 4 for a full discussion of the FDA's risk-based programs.
12	Inspections (domestic)	There are currently 1,062 FTEs who inspect food products. These FTEs are also responsible for inspection of other FDA-regulated products (Givens, 2009). CFSAN sets the food establishment inspection priorities on an annual basis. Districts give priority to an inspection based on local intelligence such as compliance follow-ups, complaint follow-ups, positive analytical results, and referrals from other federal and state stakeholders (Givens, 2009). The FDA contracts out many inspections to the states: 42 contracts, more than 10,500 inspections/year for food safety; 35 contracts, more than 5,000 inspections/year for feed and bovine spongiform encephalopathy; 18 contracts, 635 inspections/year for tissue residue. With a focus on public health outcomes, items are ranked into categories of "higher-," "medium-," or "lower-" risk based on the likelihood that a hazard in a product consumed/used will cause a health effect and the severity of that health effect (Solomon, 2009). A U.S. Government Accountability Office (GAO) report states that field-based staff responsible for carrying out inspection and enforcement activities for CFSAN-regulated products dropped by 255 staff years, or about 11.5 percent, from 2,217 in FY 2003 to 1,962 in FY 2006 (GAO, 2008a).
13	Imports	All FDA-regulated products are subject to inspection when they are being imported into the United States. Formal equivalence, or a formal determination that the exporting country has a food safety program equal to that of the United States, is not in place. Procedures vary by product. From 2001 to 2007, foreign inspections declined: GAO analysis of FDA data shows that inspections of foreign food firms, which number almost 190,000, decreased from 211 in FY 2001 to fewer than 100 in FY 2007 (GAO, 2008a).

TABLE C-1 Continued

14	Disease surveillance	The U.S. Centers for Disease Control and Prevention (CDC) is responsible for tracking individual foodborne illnesses and investigating outbreaks of foodborne illness (CDC, 2009a). For a complete list of CDC's food safety activities, see http://www.cdc.gov/foodsafety/activities.html (accessed September 21, 2009). The FDA, USDA's Food Safety and Inspection Service, CDC, and nine state health departments participate in FoodNet, which provides a network for responding to new and emerging foodborne illnesses of national importance, monitoring the burden of foodborne illnesses, and identifying the sources of such illnesses (CDC, 2009b). For a complete discussion, see Chapter 5.
15	Recall authority	Currently, the FDA lacks mandatory recall authority and relies on voluntary recalls with the participation and cooperation of the manufacturer. The FDA's Food Protection Plan and several bills[c] propose that the FDA be granted mandatory recall authority for foods (FDA, 2007; Hogan and Hartson, 2009). For a complete discussion, see Chapter 10.
16	Other U.S. regulatory agencies with responsibilities for foods	Customs and Border Protection, CDC, U.S. Department of Justice, Environmental Protection Agency, Federal Trade Commission, Library of Congress, National Library of Medicine under the National Institutes of Health, National Oceanic and Atmospheric Administration/National Marine Fisheries Service under the U.S. Department of Commerce, state and local governments, USDA (see Table C-2), U.S. Department of Homeland Security, and U.S. Department of Treasury/Bureau of Alcohol, Tobacco, and Firearms. See Table 2-1 in Chapter 2 for a complete discussion of these agencies' roles.
17	Why was there a migration to a single food agency?	Not applicable
18	How is a single food agency working?	Not applicable
19	Program evaluation	GAO, FDA Performance Budget. See Chapters 1, 2, 3, and 4 for a complete discussion.
20	Research function	See Chapter 6 for a complete discussion.

continued

TABLE C-1 Continued

21	Communication	See Chapter 9 for a complete discussion.
22	Education	The FightBAC! Program is a joint project of the FDA, USDA, EPA, and CDC funded by the contributions of industry trade and professional associations, grants, and technical assistance and in-kind support provided by government agencies and consumer organizations (PFSE, 2006). See Chapter 9 for a complete discussion.

[a] *Federal Food, Drug, and Cosmetic Act*, Public Law 75-717, 75th Cong., 3rd sess. (June 24, 1938). Title 21 U.S. Code, Section 9.
[b] *Public Health Service Act*, Public Law 78-410, 78th Cong., 2nd sess. (July 1, 1944).
[c] HR759, *Food and Drug Administration Globalization Act of 2009*, 11th Cong.

TABLE C-2 United States: Department of Agriculture/Food Safety and Inspection Service

1	Country population	307,446,061 (U.S. Census Bureau, 2009)
2	Name of organization	U.S. Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS)
3	Year created	An 1884 act established the Bureau of Animal Industry, the true forerunner of FSIS. In 1977, the Food Safety and Quality Service (FSQS) was established and was assigned the responsibility for inspection of meat and poultry products from the Animal and Plant Health Inspection Service (APHIS). Finally, in 1981, FSQS was redesignated as FSIS (FSIS, 2007a).
4	Legislation	FSIS operates under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, in addition to Executive Orders, small business protection laws, and other guidance applicable to all federal agencies (FSIS, 2007b).
5	Budget	$972 million in fiscal year 2009 (Thompson, 2009).
6	Number of employees for food	FSIS's 9,500 employees include approximately 7,800 inspection program personnel, who are assigned to approximately 6,200 federal slaughter, food processing, and import establishments (FSIS, 2008a).
7	Definition of "food"	See Table C-1, row 7.
8	Items regulated	Meat, poultry, and egg products. Catfish is a recent addition.

TABLE C-2 Continued

9	Organization	Ten offices make up FSIS (FSIS, 2009a): • Office of the Administrator—works closely with the rest of FSIS to achieve FSIS goals regarding food safety awareness and education. • Office of Data Integration and Food Protection (formerly the Office of Food Defense and Emergency Response)—coordinates and manages all homeland security activities within FSIS. It also houses the Data Analysis and Integration Group, which coordinates the agency's data collection, analysis, and integration activities across all program areas. • Office of Field Operations—manages a nationwide program of inspection and enforcement activities regarding meat, poultry, and egg products. • Office of International Affairs—provides leadership in international food safety activities. • Office of Management—provides a full range of administrative and support services to FSIS. • Office of Outreach, Employee Education and Training—provides consolidated access, resources, and technical support for small and very small plants to better assist them in providing safe and wholesome meat, poultry, and processed egg products. • Office of Public Affairs and Consumer Education (formerly the Office of Public Affairs, Education, and Outreach)—is responsible for conducting public programs to inform, educate, and work with a variety of audiences. • Office of Program Evaluation, Enforcement and Review—is responsible for assessing program functions and operations under FSIS. • Office of Policy and Program Development (formerly the Office of Policy, Program and Employee Development)—develops and makes recommendations concerning all domestic and international policy for FSIS. • Office of Public Health Science—provides scientific analysis, advice, data, and recommendations regarding matters involving public health and science that are of concern to FSIS.
10	Regulation of on-farm activity	FSIS officials have stated that the laws governing the agency provide no direct authority to regulate on-farm activity (Becker, 2009).
11	Risk-based policies, models, use of Hazard Analysis and Critical Control Points (HACCP), etc.	In order for a state to be approved for a Federal Grant of Inspection, it must provide a written hazard analysis and HACCP plan (FSIS, 2008b). USDA utilizes "public health–based inspection" (FSIS, 2008b).

continued

TABLE C-2 Continued

12	Inspections (domestic)	There are approximately 7,800 inspection program personnel, who are assigned to approximately 6,200 federal slaughter, food processing, and import establishments (FSIS, 2008a). FSIS inspects and monitors all meat, poultry, and egg products sold in interstate and foreign commerce to ensure compliance with mandatory U.S. food safety standards and inspection legislation. States can apply to operate under a cooperative agreement with FSIS; these programs must enforce requirements "at least equal to" those imposed under the Federal Meat and Poultry Products Inspection Acts (the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act), and their inspection is limited to products sold in intrastate commerce (FSIS, 2009b). Slaughter facilities and processing plants are inspected continuously and daily, respectively. FSIS also conducts a small number of in-commerce inspections (NRC, 2009).
13	Imports	USDA enforces the concept of equivalence, whereby imported meat, poultry, and egg products must originate in countries eligible to export to the United States and establishments certified by the foreign government as eligible. Once eligibility is established, the APHIS animal health restrictions determine the specific types of products that can be imported from the country (FSIS, 2008c).
14	Disease surveillance	See Table C-1, row 14.
15	Recall authority	Currently, FSIS lacks mandatory recall authority and relies on voluntary recalls with the participation and cooperation of the manufacturer. If a company refuses to recall its products, FSIS has the legal authority to detain and seize those products in commerce (FSIS, 2009c).
16	Other regulatory agencies with responsibilities for foods	See Table C-1, row 16.
17	Why was there a migration to a single food agency?	Not applicable
18	How is a single food agency working?	Not applicable

TABLE C-2 Continued

19	Program evaluation	FSIS is subject to U.S. Government Accountability Office reporting, and the agency itself has an Office of Program Evaluation and Improvement Staff, which formulates evaluation plans and conducts evaluations of existing and proposed programs, program components, inspection methods, and agency policies, directives, and regulations (FSIS, 2009d).
20	Research function	FSIS has laboratories that support its food safety mission, but these appear to be mainly, if not entirely, intended to detect foodborne hazards and chemical contamination. The agency also conducts risk assessments on a variety of threats, including, for example, *E. coli*, bovine spongiform encephalopathy, and avian influenza (FSIS, 2009e). The agency also conducts research on consumer response to and effectiveness of FSIS food safety campaigns. The Agricultural Research Service (ARS), not FSIS, is the principal in-house scientific research agency of USDA. Recent ARS food safety projects include research on treating fresh produce with cold plasma (to protect the produce from potentially dangerous microbes such as *Salmonella*, *Listeria*, and *E. coli* O157:H7) and research on food irradiation (FSIS, 2009f).
21	Communication	In 2008, FSIS launched a series of podcasts on food safety and education issues for consumers and stakeholders (FSIS, 2008d).
22	Education	Programs (FSIS, 2009g, 2010) include Be Food Safe, Thermy™, Fight BAC!®, the USDA Food Safety Mobile, Is It Done Yet?, and National Food Safety Education Month®. Also see Table C-1, row 22.

TABLE C-3 Canada

1	Country population	33,787,563 (Statistics Canada, 2009)
2	Name of organization	There are two organizations in Canada that together are responsible for food safety: • Health Canada—establishes policies and standards related to the safety and nutritional quality of food sold in Canada. • Canadian Food Inspection Agency (CFIA)—provides all federal inspection services related to food, and enforces the food safety and nutritional quality standards established by Health Canada (Health Canada, 2009). This table focuses primarily on CFIA.

TABLE C-3 Continued

3	Year created	1996 (Bakvis, 1997)
4	Legislation	CFIA is responsible for the administration and enforcement of the following 14 acts (CFIA, 2009a): • Agriculture and Agri-Food Administrative Monetary Penalties Act • Appropriation Acts • Canada Agricultural Products Act • Canadian Food Inspection Agency Act • Consumer Packaging and Labelling Act (as it relates to food) • Feeds Act • Fertilizers Act • Fish Inspection Act • Food and Drugs Act (as it relates to food) • Health of Animals Act • Meat Inspection Act • Plant Breeders' Rights Act • Plant Protection Act • Seeds Act
5	Budget	Food safety spending in fiscal year (FY) 2003 was $Canadian 360 million ($US 232 million). User fees for food inspections have been frozen at about $Canadian 40 million (about $US 26 million) since 1997 and in FY 2003 accounted for about 11 percent of CFIA's food safety spending (GAO, 2005).
6	Number of employees for food	There are a total of 7,053 CFIA staff—4,610 Inspection Staff and 3,228 Inspectors/Field Inspection Staff (CFIA, 2009b)
7	Definition of "food"	Includes any article manufactured, sold, or represented for use as food or drink for human beings; chewing gum; and any ingredient that may be mixed with food for any purpose whatever (CFIA, 2009c).
8	Items regulated	CFIA regulates all food products for humans and animals, veterinary biologics, plant seeds, fertilizers, and crops (CFIA, 2009d,e,f).
9	Organization	CFIA is responsible for all food safety inspections and related activities, including inspections of imported and domestic products, export certifications, laboratory and diagnostic support, crisis management, and product recalls. CFIA is also responsible for food quality assurance inspections and animal health and plant disease control (GAO, 2005).

TABLE C-3 Continued

10	Regulation of on-farm activity	The agricultural community has worked with CFIA and Agriculture and Agri-Food Canada to develop on-farm food safety programs and to establish a process through which these programs can be officially recognized by CFIA for technical soundness and administrative effectiveness (COFFS Working Group, 2009).
11	Risk-based policies, models, use of Hazard Analysis and Critical Control Points (HACCP), etc.	The Food Safety Enhancement Program is CFIA's approach to encourage and support the development, implementation, and maintenance of HACCP systems in all federally registered establishments (CFIA, 2009g).
12	Inspections (domestic)	There are approximately 3,000 inspectors across all business lines (GAO, 2008b). Restaurant and food service inspection across Canada is generally carried out by provincial governments, municipalities, or regional health authorities (CFIA, 2009h).
13	Imports	All food products imported into Canada must meet Canadian food safety requirements. Importers are responsible for the safety of foods they import into Canada. There are additional provisions for certain products (for example, meat and fish) that have been assessed as potentially presenting higher levels of risk because of the hazards commonly associated with those products (e.g., microbial concerns, veterinary drugs), combined with high volumes of consumption and trade. Other products (eggs, dairy products, and processed fruits and vegetables) must meet equivalence requirements. Inspection frequencies are adjusted to reflect the history of compliance associated with importers and products (CFIA, 2009i).
14	Disease surveillance	Public Health Agency of Canada and Health Canada are responsible for disease surveillance (GAO, 2008b).
15	Recall authority	When the Minister of Agriculture and Agri-Food believes that an item poses a risk to public, animal, or plant health, he/she can, under the Canadian Food Inspection Agency Act, order a company to recall a product (CFIA, 2009j).
16	Other regulatory agencies with responsibilities for foods	Health Canada (see row 2 above)

continued

TABLE C-3 Continued

17	Why was there a migration to a single food agency?	To improve effectiveness (e.g., consistency of inspections, clarification of responsibilities), to improve efficiency by reducing duplication and overlap in food safety activities, and to reduce federal spending (GAO, 2005).
18	How is a single food agency working?	Financial savings, reduced overlap in inspections, and clearer responsibilities, better coordination, and reduced gaps in oversight have resulted (GAO, 2005).
19	Program evaluation	CFIA is required to produce a Corporate Business Plan at least once every 5 years. It also produces a *Departmental Performance Report*, which evaluates how well the agency's *Report on Plans and Priorities* has been fulfilled (CFIA, 2009k).
20	Research function	Health Canada sets public health policy, conducts research and risk assessments, and sets limits on the amount of a substance that is allowed in a food product (GAO, 2005).
21	Communication	Canadian Consumer Information Gateway,[a] Canadian Partnership for Consumer Food Safety Education,[b] and Health Canada[c]
22	Education	Canadian Partnership for Consumer Food Safety Education[d]

[a] See http://consumerinformation.ca/ (accessed September 22, 2009).
[b] See http://www.befoodsafe.ca (accessed September 22, 2009).
[c] See http://www.hc-sc.gc.ca (accessed September 22, 2009).
[d] See http://www.befoodsafe.ca (accessed September 22, 2009).

TABLE C-4 Australia

1	Country population	21,779,000 (Australian Bureau of Statistics, 2009)
2	Name of organization	Food Standards Australia New Zealand (FSANZ)
3	Year created	1991 (FSANZ, 2009a)
4	Legislation	FSANZ Act of 1991
5	Budget	During the 2007–2008 fiscal year, operating revenue from the Australian and New Zealand governments was $22.113 million, and operating expenses were $22.098 million, resulting in an operating surplus of $0.015 million (FSANZ, 2008a).

TABLE C-4 Continued

6	Number of employees for food	158 (FSANZ, 2008a)
7	Definition of "food"	"Food" includes anything one eats or drinks, such as processed food, uncooked food, airline food, snacks, ingredients (e.g., herbs, spices), and food supplements (AQIS, 2009).
8	Items regulated	FSANZ is an independent binational organization responsible for developing food standards. In Australia, FSANZ works with Australian Commonwealth, state and territory, and nongovernmental organizations to protect the health and safety of Australians through the maintenance of a safe food supply. The agency itself is not responsible for enforcement (FSANZ, 2009b).
9	Organization	FSANZ is part of the Australian government's Health and Ageing portfolio. It has offices in Australia and Wellington, New Zealand, and develops and maintains food standards (regulations) for Australia and New Zealand. In Australia, it is responsible for developing food safety measures for the handling of food, including food production and processing in the primary industries, and coordinating national surveillance activities and a national food recall scheme. The agency is governed by a board with a wide range of expertise and experience in food matters, with members drawn from both countries. In 2004, FSANZ was restructured to create separate risk assessment and risk management sections (FSANZ, 2009c). Individuals and organizations can apply to amend a food standard if they can identify a regulatory problem and provide FSANZ with evidence supporting the inadequacy of existing standards or the need to create a new standard. Scientific justification for changing the Australia New Zealand Food Standards Code must be provided, including research data on consumer behavior. (FSANZ, 2008a).
10	Regulation of on-farm activity	FSANZ has developed food safety standards for Australia's primary industries, including primary production and processing standards. This work extends existing food safety provisions in the Australia New Zealand Food Standards Code for the processing and retail sectors to food production, forming a whole-chain approach to food safety, from farm to consumer (FSANZ, 2008a).

continued

TABLE C-4 Continued

11	Risk-based policies, models, use of Hazard Analysis and Critical Control Points (HACCP), etc.	FSANZ adheres to a risk analysis approach recommended by the Codex Alimentarius Commission, the recognized international agency for global food standards. This approach involves risk assessment (identifying hazards in food and likely risks to human health), risk management (developing control measures that minimize the risks), and risk communication (ensuring two-way exchange of information between all stakeholders in standards development) (FSANZ, 2008a).
12	Inspections (domestic)	State and territory agencies, the New Zealand Food Safety Authority, local government, and the Australian Quarantine and Inspection Service are responsible for the implementation of laws and enforcement actions (FSANZ, 2008a).
13	Imports	All food sold in Australia, including imports, must comply with state and territory food legislation and other legislative requirements. The Australian Quarantine and Inspection Service (AQIS) aims to ensure that imported foods are fit and safe for human consumption through a program of inspection for compliance with food standards. FSANZ provides advice to AQIS on the level of public health risk posed by specific foods, but AQIS has operational responsibility for inspection and sampling of imported foods to ensure that they are compliant with food standards (FSANZ, 2009d).
14	Disease surveillance	FSANZ acts as the central point for the collection of food surveillance data from public health units in Australia and New Zealand (FSANZ, 2009e).
15	Recall authority	The Commonwealth Minister responsible for consumer affairs and the state and territory governments have the legislative power to order a food product recall when a serious public health and safety risk exists. This is known as a mandatory recall (FSANZ, 2008b).
16	Other regulatory agencies with responsibilities for foods	Australian Competition and Consumer Commission, AQIS, Australian Pesticides and Veterinary Medicines Authority, Ministry of Health (New Zealand), National Health and Medical Research Council, National Measurement Institute, New Zealand Food Safety Authority, Office of Best Practice Regulation, Office of the Gene Technology Regulator, Standards Australia, Therapeutic Goods Administration (FSANZ, 2008a).

TABLE C-4 Continued

17	Why was there a migration to a single food agency?	The National Food Authority was formed in 1991 in an effort to effect economic reform and cooperation between the Commonwealth and the states and territories, with the aim of achieving uniformity in food standards across Australia (FSANZ, 2009a).
18	How is a single food agency working?	Some early issues, such as health claims and standards for special foods and sports foods, are still being addressed, but others, such as country-of-origin labeling, have been resolved (FSANZ, 2009a).
19	Program evaluation	An annual report is required in compliance with Section 69 of the Food Standards Australia New Zealand Act of 1991 and the Commonwealth Authorities and Companies Act of 1997. Annual surveys of consumers and stakeholders are also conducted (FSANZ, 2008a).
20	Research function	Research covers diverse topics, such as risk assessments, contamination in foods, nutritional claims, and consumer attitudes (FSANZ, 2008a).
21	Communication	Risk communication is one of the three elements of the risk analysis model used by FSANZ. Also, the agency regularly updates its consumer website, maintains a database and conducts gap analysis of consumer materials on pertinent topics, and maintains an advice line for consumers and industry (FSANZ, 2008a).
22	Education	FSANZ is a founding member of the Food Safety Information Council (FSIC), a not-for-profit group with members representing government, consumers, health professionals, and industry and with the role of educating consumers in food safety. FSIC organizes a National Food Safety Week each year (FSANZ, 2008a).

TABLE C-5 New Zealand

1	Country population	4,328,340 (Statistics New Zealand, 2009)
2	Name of organization	New Zealand Food Safety Authority (NZFSA)
3	Year created	2002
4	Legislation	NZFSA enforces the following eight laws and their amendments (NZFSA, 2009a): • Agricultural Compounds and Veterinary Medicines Act of 1997 • Animal Products (Ancillary and Transitional Provisions) Act of 1999 • Animal Products (Ancillary and Transitional Provisions) Amendment Act of 2002 • Animal Products Act of 1999 • Animal Products Amendment Act of 2002 • Dairy Industry Act of 1952 • Food Act of 1981 — Food Amendment Act of 1985 — Food Amendment Act of 1996 — Food Amendment Act (No. 2) of 1996 — Food Amendment Act of 2002 — Food Standards • Wine Act of 2003
5	Budget	Fiscal year ending June 2004: $NZ 78 million ($US 53 million). A portion of spending is financed by user fees assessed on industry for a range of regulator-provided services, including export certification, export audit arrangements, and market access efforts (GAO, 2005).
6	Number of employees for food	480 in 2004 (GAO, 2005)
7	Definition of "food"	"Food" includes any thing or article, whether processed, semiprocessed, or raw, that is intended for human consumption. This includes drink, chewing gum, and any substance that enters into or is used in the composition, manufacture, preparation, and preservation of any food or drink but does not include cosmetics or tobacco or substances used only as medicines and drugs. It includes bottled water, primary produce (e.g., live shellfish, fruit on a tree), water used in the manufacture of a food, and by-products of animals if they go into food. It may include live animals and plants (depending on intent). It excludes cookware and related products (e.g., pie dishes, packaging [except for edible packaging]) (NZFSA, 2009b).

TABLE C-5 Continued

8	Items regulated	All foods and food products (domestically produced and imported and exported), animal products, agricultural compounds (GAO, 2005).
9	Organization	NZFSA is New Zealand's controlling authority for domestic food safety; imports and exports of food and food-related products (including plant products); administration of legislation covering food sales on the domestic market; primary processing of animal products; and regulation of agricultural compounds (pesticides, fertilizers, and veterinary medicines). It also has farm-to-table responsibilities, from primary production through processing to retailers and consumer education. NZFSA's organization includes a verification agency, which audits animal product facilities to verify that exporters are following agreed-upon processes (GAO, 2005).
10	Regulation of on-farm activity	NZFSA is responsible for developing and implementing food regulations for primary production.
11	Risk-based policies, models, use of Hazard Analysis and Critical Control Points (HACCP), etc.	NZFSA applies a generic risk management framework (RMF) to systematically address all food safety issues. Systematic application of an RMF ensures that all aspects of risk analysis (risk assessment, risk management, and risk communication) work together. The system takes into account uncertainty and the need for continuous updates, and has consumer health goals (NZFSA, 2009c).
12	Inspections (domestic)	NZFSA investigates breaches of the legislation it administers, carries out compliance audits, and assists with overseas audits of New Zealand's food processing systems. The Compliance and Investigation group ensures that standards are enforced, undertakes investigations, and manages corrective actions. The group complements regulatory controls undertaken by health protection units and local authorities in the domestic arena and develops/coordinates implementation of systems and processes for response to events and emergencies. The NZFSA Verification Agency audits the food safety programs of food processors and provides export certification. Its veterinarians inspect live animals (NZFSA, 2009d).
13	Imports	Food imported into New Zealand for sale must comply with New Zealand standards. It is the importers' responsibility to ensure that all requirements are met. Prescribed foods, which present a risk to consumers, are monitored for specific hazards and must meet certain clearance procedures (NZFSA, 2009e,f).

continued

TABLE C-5 Continued

14	Disease surveillance	NZFSA and FSANZ are jointly responsible for shared information on food emergencies and surveillance (NZFSA, 2009d).
15	Recall authority	NZFSA, or the Minister for Food Safety, has the ability to initiate a recall, and this ability is not limited to matters of food safety. The wording in the Food Act of 1981 specifies "for the purpose of protecting the public," allowing considerable scope for recall, including matters relating to food safety, fraud, and noncompliance with food standards. In most circumstances, the need to exercise this legal power will result from the failure of a business to act responsibly and will be used primarily with respect to matters of food safety (NZFSA, 2009g).
16	Other regulatory agencies with responsibilities for foods	Food Standards Australia New Zealand, Officials Committee on Food Safety (creates the "whole of government food policy"), territorial authorities, and public health units (FSANZ/NZFSA, 2008).
17	Why was there a migration to a single food agency?	New Zealand wanted to address inconsistencies between the methods used in the Ministry of Agriculture and Forestry's export food safety program and the Ministry of Health's domestic food safety program (GAO, 2005).
18	How is a single food agency working?	The public, consumer organizations, and industry are more confident in the single agency (GAO, 2005).
19	Program evaluation	Every year, NZFSA releases an annual report that reviews the performance and operations for the previous financial year (1 July to 30 June). It includes financial statements for the year (NZFSA, 2009h).
20	Research function	The Food Safety Programme within NZFSA conducts research on food safety issues, including risk assessments, and investigates food safety incidents.
21	Communication	The Communications and Infrastructure group ensures that NZFSA communicates and consults effectively with all stakeholders and meets their needs for timely, accurate, and relevant information.
22	Education	NZFSA and FSANZ are jointly responsible for consumer and industry education on food standards issues (NZFSA, 2009d).

TABLE C-6 European Union

1	Country population	Approximately 495 million (European Commission, 2007a)
2	Name of organization	European Food Safety Authority (EFSA) Food and Veterinary Office (FVO)
3	Year created	EFSA: 2002 FVO: 1997
4	Legislation	Council Directive (EC) 97/78 General Food Law of 2002 Hygiene I (Regulation [EC] 852/2004) Hygiene II (Regulation [EC] 853/2004) Hygiene III (Regulation [EC] 854/2004) Hygiene IV Directive (EC) 2002/99 Regulation (EC) 882/2004 (GAO, 2008b)
5	Budget	€73million (EFSA, 2008)
6	Number of employees for food	EFSA: not applicable FVO: 163 total; of these, 81 are inspectors (FVO, 2009)
7	Definition of "food"	"Food" (or "foodstuff") means any substance or product, whether processed, partially processed, or unprocessed, intended to be or reasonably expected to be ingested by humans. "Food" includes drink, chewing gum, and any substance, including water, intentionally incorporated into the food during its manufacture, preparation, or treatment (EFIC, 2002).
8	Items regulated	Food and feed safety, nutrition, animal health and welfare, plant protection and health (EFSA, 2009a)
9	Organization	EFSA is an European Union (EU)–funded agency. It is governed by a Management Board whose members are appointed to act in the public interest and do not represent any government, organization, or sector (EFSA, 2009b). FVO staff are organized in six units with different responsibilities within the office (FVO, 2009).
10	Regulation of on-farm activity	Food and feed laws cover all stages of production, processing, and distribution (GAO, 2008b).

continued

TABLE C-6 Continued

11	Risk-based policies, models, use of Hazard Analysis and Critical Control Points (HACCP), etc.	In the European food safety system, risk assessment is done independently from risk management. As the risk assessor, EFSA produces scientific opinions and advice to provide a sound foundation for European policies and legislation and to support the European Commission, European Parliament, and EU Member States in taking effective and timely risk management decisions (EFSA, 2009a). Good Hygiene and Manufacturing Practices and HACCP principles are applied (EFSA, 2009c).
12	Inspections (domestic)	FVO is responsible for ensuring that European Community legislation on food safety, animal and plant health, and animal welfare is properly implemented and enforced. Each year, FVO develops an inspection program, identifying priority areas and countries for inspection. To ensure that the program remains up to date and relevant, it is reviewed midyear (FVO, 2009).
13	Imports	In most cases, an on-the-spot inspection by Directorate F of FVO is required before import approval can be considered. This inspection is designed to evaluate whether the animal and public health situation, the official services, the legal provisions, the control systems, the production standards, etc., meet EU requirements (European Commission, 2007b).
14	Disease surveillance	The European Centre for Disease Prevention and Control is responsible for surveillance of disease, including foodborne infection, across the EU (GAO, 2008b). Each country's epidemiologist is responsible for the national surveillance of *Salmonella*, *E. coli*, and other human gastrointestinal infections (GAO, 2008b).
15	Recall authority	The EU distinguishes between withdrawals and recalls and has authority for both. Withdrawals occur when the product is still under the control of the producer and are intended to prevent the distribution or display of a product that is dangerous. Recalls occur when the product is already available to consumers, and they are intended to achieve the return of an unsafe product (GAO, 2008b).
16	Other regulatory agencies with responsibilities for foods	Chief veterinary officers and national food safety authorities of all 27 EU Member States (EFSA, 2009d), the European Chemicals Agency, the European Centre for Disease Prevention and Control, the European Commission's Joint Research Centre (EFSA, 2009e).

TABLE C-6 Continued

17	Why was there a migration to a single food agency?	The EU aimed to harmonize and simplify its food safety legislation and to create a single, transparent set of food safety rules that is applicable to all EU member countries (GAO, 2005).
18	How is a single food agency working?	An estimated 38 percent of people in the EU stated that, overall, food safety has improved, 29 percent that it has stayed about the same, 28 percent that it has worsened, and 5 percent said they did not know. In addition, an estimated 59 percent of people in the EU agreed that food produced in the EU is safer than food imported from elsewhere, 27 percent disagreed, and 13 percent did not know. However, some problems remain: despite regulatory improvements, there is still potential for fraud in the system; resources are sometimes mismatched with problems; and the large and growing size of the food supply makes it more difficult to control (GAO, 2008b).
19	Program Evaluation	EFSA releases annual reports on trends in foodborne illness (GAO, 2008b). FVO publishes an annual report on its activities, which reviews the progress of its inspection program and presents the global results (FVO, 2009).
20	Research function	EFSA follows a workflow that extends from the moment EFSA receives a request for scientific advice or initiates its own activity to the moment it publishes and communicates its scientific findings (EFSA, 2009f).
21	Communication	Aside from risk assessment, EFSA's other main purpose is communication on risks associated with the food chain (EFSA, 2009a).
22	Education	Not applicable

TABLE C-7 Denmark

1	Country population	5,519,441 (Statistics Denmark, 2009)
2	Name of organization	Danish Veterinary and Food Administration (DVFA) under the Ministry of Family and Consumer Affairs. The Danish Institute for Food and Veterinary Research, a separate institute within DVFA, is responsible for research and risk assessment (GAO, 2005).
3	Year created	2000
4	Legislation	The Danish Food Act, adopted in 1998, reformed Danish food safety law by replacing seven existing food laws with this single law (GAO, 2005).
5	Budget	DVFA's budget for 2004 was 856 million Danish kroner (about $US 142 million) (GAO, 2005).
6	Number of employees for food	Approximately 1860 employees (DVFA, 2009b)
7	Definition of "food"	See European Union (Table C-6), row 7.
8	Items regulated	All food products from farm to fork (DVFA, 2009b)
9	Organization	DVFA is responsible for almost all food safety matters. Exceptions are the Plant Directorate, which is responsible for animal feed inspections, and the Directorate for Fisheries, which is responsible for inspection of fish on ships. These two agencies are in the Ministry of Food, Agriculture, and Fisheries (GAO, 2005).
10	Regulation of on-farm activity	DVFA is responsible for safe food production, including from field to table. Plant production falls under the Danish Plant Directorate (DVFA, 2009c).
11	Risk-based policies, models, use of Hazard Analysis and Critical Control Points (HACCP), etc.	Companies must impose self-inspection programs that must be organized in accordance with the principles embodied in the HACCP system. Self-inspection programs must also ensure that companies adhere to food-related legislation (DVFA, 2009d).

TABLE C-7 Continued

12	Inspections (domestic)	Inspection is the cornerstone of the control process with respect to companies and primary producers. Food control and veterinary inspections are handled by three regional veterinary and food control centers. Companies and producers must have so-called self-inspection programs with systematic action plans to ensure that regulations are observed in the handling of food products and livestock. Government food authorities conduct inspections to ensure that the relevant regulations are observed, and results are posted in a place visible to consumers (DVFA, 2009d). Under the new system, municipal inspectors are part of DVFA (GAO, 2005).
13	Imports	The International Trade Division of DVFA is responsible for imports (DVFA, 2009e). See also European Union (Table C-6), row 13.
14	Disease surveillance	Statens Serum Institut, the DVFA, the Danish Plant Directorate, the Danish Institute for Food and Veterinary Research, the National Board of Health, the Danish Environmental Protection Agency, and the Royal Veterinary and Agricultural University (Lo Fo Wong et al., 2004)
15	Recall authority	See European Union (Table C-6), row 15.
16	Other regulatory agencies with responsibilities for foods	Danish Food Industry Agency, Danish Plant Directorate, Danish Directorate for Fisheries
17	Why was there a migration to a single food agency?	Improve effectiveness (e.g., communications with consumers, consistency of inspections) and improve efficiency (e.g., move resources to high-risk areas, reduce overlaps in responsibility) (GAO, 2005).
18	How is a single food agency working?	Reduced overlap in inspections, risk-based inspections that put resources where they are most needed, more consistent and timely enforcement action, and reduced spending, most notably in microbiological laboratories, have resulted (GAO, 2005).
19	Program evaluation	DVFA must be able to demonstrate the probability that—all other things being equal—it has made a difference in the population's benefit from foodstuffs and helped stop the spread of livestock diseases and infections. One of the ways this probability is demonstrated is by examining the incidence of specific diseases where intervention has occurred.

continued

TABLE C-7 Continued

20	Research function	The Danish Institute for Food and Veterinary Research, a separate institute within DVFA, is responsible for research and risk assessment (GAO, 2005).
21	Communication	Evaluation of each firm is published in the form of Figure C-1 (DVFA, 2009f).
22	Education	One of the main aims of DVFA is to promote better food and a healthy diet (DVFA, 2009g).

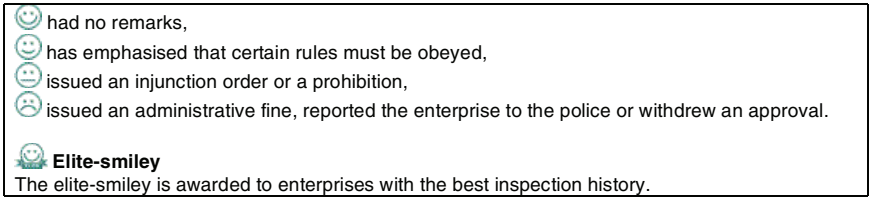

FIGURE C-1 Evaluation scheme for Danish firms.
SOURCE: DVFA, 2010.

TABLE C-8 United Kingdom

1	Country population	61.4 million (National Statistics, 2009)
2	Name of organization	Food Standards Agency (FSA)
3	Year created	2000 (FSA, 2009a)
4	Legislation	Codex Alimentarius; European Union legislation; Food Safety Acts of 1990; Food Standards Act of 1999; Hygiene Legislation of 2006; Individual laws of Scotland, Wales, and Northern Ireland (FSA, 2009a).
5	Budget	£160.4 million in fiscal year 2008–2009 (FSA, 2009b)
6	Number of employees for food	The agency employs about 2,350 staff, including 1,600 inspectors in the Meat Hygiene Service (GAO, 2008b).
7	Definition of "food"	See European Union (Table C-6), row 7.
8	Items regulated	See European Union (Table C-6), row 8.

TABLE C-8 Continued

9	Organization	Several advisory committees, with members of an overarching FSA Board appointed by individual countries' ministers and the Secretary of State for Health. Several subcommittees operate under the FSA Board, including the Meat Hygiene Service (MHS) subcommittee. The MHS subcommittee itself is responsible for safeguarding public health and animal welfare at slaughter through the effective enforcement of legislation (FSA, 2009b).
10	Regulation of on-farm activity	Farmers are to employ Hazard Analysis and Critical Control Points (HACCP) (GAO, 2008b).
11	Risk-based policies, models, use of Hazard Analysis and Critical Control Points (HACCP), etc.	FSA is the main United Kingdom (UK) body in charge of assessing food risks and focuses on processes, such as HACCP (GAO, 2008b). The agency recognizes that there is a degree of scientific uncertainty in risk assessments (FSA, 2000). See also European Union (Table C-6), row 11.
12	Inspections (domestic)	FSA works closely with local food law enforcement officers to ensure that food law is applied throughout the food chain. FSA advises and trains on enforcement issues and provides grants to local programs. The agency also ensures that local authorities' monitoring of food businesses is functioning correctly by performing audits and collating data on local authorities' enforcement activities. Additional authorities work on specific commodities, such as horticultural products, dairy, and eggs. Food outlets are given a score based on inspection findings, and these scores are posted on the door of the firm and online (FSA, 2009c).
13	Imports	FSA is responsible for the public health aspects of food imported into the United Kingdom. This means ensuring that imported food is safe for people to eat. Local and port health authorities are responsible for the enforcement of food safety and standard controls on food products. FSA's Imported Food Division helps improve the effectiveness of enforcement of imported food controls. FSA has particular responsibility for imports of fresh, dried, cooked, cured, and smoked fish and fishery products, such as canned tuna, fish sauces, and prawns. Also see European Union (Table C-6), row 13.

continued

TABLE C-8 Continued

14	Disease surveillance	FSA monitors the effectiveness of programs to control microbiological hazards through microbiological surveys. These surveys are carried out on a regular basis, focus either on particular foods or food processes, and are undertaken in response to microbiological food hazards, outbreaks of foodborne disease, or recommendations made by the independent Advisory Committee on the Microbiological Safety of Food (FSA, 2009d). The Health Protection Agency is responsible for managing infectious diseases, disease outbreaks, radiological health, and emergency planning. If a foodborne illness outbreak covers a wide area, the Health Protection Agency initiates investigations to determine the contaminant and identify its source, and provides information to FSA so it can manage the risk (GAO, 2008b).
15	Recall authority	FSA has mandatory recall authority (GAO, 2008b).
16	Other regulatory agencies with responsibilities for foods	Department for Environment, Food, and Rural Affairs, Veterinary Laboratories Agency, Animal Health, Her Majesty's Revenue and Customs, local authorities, private-sector industry organizations (GAO, 2008b).
17	Why was there a migration to a single food agency?	FSA was founded in response to (1) the loss of public confidence in the government's handling of food safety issues, such as bovine spongiform encephalopathy (BSE) and *Salmonella* in egg products, and (2) perceived conflict of interest in the Ministry of Agriculture, Fisheries, and Food, which also promoted UK agriculture (GAO, 2008b).
18	How is a single food agency working?	The UK audit office found that FSA had improved public confidence, a stated objective (GAO, 2008b).
19	Program evaluation	A strategic plan is outlined every year, and group progress reports form the basis of a report to the Executive Management Board at the end of each quarter (FSA, 2009b).
20	Research function	The agency carries out and commissions extensive scientific research and survey work to ensure that its advice to the public is based on the best and most up-to-date science. The agency is advised in its work by independent scientific committees. Studies focus on nutrition, BSE, chemical and microbial contamination, and food safety (FSA, 2009e).
21	Communication	Communication programs are in place, including blogs, YouTube videos, and podcasts (FSA, 2009a).
22	Education	Education programs are in place, including training modules, phone applications, and YouTube videos (FSA, 2009a).

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Appendix D

The U.S. Food and Drug Administration's Food Defense Program[1]

This appendix describes the U.S. Food and Drug Administration's (FDA's) food defense program from 2001 to the present. It places bioterrorism within the broader context of terrorism and the associated legal and organizational framework. It also describes the formal and informal cooperation between the FDA and other groups and organizations involved in food defense, including the creation of a government–industry partnership. Outcomes of this partnership were the development of a risk vulnerability assessment model and its application in the food industry. The appendix also reviews the issues that arise in, and approaches to, acquiring and sharing food defense data. Examples of the capacity of the FDA to respond to emergencies are provided as well. Further, the appendix describes how the FDA's 2007 Food Protection Plan (FPP) includes food defense in its goals. The progress made to date with regard to management of food defense is described, and gaps are identified. The appendix concludes with a summary and a list of opportunities for improvement in maximizing the outcomes of the industry–government partnership, developing tools for prioritization of risks, maintaining resources, and enacting needed legislation.

This appendix was written based on information gathered from interviews with representatives of federal and state government, academia, and industry; public documents from both government and industry sources; and the author's experience and expertise in food defense as former Deputy

[1] Louis Carson, Retired, FDA; former Deputy Director of the FDA Center for Food Safety and Applied Nutrition's Office of Food Safety, Defense, and Outreach.

Director of the FDA Center for Food Safety and Applied Nutrition's (CFSAN's) Office of Food Safety, Defense, and Outreach. Where comprehensive source materials were unavailable, the discussion relies on anecdotal information and inferences from program directives.

BUILDING A FOOD DEFENSE PROGRAM

"Food defense" is the collective term used by the FDA, the U.S. Department of Agriculture (USDA), the U.S. Department of Homeland Security (DHS), and others to describe activities associated with protecting the nation's food supply from deliberate acts of contamination. Shortly after September 11, 2001, the FDA and other federal agencies began developing a new program, building on a program initiated by the U.S. Department of Health and Human Services (HHS), to protect the nation's food supply from terrorist attacks. The FDA focused its efforts on targeted industry guidance and outreach, inspections, research (e.g., methods development and validation, characteristics and behavior of agents in foods, pathogenicity/toxicity in foods), and mitigation strategies to reduce potential risks in the food supply. Numerous organizations, public and private, have played a role in the FDA's food defense program to date (see Annex Table D-1).

The FDA used operational risk management (ORM) as a tool to identify food defense priorities. ORM is a management tool used by the U.S. Departments of Defense (DoD) and Transportation to identify risks and reduce them to an appropriate level, ensuring that benefits will outweigh any risks. It is an analytical tool whereby severity and probability (accessibility) of risk are measured qualitatively and assigned a rating—high, medium, or low (see Table D-1).

A CFSAN team of scientific and food production experts was charged with testing the tool on a list of threat agents, starting with the list of the U.S. Centers for Disease Control and Prevention (CDC) and expanded to other known or potential threat agents, in combination with a list of FDA-regulated foods. The class groupings were, for example, heat-labile bacterial toxins, heat-stable bacterial toxins, and spore-forming bacteria. The agents (surrogates) were also assessed on their accessibility, public health impact (morbidity and mortality), toxicity/pathogenicity, dose required to cause intended outcome, agent–food compatibility, ability to withstand processing, and changes to sensory attributes of food. (The resulting list of prioritized agent–food combinations is classified and unavailable for this discussion.) This risk assessment effort, early in the evolution of the food defense program, was crucial to identifying a finite list of agent–food combinations for further investigation and helped in understanding the potential hazards. Equipped with this risk assessment tool, the FDA focused

TABLE D-1 Risk Assessment Tool: Operational Risk Management

		Probability				
		Frequent	Likely	Occasional	Seldom	Unlikely
Severity		A	B	C	D	E
Catastrophic	I	1	2	6	8	12
Critical	II	3	4	7	11	15
Moderate	III	5	9	10	14	16
Negligible	IV	13	17	18	19	20
				Risk Levels		

NOTES:
Catastrophic—Complete business failure due to food product contamination, resulting in deaths.
Critical—Major business degradation due to food product contamination, resulting in severe illnesses.
Moderate—Minor business degradation due to food product contamination, resulting in minor illnesses.
Negligible—Less than minor business degradation and illnesses.
Frequent—Occurs often to individuals, and population is continuously exposed.
Likely—Occurs several times, and population is exposed regularly.
Occasional—Will occur and occurs sporadically in a population.
Seldom—May occur and occurs seldom in a population.
Unlikely—So unlikely one can assume it will not occur, and occurs very rarely in a population.

its resources on identifying the greatest vulnerabilities and opportunities for reducing risk in the food supply.

The FDA, with the voluntary participation of food industry trade associations, subsequently conducted a series of ORM exercises. With the information thus gathered, physical security, employee, management, and quality assurance practices were identified and published in a series of Food Security Preventive Measures Guidance documents for Industry for Food Producers, Processors, and Transporters; Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations, and Fluid Milk Processors; Retail Food Stores and Food Service Establishments; Importers and Filers; and Cosmetic Processors and Transporters. In turn, many food industry trade associations and food producers updated their facility quality assurance or crisis management plans to incorporate these features.

In an effort to further assist the industry, the outreach effort was broad in scope, encompassing all FDA-regulated food producers from farm to table. Equally important was training the FDA's own investigators and field scientists in this new threat—intentional contamination of the food supply. Training materials, face-to-face sessions, and web-based courses were developed to educate the industry and the FDA's food safety experts and to share this information with their state and local counterparts.

At the outset of this new food defense program, the FDA and its food safety/defense counterparts at CDC, USDA's Food Safety and Inspection Service (FSIS), DoD/Army Veterinary Corps, and the U.S. Environmental Protection Agency (EPA) were embarking on different paths, many using established food safety risk assessment methodologies, to protect the food supply. With the FDA's novel approach, it was prudent to ensure rigor and scientific soundness, and the risk-ranking list of agent–food combinations and the ORM tool were subjected to peer review through a contract with the Institute of Food Technologists. When the risk-ranking list and the ORM tool passed this review, the FDA further augmented its outreach to its federal and state partners and enhanced training and outreach efforts with the food industry, given their mutual responsibilities for dealing with potential food safety events.

HOMELAND SECURITY AND FOOD DEFENSE

In 2003, with the formation of DHS, emphasis was placed on infrastructure protection, a National Infrastructure Protection Plan (NIPP), a National Response Plan (NRP), and the overarching mandate to engage public and private entities in homeland security as described in various Homeland Security Presidential Directives (HSPDs). The FDA and its federal partners were challenged not only to build a working relationship with a new entity—DHS—but also, in an expedited manner, to build a food and agriculture public–private partnership; fully develop and implement a voluntary national defense program to protect the food supply from intentional contamination; update all current emergency response procedures, including those involving the new DHS; and train and educate their staff and regulated industries in this new program.

Adding to the FDA's tasks, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act of 2002),[2] which required the agency to expedite rule making for 4 new authorities and implement those authorities within a time frame of 18 months. The new authorities were registration of domestic and foreign food producers, manufactures, and distributors; prior notice of imported food shipments; record-keeping requirements; and administrative detention (see Table D-2). Given the timetable for publication and implementation of the draft rules, the FDA faced a monumental outreach and education effort in providing the necessary materials and details in simple language to enable all to comply. During the 2003–2005 time frame, the FDA/CFSAN was engaged in activities to comply with the HSPDs and congressional

[2] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, Public Law 107-188, 107th Cong., 2nd sess. (June 12, 2002).

TABLE D-2 Provisions of the Bioterrorism Act of 2002 Relating to the U.S. Food and Drug Adminisration (FDA)

Registration of food facilities	Requires food manufactures, processors, holders, and distributors to register each facility, not company, with the FDA. The registration coverage is limited and does not encompass farm to table, specifically excluding farms and retail establishments.
Prior notice of imported food shipments	The FDA must receive and confirm a prior notice • no more than 30 days before a shipment's anticipated arrival, if prior notice is submitted via Automated Broker Interface, or • no more than 15 days before a shipment's anticipated arrival, if prior notice is submitted via the FDA's Prior Notice System Interface.
Record keeping	Requires each domestic food manufacturer, processor, holder, or distributor food/feed facility to retain records of incoming ingredients and supplies and of outgoing products.
Administrative detention	Gives the FDA domestic embargo authority, whereby suspect or contaminated food in commercial channels can be stopped until judicial action is taken to seize and/or destroy it.

legislative requirements, and to educate and communicate with industry, its own staff, and state, local, and foreign counterparts.

The FDA's outreach efforts leveraged all media opportunities to educate industry and state and foreign governments in the new regulations and food defense program. The FDA teamed with USDA to develop joint food defense training materials and promoted their adoption by industry and the states. The latter effort was focused on generating awareness of the new food defense program and training food safety professionals to be the eyes and ears for potential threats to the food supply. Awareness training included how to identify potentially intentional contamination and whom to notify, as well as information about the implications of a terrorist attack on the U.S. food supply (including production agriculture). The training was offered both as a web-based course (FDA, 2009a) and in face-to-face sessions. Later, as part of this training, the FDA and USDA developed simplified tools, such as ALERT (FDA, 2009b), intended to raise awareness at all levels of food production, and FIRST (FDA, 2009c), designed for use by food industry managers to educate front-line workers from farm to table.

ESTABLISHMENT OF A PARTNERSHIP: THE FOOD AND AGRICULTURE SECTOR

By Presidential Directive, FDA/USDA and the newly formed DHS were required to establish a sector organization, that is, a partnership with all relevant federal, state, local, and industry counterparts. Although there were existing models for such a partnership in other areas, none were suitable given the diversity, scope, and magnitude of the food and agriculture sector. The FDA/USDA/DHS, with industry, formulated a governing model and operating procedures for the new Food and Agriculture Sector, with the goal of identifying and protecting critical infrastructure assets and establishing a two-way communication and analysis system to inform and notify members and analyze critical food defense information. The Food and Agriculture Sector partnership comprises two governing councils: (1) the Government Coordinating Council (GCC) and (2) the Sector Coordinating Council (SCC) (representing industry). The membership of each council was expanded over time. In addition, seven subcouncils were created under the SCC so that each industry segment—harvest, production,

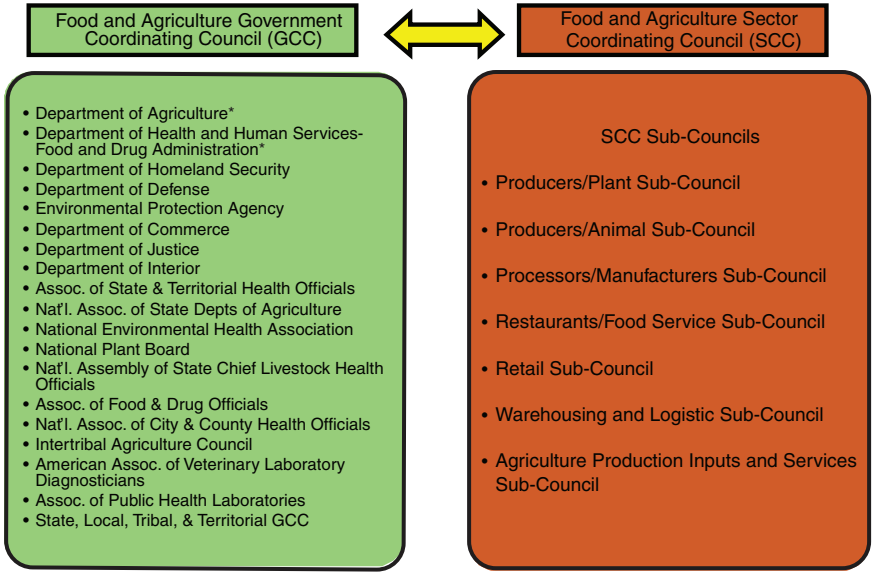

FIGURE D-1 Participant organizations of the Food and Agriculture Government Coordinating Council and Sector Coordinating Council.
NOTE: In the summer of 2009, the subcouncils integrated into one large council.
*Sector specific agencies for the Food and Agriculture Sector.

retail, distribution, and supply—would have a voice (see Figure D-1), and they were dissolved later in 2009. Since its inception, the program has relied on voluntary participation and engagement by the states and industry.

The GCC was established to enable interagency coordination of food and agriculture security strategies and activities, policy, and communication across government and between the government and each sector, with the goal of developing consensus approaches to the protection of critical infrastructure/key resources. DHS, FSIS, and the FDA co-chaired the GCC, each serving as its lead for 12 months on a rotating basis. The SCC is self-organized, self-run, and self-governed. It is composed of members that serve as the GCC's point of contact for each industry sector (i.e., plant and animal producers, manufacturers, restaurants, retail, warehouses, and agricultural production) for developing and coordinating a wide range of infrastructure protection activities and issues (e.g., research and development, outreach, information sharing, vulnerability assessments/prioritization, shielding, and recovery).

Regular conference calls and quarterly meetings of the GCC and SCC addressed organizational issues, communication efforts, emergency operations, training and planning, identification of annual priorities, and participation in such activities as emergency response exercises, the development of risk communication templates, and a Strategic Partnership Program Agroterrorism (SPPA) initiative, all in an effort to contribute to an overall NIPP (see Annex D-3 for an overview of SPPA).

CARVER + Shock as a Tool to Conduct Vulnerability Assessments

Under the auspices of the White House Homeland Security Council, the White House Interagency Food Working Group was formed with representatives from various federal agencies (e.g., USDA, EPA, HHS, DoD) to discuss issues across all of the administration's food programs. To comprehensively assess the food and agriculture supply, the group agreed that a single risk assessment model/tool—CARVER + Shock—would be used to harmonize all food and agriculture–related agency efforts.

CARVER + Shock, a military special operations forces acronym, enables cross-sector assessment of risks and vulnerabilities. The tool rates seven factors that affect the desirability of a target:

1. *Criticality*—public health or economic impact
2. *Accessibility*—physical access to target
3. *Recuperability*—ability of the system to recover from an attack
4. *Vulnerability*—ease of accomplishing the attack
5. *Effect*—amount of actual direct loss from the attack
6. *Recognizability*—ease of identifying target

7. *Shock*—combined measure of physical, health, psychological, and economic effects

CARVER + Shock enabled more in-depth analysis of a food production and distribution process and its vulnerabilities, while also adding the new factor of shock not considered in ORM assessments. The FDA and its counterparts had to learn this new tool and apply it to work already completed—termed "verifications"—and extend the assessment effort to cover new food and agriculture scenarios. These efforts again formed the foundation for strategic priorities, research directions, risk communication needs, and subsequent advice to industry with respect to food defense.

With congressional funding for security assessments of food and agriculture facilities, the Federal Bureau of Investigation (FBI) teamed with the FDA/USDA and DHS to harmonize food defense and law enforcement goals. CARVER + Shock was applied to a wide variety of high-priority food commodities in collaboration with state, federal, and industry experts on a facility-by-facility basis, and SPPA was launched. The Food and Agriculture Sector was viewed as the logical point of contact with industry to seek its voluntary participation in this endeavor. GCC co-chairs, SCC chairs, and the FBI developed SPPA so that issues of proprietary processes and potentially sensitive information would be handled properly. Findings or reports would be reviewed and approved by both industry and government before being issued as public documents, while government would retain the sensitive/classified assessments. A sufficient level of trust had been built within the Food and Agriculture Sector to accommodate this assessment program in what would become one of the Sector's major accomplishments.

These assessments supported the requirements for a coordinated food and agriculture infrastructure protection program as stated in the NIPP; Sector-Specific Plans (SSPs); National Preparedness Guidelines (released in 2007); and HSPD-9, *Defense of U.S. Agriculture and Food*. Using CARVER + Shock, SPPA assessments were conducted on a voluntary basis among one or more industry representatives for a particular product or commodity, their trade association(s), and federal and state agricultural, public health, and law enforcement officials.

As a result of each assessment, participants identified individual nodes or process points that were of greatest concern, protective measures and mitigation steps that could reduce the vulnerability of these nodes, and research gaps/needs. Discussions of mitigation steps and good security practices were general in nature, focusing on physical security improvements for food processing facilities, biosecurity practices, and disease surveillance for livestock and plants. The results can be found in the 2008 SPPA final report summary, *Strategic Partnership Program Agroterrorism (SPPA) Initiative: Final Summary Report, September 2005–September 2008* (FDA, 2009d).

From 2005 to 2007, 36 SPPA assessments were conducted on a variety of food and agriculture products, processes, or commodities. These assessments covered 1 or more of the SCC subcouncils' commodities and were completed in 31 of the 52 key sites identified under the SPPA initiative. Each SPPA assessment lasted approximately 3 days and was conducted by a team of 20 to 30 participants from federal, state, and local agricultural, food, public health, and law enforcement agencies; food and agriculture companies; and their trade associations. In preparation for the assessment, the USDA or FDA federal host (Sector-Specific Agency [SSA]) and a representative of FBI headquarters provided background and educational material. This material ensured that participants were knowledgeable about the CARVER + Shock assessment tool and plans for the assessment. Recurring themes included the need for

- better understanding of threat agent characteristics;
- better scientific capabilities, such as the development or improvement of detection methods for threat agents of concern;
- development or dissemination of models (or their results) related to the impact of a food or agricultural terrorism event;
- improved communications; and
- identification of gaps in evaluating economic impacts and effects on consumer confidence.

In addition to identifying gaps in knowledge, the tool has been used to determine commonalities across food and agricultural industries that make them more vulnerable to attack, allowing for the proposal of generic protective measures or mitigation strategies that could be beneficial to the industries assessed.

The SPPA initiative was a significant step toward hardening of critical infrastructure and greater protection of the food and agriculture industries. This was accomplished by providing industry members with training and hands-on experience with a terrorism-focused assessment. The SPPA initiative also provided federal, state, and local governments with an in-depth look at the vulnerabilities that may be associated with different facets of the food and agriculture industries. Finally, the initiative increased communication among industry, government, and law enforcement stakeholders concerned with the safety and security of the food supply.

To further assist industry and state and local government officials, various guidance has been published, such as USDA's *Guidelines for the Disposal of Intentionally Adulterated Food Products and the Decontamination of Food Processing Facilities* (FSIS, 2006) and EPA's *Federal Food and Agriculture Decontamination and Disposal Roles and Responsibilities*

(EPA, 2005). In addition, the FDA released a free software version of the CARVER + Shock assessment tool (FDA, 2009e).

Information Sharing

The Food and Agriculture Sector has made many attempts to find a suitable communication tool that fully supports its activities. Although the Food Marketing Institute[3] (FMI) supported the Food and Agriculture Sector Information Sharing and Analysis Center as a mechanism for sharing data, FMI lacked sufficient private funds to offer more than a clearinghouse/e-mail notification system. While this was useful in the Sector's early days, a more robust system was needed as its activities matured and broadened.

DHS and its component organizations developed several other information and analysis systems, such as the Homeland Security Information Network (HSIN). After almost 2 years of HSIN operation, staff have made the following recommendations for improving communications and Food and Agriculture Sector operations. First, hire a data manager to actively poll and issue information to all Sector representatives, who would in turn issue this information to all subsectors/members. Use HSIN and FoodShield, a network designed by and located at the National Center for Food Protection and Defense (NCFPD), as mechanisms for communication. Second, re-fund SPPA as a joint FBI/DHS/FDA/USDA initiative to conduct CARVER + Shock assessments at food facilities, with state participation. Third, fund full-time positions to carry out state food defense activities. It was also suggested that DHS's Homeland Infrastructure Threat and Risk Analysis Center's annual infrastructure resource assessment is not serving Food and Agriculture Sector needs, even with more than 30 states using the current Food and Agriculture Sector Criticality Assessment Tool (FASCAT).

The collection of sensitive information continues to be a challenge. The FDA and its counterparts are subject to Freedom of Information Act[4] (FOIA) requirements and must disclose information upon request unless it is excluded by a confidential business interest or is classified. Further, the FDA is subject to Paperwork Reduction Act[5] provisions, which require justification to solicit, survey, or ask questions of consumers, industry, and others. Industry has been reluctant to share technical and production information for fear it would be available to the public through FOIA. Thus it is difficult to obtain survey data on industry practices. To overcome industry's

[3] The FMI is a trade association representing food retailers and wholesalers that develops and promotes policies, programs, and forums supporting its members and their customers in the areas of government relations, food safety and defense, public and consumer information, research and education, and industry cooperation.

[4] *Freedom of Information Act*, Title 5 U.S. Code § 552.

[5] *Paperwork Reduction Act*, Title 44 U.S. Code § 3501.

reluctance to share technical and production information, a process to protect the information from FOIA, state and local disclosure laws, and civil lawsuits (DHS, 2009) was conceived—the Protected Critical Infrastructure Information (PCII) process. With this DHS/PCII process, the FDA has an avenue to receive and secure industry data. But the DHS/PCII data collection process requires substantive justification and industry cooperation. Further, DHS/PCII must concur in the agency's request so the request can receive an expedited and abbreviated Office of Management and Budget review. The FDA has employed PCII in only two instances, in 2006 and 2008–2009, to survey milk processors in the United States, as discussed further in a later section.

The classification and sharing of sensitive information related to food defense have been both a burden and a blessing. HHS Secretary Tommy Thompson, meeting with state public health officials, promised that HHS would seek a secret-level clearance for each state health department, usually the director. However, receiving a security clearance has been a challenge given the volume of requests made at the federal, state, and industry levels; the fact that many high-level officials are appointees with frequent turnover; and the strict standards for gaining a clearance that are not always met. In the case of the Food and Agriculture Sector, the GCC co-chairs and SCC chairs have received security clearances, as have some subcouncil and task force members. Even with a security clearance, however, every individual is not assured of access to all classified information. Classified information is available only on a need-to-know basis. For purposes of the Food and Agriculture Sector, classified information[6] is not available to the public. It may be gleaned from confidential sources or from compilations or analyses of existing public data that in the view of the government organization meet the definition of Title 18 of the U.S. Code.

Classified information generated by the FDA and other government agencies is secured from public access, stored in secure rooms or vaults, and accessed using a stand-alone, non-network computer or device. Like all government agencies, the FDA has specific procedures for transporting classified documents and for their storage or use. The FDA's Office of Crisis Management (OCM) is responsible for establishing and enforcing the agency's security rules. The FDA must maintain a log and document all access to classified materials. The agency is subject to a security audit on an annual basis, and adherence to procedures is strictly enforced. As noted

[6] According to Title 18 U.S.C., (1) classified information is "any information or material that has been determined by the United States Government pursuant to an Executive order, statute, or regulation to require protection against unauthorized disclosure for reasons of national security and any restricted data, as defined in paragraph r. of section 11 of the *Atomic Energy Act of 1954* (42 U.S.C. 2014 (y))"; and (2) "national security . . . means the national defense and foreign relations of the United States."

earlier, for example, the FDA's list of agent–food combinations derived from ORM and CARVER + Shock risk assessments remains classified. The SPPA joint FBI/USDA/FDA facility assessment reports are also classified.

Because some information may be sensitive but not classified, the FDA created the category of For Official Use Only (FOUO) documents, to be shared in hard copy only and with those Food and Agriculture Sector members who need the specific details contained therein. However, this FOUO information is subject to release under FOIA. As an example, in 2005 the FDA shared FOUO information with the milk industry, state milk inspectors, and others for purposes of establishing a new preventive measure to reduce the threat from a selected agent (discussed further in a later section).

As in military applications, the FDA applies the gist of classified information in formulating plans and actions to secure the food supply. Hence, the FDA's food defense program priorities, research priorities, targeted investigations, and testing are based on and consistent with classified and unclassified knowledge and information. Thus while classified information is available only to a few individuals with a need to know, its impact is shared through public action. Moreover, in the event of a threatened or actual attack, state officials, other government partners, and industry counterparts will have access to all relevant information. For example, the milk industry and state officials were provided with all relevant information regardless of its source (including information derived from classified and FOUO documents) to successfully implement a food defense preventive measure.

Outcomes

The NIPP is intended to identify critical assets and fund or assist in their protection (see Annex D-3 for an overview). Following each annual exercise to identify the Food and Agriculture Sector's assets, using ORM/CARVER + Shock (defined above) or now FASCAT, the resulting submissions by states' food and agriculture units have been deemed less qualified than those of other sectors, such as Transportation, Telecommunications, and Finance. Hence, no funding or direct program reinforcement has been generated to sustain state and industry efforts in support of Food and Agriculture Sector activities. It has been noted that the Food and Agriculture Sector's assets, usually a system and not a single facility, do not fit well within the assessment criteria of DHS's Infrastructure Protection model assessment. Therefore, DHS has not funded the protection of the Food and Agriculture Sector's self-identified critical infrastructure/key resources to date.

Additionally, the Food and Agriculture Sector has not fulfilled its ambitious promise to dedicate research efforts and funding to addressing many

of the scientific questions and intervention needs identified in joint FDA/USDA/DHS exercises and initiatives, such as SPPA. The reason is not a lack of dedication or expertise, but limited funding and a diffuse research direction that have produced some results, but not quite enough. Since 2006, for example, the industry has pointed out the lack of a coordinated, comprehensive program review of research findings from all federal and academic programs. In interviews, it was mentioned that industry members were able to secure funding this year from DHS, FDA, and USDA to begin a comprehensive compilation and review of research findings by NCFPD. This funding in support of the Food and Agriculture Sector had to be generated outside the normal DHS Science and Technology and Infrastructure Sector funding system.

Crossroads and the Future

Industry interviews suggested that the Food and Agriculture Sector must transform itself to sustain active participation in the future. Those individuals and organizations that play a critical role do so at great expense, and with the poor economy, the number of qualified, interested, and available food industry experts is dwindling. Moreover, their time and attention will proportionally be diverted to more pressing food safety issues with the increased number of outbreaks occurring. Those interviewed also cited frustration that not enough value has been derived from the time, energy, and dedication they have expended on the NIPP. The SCC has indicated willingness to work with DHS/GCC on a "value proposition" to ensure greater value for participants' time and energy, but change is also needed.

While not mentioned in interviews, another potential factor in the future role and continued existence of a robust and active Food and Agriculture Sector is the current proposed food safety and defense legislation, HR2749[7] (see Annex D-1), and similar Senate bills now being considered by Congress. It is unclear what impact new legislative authorities and enforcement tools will have on the Sector's public–private partnership. It is anticipated that new legislation will fill many gaps and needs cited by the FDA in its FPP, such as recall authority. Most government officials interviewed stated that the legislation would be a welcome addition and go a long way in helping to achieve many FPP goals. But HR2749 proposes to require all food facilities to have food safety and defense plans. Therefore, the SCC and its members would no longer have a voluntary role, but a regulated one.

[7] *Food Safety Enhancement Act of 2009*, HR2749, 111th Cong., 1st sess. (August 3, 2009).

BIOTERRORISM LEGISLATION

As mentioned earlier, Congress passed legislation in 2002 giving the FDA four new authorities under the Bioterrorism Act of 2002[8] (Table D-2). Their implications for the FDA are briefly described in this section.

Registration of Food Facilities

This authority requires food manufacturers, processors, holders, and distributors to register each facility, not company, with the FDA. As noted, the registration coverage is limited and does not encompass farm to table, specifically excluding farms and retail establishments. The purpose is to assist the FDA in conducting investigations more efficiently and effectively by having the facility name and location, products produced, and responsible official for contact. The FDA is prohibited from requiring electronic registration and so must also accept paper registrations.

While the FDA has received nearly 400,000 domestic and foreign registrations, it does not have audit authority (to check and revise data entered if mistakes are made), but must ask the submitter to make all corrections. Further, food facilities go in and out of business regularly, and again the system requires the submitting food facility (company) to make all corrections and deletions. The FDA believes the system does contain errors and is seeking legislation, in accordance with FPP needs, to make the registrations more current and accurate. The proposed HR2749 provides for this.

Prior Notice Rule

With the implementation of the prior notice rule, the FDA established a 24/7 prior notice data review function. This, again, was a new and unprecedented effort on the FDA's part; no other FDA front-line operation was 24/7. The Office of Regulatory Affairs's (ORA's) Office of Regional Operations and Division of Import Operations created the Prior Notice (PN) Center, collocated with U.S. Customs and Border Protection's (CBP's) targeting center in Reston, Virginia. With 24/7 dedicated service, the PN Center requires a full-time staff. The PN Center and CBP's targeting center staff, working together, have improved coverage not just of suspect foods, but of all imported foods.

Upon review and analysis of PN data and using an algorithm to target suspect shipments, the PN Center assigns activities for FDA and/or CBP investigators around the country to inspect, seize, or sample shipments for

[8] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, Public Law 107-188, 107th Cong., 2nd sess. (June 12, 2002).

surveillance and/or compliance purposes. It should be noted that the FDA's staffing levels for imported foods do not allow coverage of all possible U.S. ports of entry—roughly 300 in number (see also Appendix E). The FDA covers fewer than 100 ports of entry on a regular basis. CBP staffs each port of entry and, when needed and available, is called upon by the FDA to carry out activities under the Bioterrorism Act or the Federal Food, Drug, and Cosmetic Act (FDCA)[9] or other surveillance and compliance activities. For CBP to perform on behalf of the FDA, its officers must be commissioned. Commissioning permits federal and state officials to operate under the FDCA and enables those commissioned to carry out their responsibilities in reviewing FDA information. They are protected from the disclosure provisions of FOIA. The FDA has commissioned 9,500 CBP officers to expand its coverage.

From interviews, it appears that the PN Center has worked fairly well, and the FDA is apparently satisfied with it. The agency has noted that PN compliance and targeting of suspect imported foods would be improved, however, if additional needs articulated in the FPP were met. Namely, industry compliance would be greatly improved with better registration requirements. The FDA could also leverage host country competent authorities through formal cooperative agreements ensuring that food facilities in their country are complying. The FDA lacks sufficient staff to inspect all foreign food facilities and thus must preferentially target high-risk facilities for inspection to use its limited resources wisely.

Record Keeping

Record keeping requires each domestic food manufacturer, processor, holder, or distributor to retain records of incoming ingredients and supplies and of outgoing products. Since its implementation in 2004, the FDA has become more efficient and adept in meeting the SAHCDHA (serious adverse health consequences or death to humans or animals) standard for access to records. The FDA has used this authority to seek trace-back in a number of recent foodborne illness outbreaks, such as salmonella in tomatoes and melamine in pet food and infant formula.

Unfortunately, industry's record-keeping compliance remains less than adequate. In 2009, the HHS Inspector General's office conducted a survey of food facilities randomly selected from the FDA's registration database. The report of the survey concludes that most food manufacturers and distributors cannot identify the suppliers or recipients of their ingredients or products despite federal rules requiring them to do so. A quarter of the food facilities contacted by investigators as part of the study were not even

[9] *FDCA*, Title 21 U.S. Code, Section 9.

aware that they were supposed to be able to trace their suppliers. The FPP identifies the need to correct this problem, and the proposed HR2749 legislation provides for this.

Administrative Detention

Administrative detention gives the FDA domestic embargo authority whereby suspect or contaminated food in commercial channels can be stopped until judicial action is taken to seize and/or destroy it. However, this authority again requires that the FDA meet the SAHCDHA standard before holding food in domestic commerce. In interviews, FDA officials indicated that this authority has not been employed to date, and the agency continues to request state embargo authority to hold such suspect foods while seeking judicial action.

INFORMATION GATHERING AND SHARING

Intelligence Information on Threats

Since 2002, the FDA has undertaken some food defense actions based on intelligence information or increased threat level alerts from DHS. Through its Office of Criminal Investigations (OCI), the FDA has long-established linkages with the FBI and the Central Intelligence Agency (CIA), as well as a network of agents nationwide gathering surveillance information. OCI in turn has liaisons in each FDA center and the Office of Emergency Operations. On a weekly basis, OCI meets with FBI and CIA representatives to review intelligence information and leads. Further, on a monthly basis OCI convenes a meeting of FDA, DHS, USDA, DoD, Defense Threat Reduction Agency, National Center for Medical Intelligence, FBI, and CIA colleagues to discuss recent intelligence information and other matters. Through these intelligence sources and analyses, the FDA is notified 24/7 of information that may impact an FDA-regulated product, which in turn may trigger FDA emergency procedures.

When DHS heightens its alert level to orange or red, the FDA, through established corresponding readiness procedures, also takes steps in case FDA-regulated products are impacted. During the early years of the food defense initiative, intelligence reports would most often indicate a nonspecific threat or a threat to a non-FDA-regulated product, such as a threat to the transportation sector. Nonetheless, the FDA placed its personnel and operations on readiness alert. If the alert was specific to an FDA-regulated product, the agency would mobilize its resources to deal with the event.

Inspectional Activities and Industry Training

The FDA performs 10,545 food inspections annually, conducted by its own workforce and through state contracts. So it is clear that when the FDA trains its workforce, it must also train the states to ensure that consistent standards are applied. As FDA inspectors became more experienced with food defense measures, moreover, they routinely offered recommendations to, or shared educational materials with, industry facility management as part of their regular food safety inspections. The FDA, along with USDA/FSIS, has developed training materials, web-based tutorials, and awareness training modules for use by government and industry (FDA, 2009f).

The FDA also partnered with international institutions in an effort to broaden the U.S. food supply protections. Examples include a workshop with G8 countries on conducting vulnerability assessments, a workshop on conducting vulnerability assessments for Asia-Pacific Economic Cooperation (APEC) economies, a follow-on workshop on developing a food defense infrastructure for APEC, and a workshop on food defense infrastructure for Middle East Partnership Initiative countries.

The FDA also carried out specific, targeted food defense activities in which its investigators and scientists were directed to conduct inspections, sample collections, and test for potential threats to the food supply. The activities served to train FDA staff through practice and the application of food defense measures, new test procedures, and data collection methods, and were not expected to uncover actual threat agents. In contrast to regular and routine food inspections, the FDA chose to inform food trade associations and member companies of these activities so as not to cause alarm.

Finally, in 2008–2009, the FDA carried out special event activities during the preparations for the Democratic and Republican National Conventions as well as the presidential inauguration. These activities involved ensuring food safety and security.

FDA Research

As has been discussed, FDA scientists, economists, and others were instrumental in designing and shaping the risk assessment tools used for setting food defense priorities and targeting FDA resources most effectively. The FDA's fiscal year (FY) and strategic long-range research plans have always been informed by its knowledge and understanding of classified and unclassified information, agent–food lists, and SPPA facility reports identifying research questions or needs. On the basis of this information, the FDA publicly identifies strategic research needs that, when fulfilled, will meet its food defense priorities. The four major areas of interest are

- development of methods for the detection of biological and chemical agents in foods,
- development of prevention technologies for use by the industry,
- stability of chemical and microbiological agents when subjected to food processing activities, and
- oral infectious/toxic dose of a biological or chemical agent when ingested with a food.

Collaborative food defense research is conducted in and through the following:

- CFSAN Office of Regulatory Sciences, with biosafety level (BSL)-4 laboratory capability;
- ORA's field laboratories and research centers, also with BSL-4 capability;
- the National Center for Food Safety and Technology, one of the FDA's cooperative research centers, focused on food processing and technology;
- NCFPD, a DHS Office of Science and Technology Center of Excellence, consisting of a consortium of universities;
- USDA's Agricultural Research Service (ARS);
- USDA's Cooperative State Research, Education and Extension Service, a research grant agency;
- EPA's Office of Research and Development;
- DoD's Defense Advanced Research Projects Agency and the United States Army Medical Research Institute of Infectious Diseases; and
- other academic partners through competitive grants from federal sources.

Collaborations with the above organizations remain extremely important to advance the FDA's research priorities and to find solutions, preventive measures, and tools for reducing or eliminating food defense risks. During interviews, however, it became clear that staffing for the agency's food defense research coordination, oversight, and direction is inadequate. If the FDA is to retain and improve its scientific knowledge base and its ability to solve food defense problems, it will need to fill this gap. Further, a robust strategic research plan is needed to set more specific priorities, such as which agents are most important and what technologies are most promising. The lack of such a plan will perpetuate a diffuse research agenda that satisfies the needs of neither government nor regulated industry nor, ultimately, consumers.

A detailed summary of the FDA's 2007 food defense research accomplishments is shown in Table D-3.

TABLE D-3 The U.S. Food and Drug Administration's Food Defense Research Accomplishments, 2007

Topic	Findings
Stability of chemical and microbiological agents when going through the manufacturing process	• The data indicated that there were no statistically significant changes to the pH or production of lactic acid or acetaldehyde in contaminated yogurt relative to control (noncontaminated) yogurt that would indicate that *Staphylococcal enterotoxin B* (SEB) was present in either type of yogurt. The biochemical characteristics of yogurt did not present statistically significant changes (relative to control yogurt) in the presence of either thermally processed or native SEB. • *Salmonella typhi* and *Shigella dysenteriae* showed more tolerance and higher viable counts in infant formula than in flour. In addition, both species showed a preference for nitrogen storage conditions in infant formula over ambient air conditions. • *Yersinia pseudotuberculosis*, *Salmonella enteritidis*, and *Escherichia coli* O157:H7 can survive in flour and infant formula beyond 180 days. Survival in flour was best under refrigerated conditions. Humidity appeared to have the strongest effect on *Y. pseudotuberculosis* held at room temperature. • A pressure treatment designed to inactivate *Yersinia pestis* and *Francisella tularensis* live vaccine should be set at or above 500 MPa with a hold time of 2 minutes or greater to achieve a 5-log10 inactivation in milk or reduced-acid orange juice. A 3-log10 reduction of *Clostridium botulinum* type A neurotoxin was achieved in high-temperature pasteurized skim milk samples when they were pressure treated at 600 MPa at 25°C for 3 minutes. • Heating whole or skim milk spiked with picrotoxin at 85°C for 30 minutes had no effect on the toxin. Also, picrotoxin is not metabolized by yogurt starter culture bacteria, and the stability of the toxin is not affected by the physical/chemical changes in milk during yogurt manufacture. • Greater than a 4-log minimum lethal dose reduction of *C. botulinum* Type A was achieved during a 5-minute hot fill/hold procedure using a temperature of at least 80°C. In most cases, toxin was inactivated within the first minute of holding. • The presence of botulinum toxin yielded no difference in pH values, titratable acidities, and lactic acid bacteria populations, which were used as indicators for proper fermentation in yogurt samples. • Yogurt fermentation and production using milk contaminated with abrin, α-amanitin, and ricin may neither eliminate nor lower the hazard these toxins could pose to consumers.

continued

TABLE D-3 Continued

Oral toxicity of toxins produced by microorganisms	The results of a commercial enzyme-linked immunosorbent assay test for ricin and abrin in phosphate-buffered saline, apple juice, half-and-half, and bottled spring water provided a reliable indication of the amount of ricin and abrin present in each of the beverages. Differences were observed in the toxicity of ricin and abrin in phosphate-buffered saline > apple juice ≥ water ≥ half-and-half.
Effectiveness of detection methods in different food matrices	The evaluated system is capable of identifying as few as 10 colony forming units (CFU)/ml (or CFU/g) of *F. tularensis* live vaccine strain in infant formula, liquid egg whites, and lettuce and displays a broad range of detection of 108 CFU/ml (or CFU/g) to 101 CFU/ml (or CFU/g).

SOURCE: See http://www.fda.gov/Food/FoodDefense/FoodDefensePrograms/FoodDefenseResearchReports/default.htm (accessed October 8, 2010).

INFRASTUCTURE FOR FOOD DEFENSE

The FDA has probably undergone its greatest transformation in the area of food defense–related scientific testing and investigation. A significant number of changes focused on facility and personnel safety were required for proper handling of bioterrorism and other selected agents. Laboratory space had to be isolated so that high-dose or large amounts of chemicals/bacteria/toxins would not infiltrate other laboratory areas when sensitive testing was conducted on contaminants. Research on these agents posed a safety risk requiring special clothing, air/hood systems, and storage and disposal procedures.

The FDA established new procedures and conducted training and performance testing to ensure that its laboratories, and the broader Food Emergency Response Network (FERN), would be able to detect potential threat agents in a wide variety of foods. It was not a trivial matter to determine the adequacy of test methods when new foods were involved. Many of the chemicals and microbial agents of interest had not been investigated in FDA laboratory environments because natural barriers usually precluded their occurrence as contaminants in foods. Often adjustments of existing methods were sufficient, but at times whole new methods of extraction and detection were needed.

The FDA also undertook an extensive quality assurance program to ensure consistent application of microbial and chemical test methods and the accuracy of results across of all of its laboratories. Upon the formation of FERN, the quality assurance function was augmented, and state-of-the-art equipment for the laboratories was needed.

Currently there are 157 FERN laboratories: 35 federal, 111 state, and 11 local. These laboratories are staffed with 120 microbiological, 105 chemical, and 35 radiological scientists and staff. They carry out method development/validation; proficiency testing (in radiology, chemistry, and microbiology); surveillance testing; and electronic communications and collaboration. The FDA has mobilized the FERN laboratories to deal with a number of recent outbreaks, such as *E. coli* O157:H7 in spinach (2006), *Salmonella* in peppers (summer 2008), melamine in plant protein (2007), *Salmonella* in peanut butter (2009), and melamine in milk products (2008–2009). This new capacity, developed with food defense funds, has been a true asset in responding to public health emergencies, and reflects the assimilation of food defense and safety into the FDA's FPP.

An episode in 2005 tested the FDA's risk assessment and research capacity and demonstrated that the FDA, the milk industry, and the states were prepared to act quickly and effectively. All gained a better appreciation of the time and effort required to address potential food defense threats and the essential role of the new food defense capabilities as well as existing food safety systems. An article was published in a scientific journal that had the potential to frighten U.S. consumers, rather than depicting the scientific and technical challenges of protecting the U.S. food supply, in this case milk. This article described a mathematical model for the farm-to-table milk production system wherein a single milk-processing facility was the victim of a deliberate release of botulinum toxin into milk (Wein and Liu, 2005). The article suggested that if a terrorist could obtain enough toxin and introduce it into milk, rapid distribution and consumption could cause hundreds of thousands of poisonings.

The FDA and the industry were worried that the release of information on the effect of pasteurization on a terrorism hazard would cause a panic among U.S. consumers and provide a road map for a terrorist. The FDA and milk industry and state officials focused efforts on reducing the vulnerability of, and risk to, the milk supply by modifying the pasteurization parameters. Following these efforts, the FDA, using state milk inspectors, conducted surveys in 2006 and 2008–2009 to assess industry's voluntary compliance with the new parameters. Both surveys showed that better than 75 percent of milk processors had complied, thus reducing the risk to the milk supply from such an intentional contamination. This response by the FDA, the milk industry, and the state governments demonstrated their capacity to react quickly to a necessary technological change.

EMERGENCY RESPONSE

Preceding sections of this appendix have detailed FDA efforts to prevent an attack on the nation's food supply. Should such an attack occur,

however, the FDA and the administration, through the leadership of DHS, have procedures, networks, and capabilities in place to respond.

From the outset of the HHS bioterrorism efforts and the DHS/FDA/USDA food defense initiative, emergency response has been a key component. HHS's Office of Public Health Emergency Preparedness, as well as the FDA's OCM, Office of Emergency Operations, and center counterparts, developed all-hazard emergency response procedures to deal with a contaminated FDA-regulated product. In accordance with the relevant HSPD to employ the National Incident Management System (NIMS) in support of the NRP, the FDA adopted NIMS.

OCM also instituted continuity-of-operations planning, whereby the FDA and its suborganizations have an alternative site for operations should an attack or threat occur. Each suborganization had to identify essential personnel who would move to this alternative site to maintain operations, while others would be instructed to stay home and seek safety.

The FDA has conducted exercises and participated in HHS and DHS/administration training efforts to improve its preparedness, fill gaps in, or correct procedures and capacities as needed. The FDA also participated in the administration effort to review and update the NRP.

As mentioned earlier, if intelligence or FDA surveillance indicated a threat to an FDA-regulated product, this information would be communicated directly to OCM. OCM would in turn trigger its emergency response procedures, including notifying all relevant federal, state, and industry counterparts.

FOOD DEFENSE WITHIN THE FDA'S FPP

Prior to 2007, food defense and food safety program resources were usually separate in budgeting, program planning, and program goals and objectives. In 2007, the FDA combined the two under the FPP. In the context of its oversight of ever-increasing imported food shipments, a spate of domestic and imported food outbreaks, and numerous other factors, the FDA has proposed the FPP as its strategic plan for marshaling all of its expertise, systems, capabilities, and capacities to prevent, intervene in, and respond to food-related threats.

The FY 2010 FPP budget projects total full-time equivalents (FTEs) at 3,288 and funding of $8,455.8 million. This represents an increase of nearly 500 FTEs, but no increase in funding. Total FTEs for the animal drugs and feeds program are projected at 767, an increase of 105 FTEs, with funding of $171 million. The FTEs and funding are distributed among CFSAN, Center for Veterinary Medicine (CVM) headquarters, and ORA field operations for research scientists, regulatory review, program analysts, investigators, compliance, laboratory operations, etc.

The food defense components of the plan are as follows:

- The FDA will improve its ability to protect American consumers and strengthen the safety and security of the food supply chain by working with domestic and foreign industry to develop new control measures for all levels of food production and processing. The FDA will also verify that these control measures are effective when implemented.
- The FDA will strengthen food safety by improving the science on which regulatory decisions and enforcement rely. The agency will conduct risk analysis, modeling, and evaluation to improve risk-based decision making so it can better target resources to high-risk foods. This work will also include improving the FDA's ability to attribute contamination to specific foods and thereby promote faster response and better resource targeting.
- The FDA will work with the food industry, consumer groups, and federal, state, local, and foreign partners to identify and generate the additional data needed to improve understanding of food vulnerabilities and risks. This information will be used to strengthen food safety and defense.
- The FDA will expand state capacity to perform risk-based inspections by increasing the number of cooperative agreements and partnerships with states.
- The FDA will increase the number of chemical laboratories under the FERN program through cooperative agreements. The agency will also invest in high-volume laboratories for better sample analyses and faster testing.
- The FDA proposes establishing a new strategic framework for an integrated national food safety system. To achieve this objective, the FDA must build new and expand existing programs and relationships with its federal, state, local, tribal, and territorial regulatory partners. This will allow the FDA to increase information sharing and improve the quantity and quality of food safety data it receives from its food safety partners.
- The FDA will conduct research in high-priority areas, such as reducing the risk of *E. coli* in produce. The agency will speed its response to outbreaks by developing and validating technologies for subtyping pathogens and developing, evaluating, and deploying rapid detection tests.
- Working with its federal and state partners, the FDA will develop a Pet Event Tracking Network for early reporting of contaminated feed.

- The FDA will conduct research designed to limit the adverse health effects of intentional and unintentional contamination of food.
- The FDA will upgrade and integrate the information technology systems it uses to screen, sample, detain, and take enforcement actions against imported products. This effort includes developing and validating an accurate database of registered foreign facilities as well as designing and using risk-based software algorithms for import targeting.
- The FDA will improve the speed and effectiveness of its response to contamination by strengthening its ability to collect and analyze information necessary to trace products during a food emergency. The agency will also collaborate with state veterinary diagnostic laboratories to ensure more timely and accurate reporting and analysis of feed contamination.
- The FDA will aggressively strengthen its response to food-related events by instituting a more robust incident command system that fully integrates modern incident command principles into its emergency operations. The agency will also improve how it communicates with the public about food-related emergencies to ensure that such communications better meet the health and information needs of consumers.

As context for the above FY 2010 projected resources and anticipated accomplishments, it is important to review food defense budgeting and staffing generally to date. As mentioned previously, at the start of the food defense initiative, the FDA and its federal and state counterparts had no food defense experts on staff and could not hire any because none existed except for physical security experts. Therefore, food defense expertise was developed by current food safety staff and scientists. And as food defense and bioterrorism resources were appropriated, the FDA retrained and reclassified existing food safety professionals and staff to meet these obligations. This was done because, as food defense was receiving new funding, food safety funding was diminishing to the extent that FTEs and valuable expertise were being lost. Although some new staff were hired and trained over time, it was important for the FDA to retain its food safety expertise. For the near term, it redirected these resources to food defense research, training, education, risk communication, and compliance issues and problems.

Further, many of the systems and operations initiated for food defense were built upon and/or added to existing food safety operational components. So in essence, food defense and safety share resources. Therefore, for a particular fiscal year's budget and planning, the FDA can use its existing FTE resources for either program. The agency has thereby maintained a

dual focus in the face of dwindling resources, ensuring its ability to meet the full range of challenges to the food supply.

From interviews with FDA officials, it appears that currently there are a small number of FTEs dedicated to food defense in the areas of prevention, intervention, and response. While a dual focus has proven beneficial and prudent for the FDA's strategic purposes, it has also stretched and diminished the agency's food defense capacity and capabilities when food safety concerns have been a higher priority. Those interviewed mentioned the FDA's inability, due to a lack of available staff, to work on research collaboration and coordination as one example. It appears clear that the FDA does not have a dedicated food defense organizational unit(s) of sufficient critical mass to (1) sustain the development and coordination of CFSAN programs, training, and risk communications; (2) fulfill the FDA's leadership and participation with the Food and Agriculture Sector; and (3) direct, coordinate, and fund the research program on an intramural as well extramural basis.

SUMMARY AND OPPORTUNITIES FOR IMPROVEMENT

In 2001, the FDA began to define and build an intentional contamination program capacity within its food programs at CFSAN, CVM, and ORA, in line with the bioterrorism preparedness initiatives of HHS and CDC. That same year, Congress passed the Bioterrorism Act of 2002,[10] giving the FDA new authorities to better address threats from imported foods, to trace contaminated foods in distribution through record keeping, to detain contaminated foods in domestic commerce when deemed to be a serious danger to humans or animals, and to establish a database of all food producers worldwide so as to better target inspections and emergency response activities. In 2003, the administration reorganized to focus on domestic and border security functions, moving many domestic security programs from several departments to the new DHS.

The FDA, along with its federal food safety counterparts, had to forge a new working relationship with DHS to achieve its food defense goals and objectives. Through DHS's mission and scope of authorities, coupled with a series of HSPDs, the federal government, in cooperation with state, local, and industry counterparts, pursued an expanded effort to protect the nation's food supply from intentional attacks. A government–industry partnership—the Food and Agriculture Sector—allowed the FDA and other federal agencies to communicate, cooperate, and work more closely with regulated industry. The goal was to conduct vulnerability assessments and

[10] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, Public Law 107-188, 107th Cong., 2nd sess. (June 12, 2002).

identify the key critical assets within the food and animal feed systems. Using this information, the Food and Agriculture Sector's critical infrastructure protection plan, the SPPA initiative, was submitted as part of the NIPP.

Even with dedicated participation by both government and industry members, however, the Food and Agriculture Sector effort has been only moderately successful. The most recognized achievement is development of the SPPA initiative. Although the efforts expended by all members of this partnership have generated some valuable outcomes and deliverables, the general sense from industry, states, and some federal officials is that the efforts did not yield corresponding value. The FDA has built strong working relationships with its federal partners at HHS/CDC; USDA's FSIS, Animal and Plant Health Inspection Service, and ARS; EPA; DoD; and DHS. Through these partnerships, the FDA has leveraged and shared expertise, capabilities, and insight into how better to protect the nation's food supply.

In 2007, the FDA published its FPP, a strategic plan that combines food defense and safety into a single program. Since then, available resources have been applied in several instances to minimize the impact of food hazards in a rapid and effective manner. For example, the FERN laboratories have been activated to expand testing for *Salmonella St. Paul* in recent outbreaks associated with tomatoes/salsa. Bioterrorism record-keeping authority has been implemented to trace melamine-contaminated foods and animal feeds. In future budget and research planning, it will be even more important to assess relative risk in the areas of food defense and safety and to set priorities so the FDA can apply its core capacities and resources where most needed. However, combining food safety and defense priorities in a systematic and transparent process is necessary to fully integrate the components of the FPP.

As the FPP states, the FDA has devoted its food defense/protection efforts to preventing, intervening in, and responding to potential threats to the food supply. Over the years, the FDA has received additional funding for its food defense and bioterrorism program and activities. The agency has applied these funds primarily by redirecting existing scientific, program, and technical personnel to the food defense program. In so doing, the FDA has preserved its core food safety capacity and expertise while focusing its priorities on food defense issues. For example, the FDA embarked on an ambitious testing and research program; established appropriate facilities, such as BSL-4 laboratories; developed safety procedures for handling selected agents; established an expanded network of laboratory facilities (FERN) to gain surge capacity; and funded investigations for high-priority agents. Today, the agency is better equipped to respond to a chemical or microbial threat to the food supply.

At the same time, even the best planning efforts are limited by the inability to predict the future. Therefore, it is critical to retain functional expertise, capacity to act, and scientific knowledge to respond to both emerging food defense and safety events. From interviews with officials and a review of FY 2010 priorities, however, it appears that the food defense program's research and oversight functions possess less than critical mass. A review of the food defense program's progress and interviews with government and industry officials make it clear that the FDA needs additional legal authorities and technical improvements to manage and support a more functional food protection program. Congressional bills currently being discussed contain authorities to identify domestic and foreign food facilities through annual/biannual registration, to trace contaminated food products through records and impose fines when failures occur, to require food safety and defense prevention plans at each food facility or allow the FDA to impose fines for failures to maintain such plans, and to issue mandatory recall/stoppage of contaminated foods in commercial channels. With these additional legal authorities and associated funding, the FDA should have sufficient means to meet its ambitious goals for improving the overall safety of the nation's food supply.

Based on the information in this appendix, the author has identified the following opportunities for greatly improving the ability of the FDA to protect the public against potential intentional contamination of the nation's food supply:

- Develop the Food and Agriculture Sector partnership of a greater "value proposition" (i.e., a new mode of operation with valuable outcomes), acceptable to the GCC and SCC, that would address all hazards, encompassing food defense, natural disasters, nationwide events, and other challenges outlined in the FDA's FPP.
- Develop and apply a mechanism for prioritizing combined food defense and safety risks and generating a single ranked listing of food protection priorities for purposes of strategic, long-range planning.
- Develop a sufficient critical mass of core capacities, staff, and resources in the food defense program to (1) sustain the development and coordination of CFSAN and CVM programs, including training and risk communications; (2) fulfill the FDA's co-lead position on the GCC; and (3) direct, coordinate, and fund the agency's research program on a intramural as well extramural basis.
- Enact legislation and associated appropriations so the FDA has the legal and operational tools needed to achieve the FPP's goals and objectives.

ANNEX D-1

SUMMARY OF HR2749,[11] PROPOSED FOOD PROTECTION LEGISLATION

- **Creates an up-to-date registry of all food facilities serving American consumers:** Requires all facilities operating within the United States or importing food to the United States to register with the FDA annually.
- **Generates resources to support FDA oversight of food safety:** Requires payment of an annual registration fee of $500 per facility to generate revenue for food safety activities at the FDA.
- **Prevents food safety problems before they occur:** Requires foreign and domestic food facilities to have safety plans in place to identify and mitigate hazards. Safety plans and food facility records would be subject to review by FDA inspectors and third-party certifiers.
- **Increases inspections:** Sets a minimum inspection frequency for foreign and domestic facilities. Each high-risk facility would be inspected at least once every 6 to 12 months; each low-risk facility would be inspected at least once every 18 months to 3 years; and each warehouse would be inspected at least once every 5 years. Refusing, impeding, or delaying an inspection would be prohibited.
- **Requires demonstrating safety for food imports:** Directs the Secretary of HHS to require certain foreign foods to be certified by third parties accredited by the FDA as meeting all U.S. food safety requirements.
- **Creates a fast-track import process for food meeting security standards:** Directs the FDA to develop voluntary safety and security guidelines for imported foods. Importers meeting the guidelines would receive expedited processing.
- **Requires safety plans for fresh produce and certain other raw agricultural commodities:** Directs the FDA, in coordination with USDA, to issue regulations for ensuring the safe production and harvesting of fruits and vegetables and other raw agricultural commodities, such as mushrooms.
- **Improves traceability:** Significantly expands the FDA's trace-back capabilities in the event of a foodborne illness outbreak. Directs HHS to issue trace-back regulations that enable the Secretary to identify the history of the food in as short a time frame as prac-

[11] *Food Safety Enhancement Act of 2009*, HR2749, 111th Cong., 1st sess. (August 3, 2009).

ticable, but no longer than 2 business days. Prior to issuing such regulations, the Secretary would be required to conduct a feasibility study, public meetings, and one or more pilot projects. There would be exemptions for certain foods or facilities.

- **Requires country-of-origin labeling:** Requires labels on all processed food to indicate the country in which final processing occurred. Requires country-of-origin labeling for all produce.
- **Expands laboratory-testing capacity:** Requires the FDA to establish a program for recognizing laboratory accreditation bodies and to accept test results only from duly accredited laboratories. Requires laboratories to send certain test results directly to the FDA.
- **Provides strong, flexible enforcement tools:** Provides the FDA new authority to issue mandatory recalls of tainted foods. Strengthens penalties imposed on food facilities that fail to comply with safety requirements.
- **Advances the science of food safety:** Directs the Secretary to enhance foodborne illness surveillance systems so as to improve the collection, analysis, reporting, and usefulness of data on such illnesses. Requires the Secretary to provide greater coordination among federal, state, and local agencies.
- **Enhances the transparency of the "generally recognized as safe" (GRAS) program:** Requires posting on the FDA's website of documentation submitted to the FDA in support of GRAS notification.
- **Allows the FDA to charge a fee to cover the cost of additional inspections of facilities that previously committed a violation of the act related to food.**
- **Enhances oversight of the safety of new infant formulas:** Requires that the manufacturer of a new infant formula submit certain safety information regarding new ingredients. Grants the FDA additional time to review such new ingredients.
- **Enhances the FDA's ability to administratively detain tainted food products.**
- **Allows the Secretary to prohibit or restrict the movement of harmful food products:** If the Secretary, after consultation with the governor of a state, determines there is credible evidence that an article of food presents an imminent threat, he or she can prohibit or restrict movement of that food in the state or portion of the state.
- **Creates an up-to-date registry of importers:** Requires all importers of foods to register with the FDA annually and pay a registration fee.
- **Requires unique identification numbers for facilities and importers:** To improve the accuracy of data and the ability of the FDA to identify parties involved in a crisis situation more quickly, creates unique identification numbers for all food facilities and importers.

- **Provides protection for whistleblowers that bring attention to important safety information:** Prohibits entities regulated by the FDA from discriminating against an employee in retaliation for assisting in any investigation regarding any conduct the employee reasonably believes constitutes a violation of federal law.
- **Grants the FDA new authority to subpoena records related to possible violations.**

ANNEX D-2

AUTHORITIES

Under the FDCA,[12] the FDA regulates 80 percent of the nation's food supply, including all foods and animal feeds except for meat, poultry, and egg products, which are regulated by USDA. The FDA may take enforcement action when a food or feed is found to be adulterated. The term "adulteration" is defined in section 402 of the act. The FDA's food programs also operate under the following legal authorities: the FDCA; the Federal Import Milk Act;[13] the Public Health Service Act;[14] the Food Additives Amendment of 1958;[15] the Color Additives Amendments of 1960;[16] the Fair Packaging and Labeling Act of 1966;[17] the Safe Drinking Water Act of 1974;[18] the Saccharin Study and Labeling Act of 1977;[19] the Infant Formula Act of 1980;[20] the Drug Enforcement, Education, and Control

[12] *FDCA*, Public Law 75-717, 75th Cong., 3rd sess. (June 24, 1938). Codified as Title 21 U.S. Code, Section 9.

[13] *Federal Import Milk Act*, Title 21 U.S. Code, Chapter 4 §141-149.

[14] *Public Health Service Act*, Public Law 78-410, 78th Cong., 2nd sess. (July 1, 1944).

[15] *Food Additives Amendment of 1958*, Public Law 85-929, 85th Cong., 2nd sess. (September 6, 1958). Codified as Title 21 U.S. Code § 321.

[16] *Color Additives Amendments of 1960*, Public Law 86-618, 86th Cong., 2nd sess. (July 12, 1960). Codified as Title 21 U.S. Code § 321.

[17] *The Fair Packaging and Labeling Act of 1966*, Public Law 89-755, 89th Cong., 2nd sess. (November 3, 1966).

[18] *The Safe Drinking Water Act of 1974*, Public Law 93-523, 93rd Cong., 2nd sess. (December 14, 1974).

[19] *Saccharine Study and Labeling Act of 1977*, Public Law 95-203, 95th Cong., 1st sess. (November 23, 1977).

[20] *Infant Formula Act of 1980*, Public Law 96-359, 96th Cong., 2nd sess. (September 26, 1980).

Act of 1986;[21] the Nutrition Labeling and Education Act of 1990;[22] the Dietary Supplement Health and Education Act of 1994;[23] the Food Quality Protection Act of 1996;[24] the Federal Tea Tasters Repeal Act of 1996;[25] the Safe Drinking Water Act Amendments of 1996;[26] the Food and Drug Administration Modernization Act of 1997;[27] the Antimicrobial Regulation Technical Corrections Act of 1998;[28] the Public Health Security and Bioterrorism Preparedness and Response Act of 2002;[29] the Food Allergen Labeling and Consumer Protection Act of 2004;[30] the Sanitary Food Transportation Act of 2005;[31] the Dietary Supplement and Nonprescription Drug Consumer Protection Act;[32] and the Food and Drug Administration Amendments Act of 2007.[33] USDA regulates meat, poultry, and egg products under the Meat and Poultry Act, largely through premarket inspection and approval for sale.

Both the FDA and USDA have limited food defense enforcement authority, except for the Bioterrorism Act of 2002. Most of their initiatives are voluntary. Hence the food defense program, even at USDA with its authority to withhold its seal of approval, has been limited to issuing guidance and working with industry to encourage participation in food defense activities.

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[21] *Drug Enforcement, Education, and Control Act of 1986*, Public Law 99-570, 99th Cong., 2nd sess. (October 27, 1986).

[22] *Nutrition Labeling and Nutrition Act of 1990*, Public Law 101-535, 101st Cong., 2nd sess. (November 8, 1990).

[23] *Dietary Supplement Health and Education Act of 1994*, Public Law 103-417, 103rd Cong., 2nd sess. (October 25, 1994).

[24] *Food Quality Protection Act of 1996*, Public Law 104-170, 104th Cong., 2nd sess. (August 3, 1996).

[25] *Federal Tea Tasters Repeal Act of 1996*, Public Law 104-128, 104th Cong., 2nd sess. (April 9, 1996).

[26] *Safe Drinking Water Act Amendments of 1996*, Public Law 104-182, 104th Cong., 2nd sess. (August 6, 1996).

[27] *Food and Drug Administration Modernization Act of 1997*, Public Law 105-115, 105th Cong., 1st sess. (November 21, 1997).

[28] *Antimicrobial Regulation Technical Corrections Act of 1998*, Public Law 105-324, 105th Cong., 2nd sess. (October 30, 1998).

[29] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, Public Law 107-188, 107th Cong., 2nd sess. (June 12, 2002).

[30] *Food Allergen Labeling and Consumer Protection Act of 2004,* Public Law 108-282. 108th Cong., 2nd sess. (August 2, 2004).

[31] *Sanitary Food Transportation Act of 2005*, Public Law 109-59, 109th Cong., 1st sess (August 10, 2005).

[32] *Dietary Supplement and Nonprescription Drug Consumer Protection Act*, Public Law 109-462, 109th Cong., 2nd sess. (December 22, 2006).

[33] *Food and Drug Administration Amendments Act of 2007*, Public Law 110-85, 110th Cong., 1st sess. (September 27, 2007).

ANNEX D-3

OVERVIEW OF THE NIPP

HSPD-7 identifies 17 critical infrastructure and key resources (CIKR) sectors and designates federal government SSAs for each of the sectors. Each sector is responsible for developing and implementing an SSP and providing sector-level performance feedback to DHS to enable assessment of national cross-sector CIKR protection program gaps. SSAs are responsible for collaborating with private-sector security partners and encouraging the development of appropriate information sharing and analysis mechanisms within the sector. HSPD-9 establishes a national policy to defend the food and agriculture system against terrorist attacks, major disasters, and other emergencies.

SECTOR OVERVIEW

The Food and Agriculture Sector has the capacity to feed and clothe people well beyond the boundaries of the nation. The Sector is almost entirely under private ownership and is composed of an estimated 2.1 million farms, approximately 880,500 firms, and more than 1 million facilities. This Sector accounts for roughly one-fifth of the nation's economic activity and is overseen at the federal level by USDA and the FDA within HHS.

USDA is a diverse and complex organization with programs that touch the lives of all Americans every day. More than 100,000 employees deliver more than $75 billion in public services through USDA's more than 300 programs worldwide, leveraging an extensive network of federal, state, and local cooperators. One of USDA's key roles is to ensure that the nation's food and fiber needs are met. USDA is also responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, as well as protecting and promoting U.S. agricultural health.

The FDA is responsible for the safety of 80 percent of all of the food consumed in the United States. While its mission is to protect and promote the public health, that responsibility is shared with federal, state, and local agencies; regulated industry; academia; health care providers; and consumers. The FDA regulates $240 billion of domestic food and $15 billion of imported food. In addition, roughly 600,000 restaurants and institutional food service providers, an estimated 235,000 grocery stores, and other food outlets are regulated by state and local authorities that receive guidance and other technical assistance from the FDA.

The Food and Agriculture Sector is dependent upon the Water Sec-

tor for clean irrigation and processed water; the Transportation Systems Sector for movement of commodities, products, and livestock; the Energy Sector for powering of the equipment needed for agricultural production and food processing; and the Banking and Finance, Chemical, Dams, and other sectors as well.

SECTOR PARTNERSHIPS

In 2004, the Food and Agriculture Sector Coordinating Council (FASCC) was formed. The FASCC comprises a GCC and a private-sector coordinating council. The FASCC hosts quarterly joint meetings that provide a public–private forum for effective coordination of agriculture security and food defense strategies and activities, policy, and communications across the entire Sector to support the nation's homeland security mission. It provides a venue for mutually planning, implementing, and executing Sector-wide security programs, procedures, and processes, as well as for exchanging information and assessing accomplishments and progress in defending the nation's food and agriculture critical infrastructure. It is a central forum for introducing new initiatives for mutual engagement, evaluation, and implementation; issue resolution; and mutual education. Joint initiatives include identifying and prioritizing items that need public–private input, coordination, implementation, and communication; coordinating and communicating issues to all members; and identifying needs/gaps in research, best practices/standards, and communications.

PRIORITY PROGRAMS

The SPPA Initiative

To assist in protecting the nation's food supply, the FBI, DHS, USDA, and HHS/FDA developed a joint assessment program—the SPPA initiative. This initiative included a series of assessments of the Food and Agriculture Sector in collaboration with private industry and state volunteers. These assessments supported the requirements for a coordinated food and agriculture infrastructure protection program as stated in the NIPP, SSPs, and HSPD-9. SPPA assessments were conducted on a voluntary basis among one or more industry representatives for a particular product or commodity, their trade association, and federal and state government agricultural, public health, and law enforcement officials. Together they conducted a threat assessment of that industry's production process, enabling the participants to identify nodes or process points of highest concern, protective measures and mitigation steps that could reduce the susceptibility of these nodes, and research gaps and needs. Between November 2005 and May 2008, the

teams completed 36 assessments in 28 states with industry partners, and identified generic protective measures or mitigation strategies that could be beneficial to many Sector industries. The first- and second-year status reports for the SPPA initiative are available at http://www.fda.gov/Food/FoodDefense/FoodDefensePrograms/FoodDefenseResearchReports/default.htm (accessed October 8, 2010).

FASCAT

The Food and Agriculture Sector GCC has partnered with one of DHS's Centers of Excellence, the NCFPD, to develop an assessment tool to assist states in determining and documenting the most critical elements and systems/subsystems of food and agriculture infrastructure at the state level. This tool is called FASCAT. It provides

- a means to identify sector elements and systems that are critical to key state commodity chains or food distribution systems,
- a method of prioritization for further state or private-sector vulnerability assessments and possible development of a protective measure(s) or mitigation strategies,
- documentation and improved characterization of a state's Food and Agriculture Sector risk profile, and
- an effective response to future DHS national calls for information on critical Food and Agriculture Sector infrastructure components.

The complete FASCAT module, its instructions, and an online video tutorial are available at the University of Minnesota's NCFPD website: www.ncfpd.umn.edu (accessed October 8, 2010).

Tabletop Exercises

As part of its goal to improve preparedness, the Food and Agriculture Sector is committed to conducting tabletop exercises to demonstrate how government and industry can work together more effectively during a food contamination incident or a foreign animal or plant pest or disease outbreak. The Sector will continue to host tabletop exercises that focus on response and recovery coordination among federal, state, tribal, local, and industry stakeholders.

Training

The FDA and USDA developed an online Food Defense Awareness training course targeting federal, state, and local regulators; local law

enforcement; food program administrators; and industry. The goal of the course is to increase awareness of the potential for intentional adulteration of the food supply. The course is available online at www.fda.gov/ora/training/orau/FoodSecurity/startpage.html (accessed October 8, 2010). In addition, the FDA has launched the ALERT initiative (acronym based on the words Assure, Look, Employees, Reports, Threat). This initiative is intended to raise awareness among state and local government agency and industry representatives regarding food defense issues and preparedness. It is generic enough to apply to all aspects of the farm-to-table supply chain and is designed to spark thought and discussion with a variety of stakeholders. ALERT identifies five key ways in which industry and businesses can decrease the risk of intentional food contamination at their facilities. More information on ALERT is available online at http://www.cfsan.fda.gov/~dms/alert.html (accessed October 8, 2010).

ANNEX D-4

HHS OFFICE OF INSPECTOR GENERAL REPORT: *TRACEABILITY IN THE FOOD SUPPLY CHAIN*[34]

SUMMARY[35]

Objectives

1. To assess the traceability of selected food products.
2. To determine the extent to which selected food facilities maintain information required by the FDA in a food emergency.

Background

Beginning in 2005, the FDA required certain food facilities to maintain records identifying the sources, recipients, and transporters of food products. The purpose of these records is to allow the FDA to trace an article of food through each stage of the food supply chain—from a retail shelf back to a farm—if the FDA has a reasonable belief that a food product is adulterated and presents a serious health threat.

[34] Office of Inspector General. 2009. *Traceability in the Food Supply Chain.* Report number: OIE-02-06-00210. Washington, DC: OIG.

[35] Excerpted from the report.

Traceability is the ability to follow the movement of a food product through the stages of production, processing, and distribution. Traceability includes both traceback and trace forward. Traceback is the ability to trace a food product from the retail shelf back to the farm. Conversely, trace forward is the ability to trace a food product from the farm forward to the retail shelf. Traceability is often needed to identify the sources of food contamination and the recipients of contaminated food in product recalls and seizures. This study refers to such a situation as a "food emergency."

This study is based on two primary data sources: (1) a traceability exercise of 40 selected food products and (2) structured interviews with the managers at the food facilities that handled the selected food products. For the traceability exercise, we purchased 40 food products from different retail stores and attempted to trace them through each stage of the food supply chain back to the farm(s) or the border. We asked the facilities that handled the food product for information about their sources, recipients, and transporters, which we used in an effort to trace the product.

Findings

We were able to trace 5 of the 40 products through each stage of the food supply chain; for most of the other products, we could identify the facilities that likely handled them. Not all facilities are required to maintain lot-specific information in their records, and those that are required to maintain lot-specific information are required to maintain it only if it exists. As a result, we were able to trace five of the specific products through each stage of the food supply chain. The facilities that handled each of these products were able to provide information about the specific product we purchased or were able to link that product to lot-specific information in their records.

For 31 of the 40 products, we were able to identify the facilities that likely handled the products. Most facilities that handled these products did not maintain lot-specific information in their records and could only estimate a range of deliveries (from one or more facilities) that may have included the product we purchased. As a result, we were not able to trace these specific products through each stage of the food supply chain. In addition, these estimates may have included more facilities than those that actually handled the product or may not have included all of the facilities that handled the product. For example, for one product—a bag of flour—the storage facility did not know the exact farms that contributed to the product and, therefore, had to give us information about every farm that provided wheat during the previous harvest season.

For the remaining four products, we could not even identify the facili-

ties that likely handled them. In these cases, at least one facility in the food supply chain failed to provide any information about the potential sources of the products.

Several factors prevented us from tracing the specific products through the food supply chain. Several factors limited our ability to trace the specific food products through each stage of the food supply chain. These factors included (1) processors, packers, and manufacturers not always maintaining lot-specific information as required; (2) other types of facilities not maintaining lot-specific information because it is not required; (3) retailers receiving products not labeled with lot-specific information; and (4) the mixing of products from a large number of farms. These factors also affect the speed with which the FDA can trace specific food products through the food supply chain.

Fifty-nine percent of the food facilities did not meet the FDA's requirements to maintain records about their sources, recipients, and transporters. Fifty-nine percent (70 of 118) of the food facilities in our traceability exercise did not provide all of the required contact information about their sources, recipients, and transporters. Twenty percent did not provide all of the required information about their sources, 52 percent did not provide all of the required information about their recipients, and 46 percent did not provide all of the required information about their transporters.

Facilities could not provide all required contact information for several reasons. In some cases, managers had to look through large numbers of records—some of them paper based—for contact information. Additionally, some facilities did not have integrated record-keeping systems that linked sources and recipients to specific shipments or to transporters, and managers had to search separate systems to obtain the contact information.

One-quarter of the food facilities were not aware of the FDA's records requirements; others highlighted practices designed to improve traceability. Twenty-five percent (26 of 104) of the managers who responded to our questions were not aware of the FDA's records requirements. Specifically, 50 percent of the managers at retail facilities were not aware of the FDA's records requirements, compared to 21 percent of the managers at distributor, wholesale, and storage facilities and 13 percent of the managers at processing, packing, and manufacturing facilities.

Over half of the managers (43 of 78) who were aware of the FDA's records requirements reported making changes to their record-keeping practices to meet these requirements. These changes included switching from paper-based to electronic record-keeping systems, improving their existing electronic systems, and improving their facilities' ability to maintain lot-specific information.

Recommendations

To address the findings in this report, we recommend that the FDA:

- Seek statutory authority, if necessary, to strengthen existing records requirements regarding lot-specific information.
- Consider seeking additional statutory authority to improve traceability.
- Work with the food industry to develop additional guidance to strengthen traceability.
- Address issues related to mixing raw food products from a large number of farms.
- Seek statutory authority to conduct activities to ensure that facilities are complying with its records requirements.
- Conduct education and outreach activities to inform the food industry about its records requirements.

ANNEX D-5

BUDGET REQUEST FOR THE FOODS PROGRAM

The FY 2010 President's Budget requests $845,617,000 in program level funding for the Foods Program, including user fees, in the support of 3,516 FTEs. The CFSAN portion of the request is $244,981,000 and 947 FTEs, an increase above the FY 2009 Omnibus of $34,495,000 and an increase of 93 FTEs to maintain current service levels. The Field portion of the request is $600,636,000 supporting 2,569 FTEs, an increase above the FY 2009 Omnibus of $162,400,000 and 404 FTEs.

In FY 2010, CFSAN will continue to take the lead in maintaining and improving an already sound food safety protection capability by accomplishing the goals and objectives established in the FDA FPP and the Import Safety Action Plan as well as continuing cooperation and information sharing between the United States and China.

The FDA envisions establishing a new strategic framework for an integrated national food safety system. In order to efficiently and effectively establish a fully integrated national food and feed safety system, the FDA must build and expand existing programs and relationships with its regulatory partners, specifically its federal, state, local, tribal, and territorial partners. The FDA is requesting funding in FY 2010 to begin establishing the necessary infrastructure for the Field Food and Feeds Programs in the following four areas:

1. Develop a National Work Plan that includes the inspections of food manufacturing and distribution facilities and the collection and analyses of compliance, surveillance, and environmental samples.
2. Ensure that programmatic objectives and implementation are coordinated.
3. Continue to develop uniform national standards for such subjects as manufacturing, inspections, and enforcement.
4. Build training courses and a certification program to be delivered to state, local, and tribal regulatory partners, and increase programmatic oversight and develop a more robust audit program.

A system of this magnitude may require new authorizations such as multi-year budget authority for federal, state, local, tribal, and territorial regulatory partners and the authority to share non-public information with our regulatory partners when it is necessary to protect public health. However, this request is necessary to begin building the framework for an integrated national food safety system.

Furthermore, ORA is requesting funding in FY 2010 to continue building its workforce for more field food and feed work and support for the field food and feed work. In order to do so, ORA is requesting funding to continue hiring investigators, analysts, and support staff in order to continue to increase field and food work, such as:

- an increase of 20,000 food and feed import exams by the end of 2011,
- an increase of 2,000 domestic food and feed inspections by the end of 2012, and
- an increase of 50 foreign food and feed inspections by the end of 2012.

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ANNEX TABLE D-1 Participants in the Food Defense Program

White House	
Interagency Food Working Group	An interagency working group consists of representatives from multiple federal agencies (e.g., U.S. Department of Agriculture [USDA], U.S. Environmental Protection Agency [EPA], U.S. Department of Health and Human Services [HHS], U.S. Department of Defense [DoD]) empaneled to discuss issues related to a particular topic. This group was formed under the White House Homeland Security Council.
HHS	
Office of Public Health Emergency Preparedness (OPHEP)	OPHEP serves as the principal advisory staff to the Secretary of HHS on matters related to bioterrorism and other public health emergencies. It coordinates interagency activities among HHS; other federal departments, agencies, and offices; and state and local officials responsible for emergency preparedness and protection of the civilian population from acts of bioterrorism and other public health emergencies.
U.S. Centers for Disease Control and Prevention (CDC)	CDC identifies foodborne illnesses and leads HHS efforts in bioterrorism. CDC works with the U.S. Food and Drug Administration (FDA) and/or USDA to conduct follow-up on foodborne illness events and coordinate emergency response and surveillance activities. CDC's Laboratory Response Network is a network of state public health laboratories developed to provide surge capacity for samples resulting from a public health emergency caused by a selected agent. Its counterpart, the FDA/USDA Food Emergency Response Network (FERN), comprises laboratories that perform testing and analysis for selected agents when foods, feeds, and associated materials are implicated.

continued

ANNEX TABLE D-1 Continued

FDA	The FDA regulates 80% of foods, biologics, animal feeds and drugs, medical devices, and human drugs. In 2008, the FDA created the Office of Food Protection. This agency-level office is transitioning to the Deputy Commissioner for Foods. The FDA comprises nine centers and offices. Of these, the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the Office of Regulatory Affairs (ORA) house the management, investigation, scientific/laboratory, and enforcement personnel that develop, coordinate, and implement the food defense/safety/protection program. In addition, • The Office of Crisis Management coordinates emergency and crisis response activities involving FDA-regulated products or situations in which FDA-regulated products need to be utilized or deployed. It coordinates intra-agency and interagency crisis management activities, emergency preparedness and response, and security operations. • The Emergency Operations Center serves as the FDA's focal point for all emergency response activities 7 days a week, 24 hours a day. It receives notification of an emergency through a variety of means, including from FDA Headquarters, CDC, USDA, FDA district offices, FDA centers, other federal and state agencies, consumers, and the media. Within each FDA center and each ORA region and district exists a corresponding food emergency response staff or coordinator dealing solely with food-related recalls, outbreaks, and emergency response procedures.

ANNEX TABLE D-1 Continued

CFSAN	CFSAN is responsible for ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled. The FDA Food Protection Plan (FPP) covers all programs within CFSAN. • Office of Food Defense, Communication and Emergency Response: With the Food and Agriculture Sector, coordinates and takes the lead on food defense policy, programs, extramural research, and outreach. • Office of Regulations, Policy, and Social Studies: lead unit for regulation development. • Office of Compliance: lead unit for investigations, enforcement coordination and policy, and compliance program direction for all CFSAN programs and activities. • Office of Regulatory Science: lead unit for intramural food defense research, FERN method development and quality assurance, and the FERN storehouse. Has microbiological, chemical, and radiological capabilities. • Joint government, academic, and industry cooperative research entities: — Joint Institute for Food Safety and Applied Nutrition (University of Maryland): focus on nutrition and produce. — National Center for Food Safety and Technology (NCFST) (Illinois Institute of Technology): focus on food processing and biosafety level (BSL)-4 pilot plant. Key FDA participant in food defense research.
CVM	CVM regulates the manufacture and distribution of food additives and drugs given to animals. The FDA FPP covers the Animal Feed Safety System program within CVM—a draft comprehensive, risk-based system that describes how animal feeds (individual ingredients and mixed feeds) should be manufactured and distributed to minimize risks to animals consuming the feed and people consuming food products from those animals.
ORA	ORA coordinates and oversees all field organizations, and is made up of (1) the Office of Regional Operations, which oversees and coordinates domestic and import investigations and laboratory and research operations and policy; (2) the Office of Enforcement, which oversees compliance and enforcement operations; (3) the Office of Administration and Budget, which oversees administrative operations, including information technology, hiring, budgeting, and planning; and (4) the Office of Criminal Investigations, which houses the lead criminal investigators for all FDA-regulated products and serves as the Federal Bureau of Investigation (FBI)/Central Intelligence Agency (CIA) law enforcement and intelligence liaison.

continued

ANNEX TABLE D-1 Continued

USDA	USDA regulates 20 percent of the nation's food supply, namely meat, poultry, and egg products. It performs on-site inspection at each meat or poultry facility, monitors animal and plant disease, is involved in agriculture marketing, and develops school lunch and nutrition cooperative programs. • Food Safety and Inspection Service: responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. • Animal and Plant Health Inspection Service: Responsible for animal and plant disease prevention and control. • Agricultural Marketing Service: Provides quality assurance and training services for certain market-based food programs. • National Institute of Food and Agriculture, formerly Cooperative State Research, Education, and Extension Service. • Food and Nutrition Service: Manages programs that provide children and low-income people access to food, a healthful diet, and nutrition education. • Federal Grain Inspection Service: Helps move U.S. grain harvests into the marketplace by providing farmers, handlers, processors, exporters, and international buyers with sampling, inspection, process verification, weighing, and stowage examination services that accurately and consistently describe the quality and quantity of the commodities being bought and sold. • Agricultural Research Service: Chief scientific research agency responsible for the safety of meat, poultry, and eggs and for identifying and solving problems associated with agricultural commodities.
EPA	EPA's mission is to protect human health and the environment. EPA also leads the nation's environmental science, research, education, and assessment efforts. In the FPP, EPA is responsible for environmental and water safety, setting tolerances or safe levels for food and feed toxicants such as pesticides and industrial chemicals, which the FDA enforces. Its Office of Research and Development is the scientific research arm providing the underpinning of science and technology for the agency.

ANNEX TABLE D-1 Continued

U.S. Department of Homeland Security (DHS)	DHS has three primary missions: (1) to prevent terrorist attacks within the United States, (2) to reduce America's vulnerability to terrorism, and (3) to minimize the damage from potential attacks and natural disasters: • Office of Infrastructure Protection: establishes state homeland security offices, awards state grants to address vulnerabilities, develops and coordinates the National Infrastructure Protection Plan. • Office of Health Affairs: oversees public health emergencies. • Office of Science and Technology: establishes research agendas for Centers of Excellence. • National Center for Food Protection and Defense: with numerous partner universities, supports the Food and Agriculture Sector's scientific and risk communication research needs. • U.S. Customs and Border Protection: conducts border surveillance and customs inspections, and serves on the FDA's behalf to assist with or initiate imported food directives at ports of entry. • Federal Emergency Management Agency (FEMA): leads the effort to prepare the nation for all hazards and effectively manage federal response and recovery efforts following any national incident. FEMA is a key FDA FPP partner in the coordination of food protection emergency response exercises, including Food and Agriculture Sector exercises.
DoD	In addition to its mission to provide military forces and protect the national security, DoD houses veterinary, medical, biological, and chemical research organizations. The Defense Advanced Research Projects Agency is DoD's central research and development office. The U.S. Army Medical Research Institute of Infectious Diseases spearheads research to develop medical solutions to protect service members from biological threats. Capabilities include BSL-3 and -4 laboratories, expertise in the generation of biological aerosols for testing candidate vaccines and therapeutics, and fully accredited animal research facilities. DoD is a key FDA FPP participant, providing the capability to conduct high-priority food defense research.
U.S. Department of the Interior (DoI)	DoI's Fish and Wildlife Service (FWS) serves on the Government Coordinating Council (GCC). FWS's mission is to work with others to conserve, protect, and enhance fish, wildlife, plants, and their habitats for the continuing benefit of the American people.

continued

ANNEX TABLE D-1 Continued

U.S. Department of Commerce (DoC)	DoC's mission includes fish and aquaculture operations under the National Oceanic and Atmospheric Administration (NOAA). NOAA is a member of the GCC and represented by the National Marine Fisheries Service (NMFS). NMFS's mission is the conservation, protection, and management of living marine resources to ensure their continuation as functioning components of marine ecosystems, afford economic opportunities, and enhance the quality of life for the American public.
U.S. Department of Justice (DOJ)	DOJ's mission, in part, is to enforce the law and defend the interests of the United States according to the law. DOJ's FBI is a key participant and counterpart in food defense intelligence gathering and a lead for tampering act enforcement and investigations.
State and Tribal Government Counterparts	
Association of Food and Drug Officials	An organization of state food and drug officials that serves the function of implementing state and federal food safety regulations and policy. Serves as the FDA's primary counterpart in state government.
Association of Public Health Laboratories (APHL)	A nonprofit organization that works to safeguard the public's health by strengthening public health laboratories in the United States and across the world. APHL advances laboratory systems and practices and promotes policies that support healthy communities.
Association of State and Territorial Health Officials	A national nonprofit organization that formulates and influences sound public health policy and represents the state and territorial public health agencies of the United States, the U.S. territories, and the District of Columbia.
American Veterinary Medical Association (AVMA)	A nonprofit association representing veterinarians that is the authorized voice for the profession in presenting its views to government, academia, agriculture, pet owners, the media, and others. Members of the National Assembly of State Chief Livestock Health Officials and American Association of Veterinary Laboratory Diagnosticians represent AVMA on the GCC.
Council of State and Territorial Epidemiologists	Represents the epidemiology and surveillance components of public health. Works with CDC to improve the public's health by supporting the efforts of epidemiologists working at the state and local levels, promoting the effective use of epidemiologic data to guide public health practice and improve health.

ANNEX TABLE D-1 Continued

National Association of County and City Health Officials (NACCHO)	A national organization representing local public health agencies (including city, county, metro, district, and tribal agencies), with the goal of protecting and promoting the health of communities. NACCHO supports public health in local communities by calling for strong national policy, developing useful resources and programs, seeking health equity, and supporting effective local public health practice and systems.
National Association of State Departments of Agriculture	A nonprofit organization that represents the state departments of agriculture in the development, implementation, and communication of sound public policy and programs that support and promote the American agricultural industry while protecting consumers and the environment.
National Plant Board	A nonprofit organization of regulatory agencies of each of the states and Puerto Rico. Its purpose is to foster effective and harmonized plant health programs; to act as an information clearinghouse on plant pest prevention and regulatory matters; to make recommendations to the regional boards for the promotion of efficiency, harmony, and uniformity in and among the states in the field of plant pest prevention and regulation; to collaborate and communicate effectively with public and private agencies and organizations on plant health and pest regulatory issues that affect the states; and to protect agriculture, horticulture, forestry, and the environment at the state, national, and international levels.
National Environmental Health Association	Works to advance, in terms of education and motivation, the environmental health and protection professional for the purpose of providing a healthful environment for all.
Intertribal Agriculture Council (IAC)	Founded in 1987, IAC's mission is to pursue and promote the conservation, development, and use of agricultural resources for the betterment of Native American and Alaskan tribes. IAC works on behalf of individual Indian producers and tribal enterprises with federal government agencies and the agricultural sector. It is the most respected voice within the Indian community and government circles on agricultural policies and programs.
Private-Sector Counterparts	
Institute of Food Technologists	A nonprofit scientific society dedicated to advancing the science and technology of food and related professions in industry, academia, and government.

Appendix E

The U.S. Food and Drug Administration and Imported Food Safety[1,2]

In the United States, an apple grower knows what pesticides the U.S. Environmental Protection Agency (EPA) has approved for use in apples, their application rates, and preharvest intervals. Similarly, a dairy farmer and his/her veterinarian can look at a U.S. Food and Drug Administration (FDA)-approved label on an FDA-approved veterinary drug and know whether the drug can safely be used in cows producing milk and for how long the milk must be discarded. Domestic food manufacturers, food warehouses, and farms recognize that they can be inspected and their products sampled. Domestic producers worry about maintaining the integrity and good reputations of their brands. U.S. trade organizations educate their members about food safety and FDA regulations. When a foodborne outbreak occurs, the FDA and states can investigate quickly and usually track down the source.

Imported foods come to the United States from nearly 200 countries, none of which have exactly the same pesticide, food additive, and veterinary drug approval systems as the United States, and many of which do not have such systems at all. Foreign producers may be ignorant of U.S. food safety requirements or may produce for multiple foreign markets.

[1] Catherine Carnevale, V.M.D., Retired, FDA; former Director of International Affairs at the FDA Center for Food Safety and Applied Nutrition and lead U.S. Delegate to the Codex Alimentarius Committee on Food Import/Export Inspection and Certification Systems.

[2] Because of the broad scope of this appendix, laws, regulations, proposed legislation, trade agreements, guidance, activities, and issues have been summarized and paraphrased for the sake of brevity. A few topics are discussed in detail based on specific requests of the committee and staff, but most are not. Thus, the discussion is not meant to be comprehensive.

Domestic food safety systems in exporting countries may vary from excellent to nonexistent. Potable water may not be available for irrigation; waste and sewage treatment may be absent or inadequate. Nevertheless, many exporting countries that lack domestic food safety programs are willing to do what they can to ensure export markets for their products, including employing food safety measures to satisfy importing country requirements if doing otherwise could cause problems or a loss of market access.

While no importing country is able to examine all imported foods for all possible chemical residues and contaminants, microbiological pathogens, and physical hazards, many importing countries have achieved excellent imported food safety records by focusing resources on higher-risk foods and preventive mechanisms and confronting food-related public health problems when they occur. As discussed in this appendix, import programs for food safety can employ many methodologies to foster safer imports and provide incentives for foreign producers/food importers to comply with importing country requirements. Just as imported food presents different food safety challenges from those encountered with domestically produced foods, so, too, do they require a different paradigm for regulation.

BACKGROUND

The FDA's overall foods program is distinct in several respects from the agency's other public health regulatory program areas. First—with the exception of food and color additive approvals and premarket notification for certain foods—foods under FDA jurisdiction, whether produced within or outside the United States, do not require premarket approval. Thus, the foods program overall is generally a postmarket program. A second difference is that the foods regulatory program, to date, is not supported in any way by user fees, while all agency premarket approval programs are, as well as all agency export certificate programs, except for foods. Thus the foods program, at present, is totally dependent on congressional appropriations. Third, whereas most of the FDA's other centers generally have regulatory autonomy over their respective product areas, the Center for Food Safety and Applied Nutrition (CFSAN) must interface with other federal departments and agencies, as well as the 50 states, to ensure consistent and comprehensive coverage of the entire U.S. food supply at all levels. While the regulatory roles of U.S. food safety partners are well delineated, smooth operation of the U.S. food control system requires constant communication to ensure that the roles mesh efficiently. Finally, the foods program differs from other FDA programs in that, by volume of product and number of consignments, the realm for regulatory oversight is vast. These four differences are important to remember and fundamental in considering potential improvements in the FDA's foods program because one needs to understand

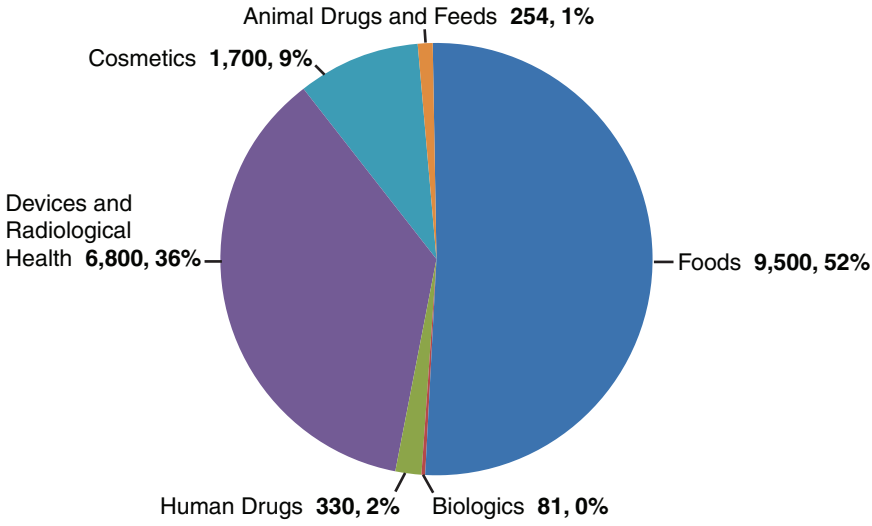

FIGURE E-1 Fiscal year 2009 estimated import lines by program area (in thousands): total 18.7 million lines.
SOURCE: Personal communication, Steven Solomon, Office of Regulatory Affairs, July 2009.

the regulatory context in which the program operates in regulating 80 percent of the nation's food supply (Meadows, 2006). The differences between other FDA programs and the foods program are especially apparent in light of the special challenges inherent in regulating imported food safety.

The estimated total of food import entry lines[3] for fiscal year (FY) 2009 is 9.5 million, or 52 percent of the estimated total of 18.7 million lines for all FDA-regulated imported products (see Figure E-1).[4] Food imports now account for approximately 15 percent of the foods and 80 percent of the seafood consumed in the United States (Acheson and Glavin, 2007). In addition to quantity, the variety of imported product types is challenging to regulate, ranging from highly perishable produce, to dairy, to shellfish, to canned products, to bakery goods. The number and types of countries exporting products to U.S. shores are also wide-ranging, from less developed countries with, at best, rudimentary food regulatory systems to developed economies with highly regarded food safety controls.

[3] An entry line is each portion of an import shipment that is listed as a separate item on an entry document. Items in an import entry having different tariff descriptions must be listed separately.

[4] Personal communication, Steven Solomon, Office of Regulatory Affairs, FDA, July 2009.

Although many countries may have a limited spectrum of products that they export, almost every country exports agricultural commodities, and almost 200 countries export such commodities to the United States (FAS, 2009).

Regulating imported foods can be complex. With such foods, the FDA may need to consider not only the exporting country's food control system but also the environment in which the food is grown, including the availability of potable water for irrigation and washing, and diseases of farm workers and farm animals that could impact the safety of the food. In addition to working with other U.S. food-related agencies and states, as it does for its domestic food safety program, for its imported food program the FDA must interface with U.S. Customs and Border Protection (CBP, in the U.S. Department of Homeland Security), the Office of the U.S. Trade Representative, the Foreign Agricultural Service, the Departments of State and Commerce, and exporting country governments themselves. Compliance with international trade agreement obligations is important in dealing with imports, including ensuring that the scientific basis for all FDA regulatory measures that may impact trade is clear and no more trade-restrictive than necessary. Imported foods are infrequently examined at the border, often being sampled for analysis less than 1 percent of the time (GAO, 2008).[5] There are simply too many imported food shipments for the FDA resources available. Certainly there are too many foreign firms to consider on-site inspections on a routine basis, and the few such inspections performed can only provide a snapshot of a country's internal food regulatory system. Most foreign facilities that produce, manufacture, process, or store foods consumed in the United States must register under the bioterrorism regulations (FDA, 2009a); however, there is no mechanism for putting foreign food producers and shippers on notice that U.S. food safety laws must be followed, other than the laws and regulations themselves. Clearly, the FDA's imported food program needs a fresh review.

The Concept and Design for the FDA's Imported Food Program

In large part, the FDA's food laws and programs were built around a domestic food industry. Domestic food facilities were to be inspected, with the FDA focusing on products involved in interstate commerce and states concentrating on retail and intrastate establishments. Sampling of food was conducted during inspections of firms to detect problems or to confirm a safety concern when one was suspected. Sampling of products being moved in commerce was done primarily on a surveillance basis and often close to

[5] The FDA examined less than 1 percent of the 7.6 million fresh produce lines imported from FY 2002 through 2007.

the farm gate or boat. Foods were not transported long distances; only a tiny fraction of foods consumed came from other countries, and these were traditional imports such as bananas and coffee.

Until very recently, the FDA approached food imports with a philosophy similar to that of its domestic program. All foods, whether domestic or imported, must comply with the same food safety standards, and, as with domestic foods, it is the responsibility of foreign companies—growers, manufacturers, packers, warehouses—and importers to know and comply with applicable laws and regulations. The FDA maintains a comprehensive website that provides all this information, generally in English only (FDA, 2009b). Although it can be argued that knowing the food safety requirements of the importing country should be integral to conducting a food export business, it may also be noted, with some exceptions, that until quite recently the FDA did not actively pursue outreach to foreign countries, their industries, or importers regarding its food safety requirements. The agency has conducted annual meetings with Washington embassies on its programs (in all FDA product areas). It also carried out a massive outreach program on the implementation of its bioterrorism regulations a few years ago through meetings with embassies, World Bank–assisted regional videoconferences, and question/answer sessions at the World Trade Organization (WTO) in Geneva.

In the case of meat, poultry, and processed egg products, by law the U.S. Department of Agriculture (USDA) cannot grant market access until the exporting country's system has been evaluated and determined to be equivalent to the U.S. system in the level of protection provided.[6] By contrast, the FDA has seen its job with food imports primarily as one of checking the products at ports of entry. However, the FDA cannot begin to examine the vast number and variety of food shipments arriving at about 300 ports of entry throughout the United States (GAO, 2008).

Today, with approximately 15 percent of all foods consumed in the United States being imported, amounting to millions of shipments and hundreds of millions of dollars, the FDA continues to look at as many shipments as possible and sample products mainly on a surveillance basis—that is, not "for cause." Nevertheless, recognizing that its import surveillance resources are limited, the agency has always prioritized food safety sampling in its compliance programs to look for chemical contaminants, microbes, and other problems in specific foods in which such problems are more likely to be found based on historical and available intelligence.

[6] For meat: Animal and Animal Products, 9 Code of Federal Regulations (CFR) 327.2; for poultry, Animal and Animal Products, 9 CFR 381.196; for processed egg products, Inspection of Eggs and Egg Products, 9 CFR 590.910.

The FDA's Process for Dealing with Imported Foods

The process the FDA follows in examining food import documents and the foods themselves is summarized in Figure E-2 (Veneziano, 2008).

The procedures for the FDA's handling of imported foods are found in the FDA's *Investigations Operations Manual*, Chapter 6, "Imports" (FDA, 2009c). Any article that is offered for entry into the United States and subject to the laws administered by the FDA with a value greater than $2,000 is considered a formal entry. Formal entries require that a bond be filed with CBP; this bond includes a condition for redelivery of the merchandise at any time or, in case of default, the collection of liquidated damages. Notification of the CBP entry is usually accomplished by electronic submission through the CBP Automated Commercial System (ACS). The FDA reviews the entry documents electronically through the FDA/ACS interface and decides whether the shipment may proceed into U.S. commerce or should be examined further. The FDA also reviews informal entries and, if it decides to take action on such an entry, asks CBP to convert it into a formal consumption entry.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) requires that domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States register with the FDA (FDA, 2009a). The Bioterrorism Act also requires that the FDA receive advance notice of food to be imported into the United States before the food arrives—called prior notice (FDA, 2009d). The information required for prior notice to the FDA is basically the same as that usually required by CBP. Prior notices can be submitted either through the Automated Broker Interface/ACS or the FDA's Prior Notice System Interface. Products being transported by road require 2 hours prior notice, those being transported by rail or air 4 hours notice, and those by water 8 hours. As a rule, prior notice must be given for all foods under FDA jurisdiction, with the exception of foods made by individuals as a gift or food carried with a traveler for personal consumption or consumption by family or friends. Food that is imported or offered for import with inadequate prior notice is subject to refusal and holding at the port or in secure storage.

The FDA's Prior Notice Center, operating 24 hours a day, 7 days a week, reviews the prior notices received. The review process is designed to identify food products that may pose serious risks to public health under the Bioterrorism Act so that appropriate action can be taken when the food arrives at the port of entry. If the food meets the prior notice requirements, the FDA's Operational and Administrative System for Import Support (OASIS) data system review (discussed later in the section on Predictive Risk-Based Evaluation for Dynamic Import Compliance Target-

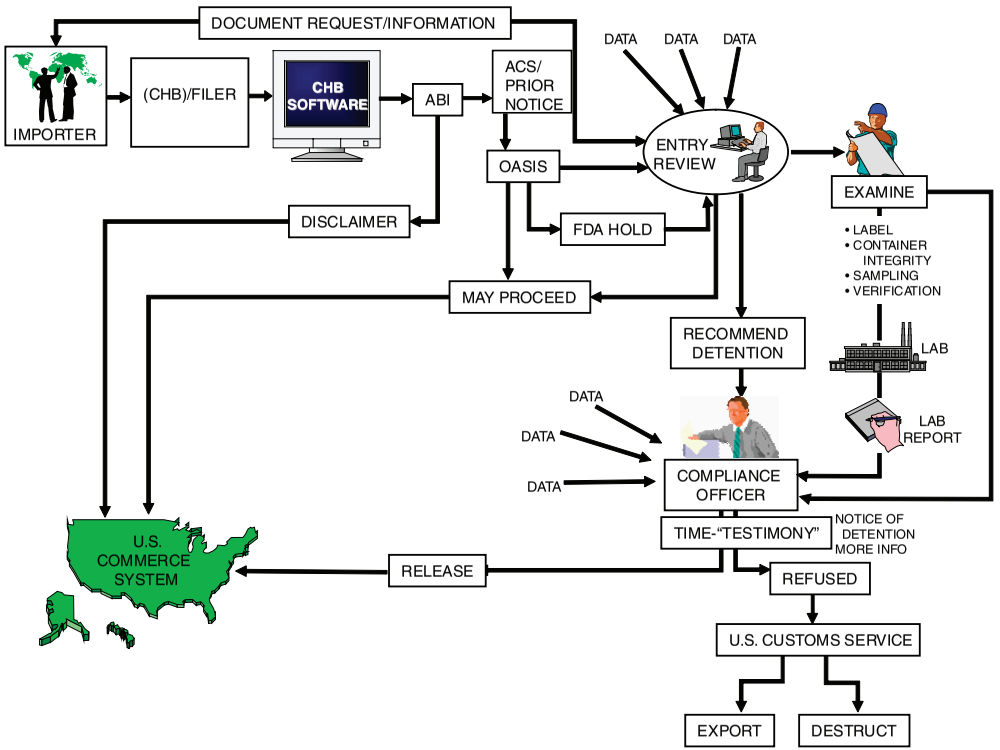

FIGURE E-2 Process used by the U.S. Food and Drug Administration (FDA) to examine imported food and related documents. NOTE: ABI = Automated Broker Interface; ACS = Automated Commercial System; CHB = Customs House Broker; OASIS = Operational and Administrative System for Import Support.

ing [PREDICT]) determines whether further evaluation of the shipment is necessary under section 801(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) before the food can enter U.S. commerce. For example, if a particular product falls under an FDA import alert, OASIS may flag the shipment for detention without physical examination (DWPE). The food may also be flagged for sampling or examination under a CFSAN compliance program or sampling assignment. In addition, an FDA reviewer may decide to examine a product (e.g., to check its labeling or the integrity of cans) or collect samples for analysis in an FDA laboratory.

If a product arrives at a point of entry where an FDA official is not expected to be present, the responsible FDA district office may ask CBP to collect a sample for forwarding to the FDA servicing laboratory. If the shipment is found to be in compliance after examination or analysis, the importer of record, consignee, or filer and CBP receive a Notice of Release. If a violation is found or the product appears to be in violation, the district office will decide whether the product should be detained. The filer, owner, and consignee, where applicable, are advised of such action by a Notice of Detention and Hearing. This notice specifies the nature of the violation and designates a site where the owner or consignee can come for an informal hearing. The owner may be able to correct the problem by relabeling or reconditioning the product, in which case the product is released. If this is not possible or not done when possible, the district may issue a Notice of Refusal of Admission by request of the importer or on its own decision. The FDA charges for its services in overseeing relabeling, destruction of product, or other action and sends these charges to CBP, which in turn sends a notice for payment to the identified importer of record. The remittance by the owner or consignee must be to CBP, not to FDA district offices. CBP will issue a demand for redelivery at the request of the FDA. Exportation of refused merchandise is done under CBP supervision. Failure to redeliver results in CBP issuance of a liquidated damage for up to three times the value of the shipment.

The FDA's New Foreign Posts

One recent step forward in working with other countries on food safety is the FDA's opening of foreign posts. These posts are located in China (Beijing, Guangzhou, and Shanghai), the European Union (EU) (Belgium, Italy, and the United Kingdom), India (Mumbai and New Delhi), and Latin America (Chile, Costa Rica, and Mexico). A table provided by the FDA, dated August 20, 2009, gives the status of staffing of these foreign posts (GAO, 2009). Fifteen of these positions are to be focused specifically on foods, as opposed to other FDA jurisdictional areas. The foreign posts have many purposes, including technical cooperation with foreign regulators,

information exchange, better understanding of each other's systems and requirements, and, where appropriate, inspections.

Differences Between Domestic and Imported Food Regulation

All in all, differences between the FDA's domestic and imported food programs are readily apparent. With domestic firms, FDA field offices have access to and the ability to inspect the firms. They know where these firms are. The domestic food industry is more likely to know, understand, and be constrained by U.S. food safety laws. Industry trade and agricultural organizations actively communicate changes in U.S. regulations to firms and farmers. U.S. farmers and processors have access only to U.S.-approved pesticides and food and color additives, and thus cannot use products banned or never approved in the United States. The same applies to animal drugs used in meat or poultry production, recognizing that meat and poultry regulation falls under the purview of USDA's Food Safety and Inspection Service (FSIS). And when a significant regulatory action is taken within the United States, the impact is felt not only by the target of that action but also by the industry as a whole, as industry trade groups publicize such actions to their membership. With imported foods, foreign producers may have difficulty understanding or accessing FDA requirements (although the FDA has put more foreign-language information on its website). Foreign producers may not have access to EPA-approved pesticides or FDA-approved veterinary drugs. Or producers, exporters, and importers simply may not do the homework. Despite globalization of the marketplace, word usually does not travel very far within a country when the FDA takes action on import shipments. The affected country may correct the immediate problem, but rarely does the message reach other countries to have a deterrent effect. Because of these and other differences between the FDA's domestic and imported food programs, the agency faces more challenges in regulating imported foods in many respects.

The FDA and Food Exports

Unlike a number of other U.S. agencies that deal with food, the FDA does not have a food export program per se. The FDA was established as a scientific regulatory agency that would protect the U.S. consumer, and that has remained its primary mission. Until fairly recently, the statutes underpinning the FDA's mission did not focus on responsibilities outside U.S. borders. In 1996, Congress passed the FDA Export Reform and Enhancement Act, which affirmatively established export responsibilities, but very little of this act applied to foods. In fact, a system of user fees for issuing export certificates for drugs and devices was included in the law, but nothing was

included on export certificates for foods. The FDA continues to discourage the issuance of food export certificates of any sort because the cost of their preparation far exceeds the $10 fee the agency collects under Freedom of Information Act (FOIA) provisions (actually, even that small fee does not go into supporting the export certificate activity within CFSAN). The FDA's expectation is that the private sector should be responsible for knowing and observing the food safety requirements of other countries when exporting foods. The FDA has no part in monitoring the safety of food shipments exported from the United States, although all foods produced within the United States are subject to the FDA's regulatory oversight. Generally, the FDA is willing to say, when it does issue an export certificate, that the product produced in the United States was subject to the laws of the United States, or words to that effect. The FDA does, however, work closely with other countries when they find an unsafe U.S food product to determine the cause and correct the situation. The same foods may pose a risk to the U.S. population or to other countries. The FDA also notifies governments of other countries when U.S.-produced foods found to be adulterated have been exported abroad.

Other U.S. food-related agencies, such as FSIS, the Federal Grain Inspection Service, and the Animal and Plant Health Inspection Service (APHIS), have export trade-related missions and laws to enforce. These agencies may require and issue export certificates or mandate and demonstrate equivalence of their programs to those of foreign systems. The FDA does have export rules under section 801(e) of the FDCA, basically saying that the agency will not find a product adulterated or misbranded if it is marked for export, accords with the laws of the importing country, was never offered for sale in U.S. commerce, and meets the foreign purchaser's specifications. It is important to note, however, that this provision is applicable only when a product is found to be adulterated or misbranded. The FDA does not routinely check food products being exported from the United States.

OTHER FEDERAL AGENCIES' APPROACHES TO REGULATING IMPORTED FOODS

Several agencies have responsibilities in regulating various aspects of the importation of food. For present purposes in comparing regulatory approaches, the focus is on USDA's FSIS—responsible for the safety of meat, poultry, and processed egg products—and its APHIS, responsible for protecting U.S. agriculture (which may include fresh produce, meat and poultry, live animals, and forests) from exotic diseases and pests.

FSIS

Under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act, and the Egg Products Inspection Act, imported products are prohibited from entering the United States unless the exporting country meets all food safety public health standards applicable to similar products produced in the United States. FSIS evaluates foreign regulatory systems in advance of any product being exported to ensure a program and requirements equivalent to those of the United States. Although FMIA contained the concept of "at least equal to" prior to the WTO obligation in the Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures that WTO members allow for equivalence of other countries' food control systems (Article 4), FSIS rethought its program after the SPS Agreement went into effect to ensure full compliance with the Agreement and prepared new guidance on FSIS equivalence procedures (FSIS, 2003).[7]

FSIS deals directly with the competent authority in the exporting government in negotiating the equivalence determination, as the government is responsible for both demonstrating and maintaining the equivalent system. FSIS's import program uses a three-part process to determine and maintain equivalence: (1) recurring analysis of the salient laws, regulations, and implementing policies and discussions with the exporting country to understand how the program operates; (2) on-site audits to verify the delivery of the program; and (3) continuous port-of-entry inspection of products shipped from eligible countries and foreign establishments. FSIS does not conduct actual inspections of facilities in the foreign country or certify foreign establishments for export to the United States. After a country has been judged to have an equivalent food regulatory system, FSIS relies on the country to carry out daily inspections, and the country's chief inspection official must certify a list of those establishments operating under its control that meet U.S. import requirements. FSIS also requires consignment-by-consignment import certificates. Eligible countries are listed in FSIS regulations 9 CFR 327.2 for meat, 381.196 for poultry, and 590.910 for egg products. There were 29 countries actively exporting meat, poultry, and egg products in 2008, with Canada being the only country exporting

[7] The FDA partnered with FSIS in preparing the first version of this guidance, as the FDA was at the time preparing equivalence guidance of its own. The FDA's draft guidance was published in 1997 (*Draft Guidance on Equivalence Criteria for Food,* 62 FR 30593, June 4, 1997). Final FDA guidance was never published. Instead, the FDA turned its full attention to working within the Codex Alimentarius process on the preparation of the Codex guidance on equivalence (*Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems,* CAC/GL 53-2003, www.codexalimentarius.net/download/standards/10047/CXG_053e.pdf).

egg products (FSIS, 2008). An FSIS presentation on its equivalence determination process is available online (Swacina, 2004).

APHIS

APHIS's responsibilities extend to protecting animal and plant health, as opposed to protecting humans from unsafe foods. Therefore, for present purposes, it is important simply to be aware that APHIS has oversight over imported food to ensure that exotic diseases and pests that might threaten U.S. agriculture and forests are not brought into the United States. In exercising its authority, APHIS requires import certificates and issues export certificates pertaining to animal and plant health to meet other countries' needs in safeguarding against the entry of exotic animal and plant diseases and pests into their countries (APHIS, 2008). APHIS also evaluates and establishes quarantine treatments for foodstuffs needing treatment before entering the United States. In addition, it works closely with countries on their disease and pest status, which bears on whether and under what conditions they can export to the United States. While APHIS sets the rules, CBP has operational responsibility for implementing these rules at the border.

ROLES OF STATES IN REGULATING FOOD IMPORTS AND EXPORTS

As a general rule, states have been responsible for regulating foods in intrastate commerce, while the FDA's authority focuses on foods in interstate commerce, which include foods moving in international commerce to or from the United States. Thus, states have not had a significant role in regulating imported foods, except those already in domestic commerce. States concentrate on retail food stores, restaurants, grocery stores, roadside stands, and so on. They usually have embargo authority, which the FDA does not, and can use this authority when partnering with the FDA in controlling the movement of adulterated foods when a problem arises. The FDA and the states work together, often through the Association of Food and Drug Officials (AFDO), to promote consistency in state food laws and their implementation (e.g., model food laws and the Food Code). Through federal–state contracts, the FDA deputizes state officials to conduct FDA inspections of food facilities; these inspections became increasingly commonplace as the FDA's food program resources diminished. The FDA currently has 42 of these contracts, accounting for more than 10,500 inspections a year, including Good Manufacturing Practices sanitation, seafood and juice Hazard Analysis and Critical Control Points (HACCP), and low-acid canned food inspections (Solomon, 2009). States have taken actions to stop the sale of imported Grade A dairy products, not because

the products were adulterated but because they were not produced under the federal–state cooperative program for such products. Also, a few states have tested imported foods in domestic commerce for pesticides and examined imported dairy products to check for compliance with the federal–state Grade A program. In these cases, results have been shared with the FDA. Recently, the FDA and the states have been considering giving state inspectors a larger role in dealing with imported foods.[8]

While not a food import issue per se, it should be noted that virtually all states issue export certificates for food and other products produced in the state. During meetings of the Export Certificate Working Group under AFDO, a number of states suggested to this author, who chaired that group, that the federal government should bear the full responsibility for issuance of export certificates, which they regard as a federal government matter involving international trade. Nevertheless, when the flow of international commerce can be hastened for an in-state product, the states are willing to issue certificates—if necessary within a 24–48 hour time frame—while the FDA may take significantly longer to issue a certificate. Most states charge a fee, usually modest but up to around $175, for a certificate. Their certificates may attest to free sale, the regulatory standing of a firm, or other matters that can be substantiated without laboratory tests or on-demand inspections. The State of Oregon has a special unit that provides fee-for-service laboratory testing as a service to industry to support issuance of export certificates (Oregon Department of Agriculture, 2009).

IMPORTED FOOD SAFETY CONTROL SYSTEMS IN OTHER COUNTRIES

In reviewing the food safety systems of other countries, it is useful to know the philosophical, political, or event-driven basis for their development and structure. In any case, it can be instructive to learn more about those programs that provide the citizens of other countries with safe and high-quality foods. While recognizing that it is impossible to provide detail here on the background, legislation, organization, and operations of each such food control system, several such systems are highlighted in this section (see also Appendix C).

Canada

Canada reorganized its food safety system in 1997. The Canadian Food Inspection Agency (CFIA) was created to clarify roles and responsibilities pertaining to food safety, to reduce overlap and duplication, and to improve

[8] Personal communication, Steven Solomon, Office of Regulatory Affairs, FDA, July 2009.

delivery of services, federal/provincial harmonization and cooperation, and reporting to Parliament. In CFIA, Canada consolidated all federally mandated food, plant, and animal inspection and quarantine services formerly provided by the Departments of Agriculture and Agri-Food Canada, Health Canada (HC), Fisheries and Oceans Canada, and Industry Canada. Prior to this reorganization, the government carried out extensive outreach with all stakeholders, including foreign countries.

Under the CFIA Act, the Minister of Health (HC) establishes standards and policies governing the safety and nutritional quality of all food sold in Canada. HC is responsible for risk assessment pertaining to food safety with regard to human health. HC identifies and prioritizes issues based on scientific evaluation of the likelihood that a specific adverse health effect will occur and carries out foodborne illness surveillance, providing a system for early detection and warning and a basis for evaluating control strategies. HC also was given authority to assess the effectiveness of CFIA activities, thus providing checks and balances on the food safety system to ensure that assessed risks are being managed appropriately.

CFIA, reporting to the Minister of Agriculture and Agri-Food, is responsible for enforcing the policies and standards established by HC. It is responsible for both risk assessment and management in the areas of animal health and plant protection. CFIA was also established as a corporate structure with a president at its head. All import and international trade activities pertaining to foods fall under CFIA. Part of the assessment performed in establishing CFIA was to determine which activities benefited the public good and thus would be supported through tax dollars and which should be cost-recovered as they benefited industry. At present, the food safety and quality programs for the Meat Inspection Act, Fish Inspection Act, and Canada Agricultural Products Act are subject to user fees, but only a small percentage of CFIA's overall budget is cost recovered (CFIA, 2009a). It should be noted that Canadian provinces play a large role in ensuring the safety of food products within their jurisdictions, but not in the regulation of food imports/exports.

There are a number of significant differences between the U.S. and Canadian food import systems that should be noted, although most of the mechanisms and goals are quite similar. Canada conducts "monitoring sampling," that is, "unbiased sampling" to "assess human dietary exposure, perform risk assessments, monitor trends, identify potential problems and at-risk population groups, set standards and guidelines, and evaluate the effectiveness of programs." It also conducts "directed sampling" or "biased sampling," that is, "directed at targeted sample populations . . . to investigate and verify any suspected problems of potential health risk suggested by the monitoring program." Although directed sampling can lead to detention of a product, products that are tested under monitoring

and directed sampling are not required to be held pending analysis (CFIA, 2005). When violations are found during monitoring sampling, importers must demonstrate that subsequent shipments from that source meet standards (CFIA, 2008). "Compliance testing is directed at specific samples suspected of not complying with specific regulations. . . . The product is usually detained until the test results indicate the appropriate disposition" (CFIA, 2005). The FDA's surveillance sampling is similar to Canada's monitoring sampling; however, products must be held pending sampling results. Canada also carries out special surveys, blitzes, and legal sampling, the latter applying when legal action is anticipated to ensure appropriate sampling and testing procedures.

Canada and the FDA have taken some different approaches toward violative residues. Canada generally establishes finite limits for situations in which there is no official maximum residue limit/tolerance for a particular chemical residue or contaminant. For example, the FDA generally has taken action on pesticide residues based on the level at which the chemical can be reliably identified and measured, which evolving technologies may drive to ever lower levels. With other contaminants, Canada and the FDA usually follow a similar risk-based approach. Another difference in Canada's program is that seafood importers are licensed. Canada provides educational sessions for fish import license holders to help them understand Canadian requirements and license holder responsibilities (CFIA, 2009b). If violations are repeatedly found with an importer's products, the license can be revoked (CFIA, 2009c). Finally, for any type of product, Canada generally does not move, even when multiple violations are found, to countrywide detention, but continues to place individual importers/firms with violative products on a list requiring that their products be tested before they can be imported (CFIA, 2009d).

EU

The EU also separated risk assessment from risk management when the European Commission established its food safety structure. The U.S. food safety regime, including the FDA, was one of the country systems studied and visited when the European Commission's system was developed. The resulting *White Paper on Food Safety* (European Commission, 2000) sets forth a "farm to table" approach. Simply described, the European Commission (in which food falls under the Directorate General for Health and Consumers, also known as DG SANCO) ensures that food safety legislation established by the Council of the European Union (Council) and the European Parliament (the two legislative bodies in the EU) is transposed into national law and properly implemented. Each member state must incorporate European Commission food rules and standards into its national

legislation to ensure consistency and effectiveness in regulating food safety throughout the 27 Member States. The Member States are the operational units of the food safety program. The Commission's Food and Veterinary Office (FVO) (located in Grange, Ireland) audits each Member State's programs on a schedule. The independent European Food Safety Authority has the responsibility for risk assessment, including compiling and assessing the scientific basis underpinning the EU food safety legislation.

The EU has a list of high-risk food products, generally products of animal origin, including meat and poultry, game meats, gelatin, dairy, seafood, pet foods, and honey (Agreement on Sanitary Measures, 1998). For these products, the Commission requires that all importing countries have a system in place that provides the same level of safety as that for foods produced within the EU. DG SANCO has equivalence agreements with other countries, including the United States, for one or more of these products (DG SANCO, 2009a). For these products, the EU also requires a minimum number of physical checks per annum, just as is required for EU Member States, as well as import certificates on a consignment-by-consignment basis from the exporting countries. For all foods in this high-risk category, each consignment must undergo an official veterinary check at the entry post. Entry posts are limited in number to enable these inspections. Just as the FVO conducts periodic audits of each Member State's program, it also audits other countries' programs to ensure that the level of food protection is being upheld by all parties producing food for consumption within the EU (DG SANCO, 2009b).

Australia and New Zealand

Australia's Imported Food Inspection Scheme is run jointly by the Australian Quarantine and Inspection Service (AQIS) and Food Standards Australia New Zealand (FSANZ). The Imported Food Control Act of 1992 provides the legal basis for the program. The program is risk-based, with FSANZ advising on food risk assessment policy, as well as food inspection and testing under its Food Standards Code, and AQIS staff having operational responsibility for inspection and sampling. FSANZ classifies all foods into one of three inspection categories, which determines their inspection frequency: risk, active surveillance, or random surveillance. Foods in the risk category pose a medium or high risk to public health. These foods require 100 percent referral to AQIS from Australia Customs for inspection. Shipments tested are held pending analytical results. From this point, inspection frequency is based on a particular producer's performance. The first 5 shipments from a producer are inspected, and if these shipments are in compliance, the inspection frequency is reduced to 1 in 5, with 1 shipment being inspected and the other 4 released with no inspection, for a total

of 20 shipments. Thereafter, if all inspections are cleared, the inspection rate is reduced to 1 in 20 shipments. A single violation can cause the testing rate to revert to the 100 percent level.

For foods in the active surveillance category, 10 percent of shipments from each supplying country are referred to AQIS for inspection, and the products are released after sampling. The test results are analyzed periodically by FSANZ to determine whether the category classification is still appropriate or should be changed. For foods in the random surveillance category, 5 percent of all consignments are inspected, and the products are released after sampling. If an active or random surveillance food does not comply with the Food Standards Code, a holding order may be issued against the foreign supplier, meaning that the food has been raised to the risk inspection category or 100 percent inspections.

Referral for AQIS inspection does not mean that all shipments are tested. Inspectors examine all referred foods visually, looking for labeling and packaging defects and indications of contamination. Samples may also be taken to test for pathogens, chemical residues and contaminants, additives, and adherence to compositional requirements (FSANZ, 2003).

All inspection and laboratory work is cost recovered and charged to the importers, to whom the government has given the responsibility of meeting country requirements. AQIS is required to recover 100 percent of the cost of running its inspection system through charging fees. In the case of low-risk foods, because it would be inequitable to charge only importers who happened to have their products tested under the 5 percent sampling rate, all importers pay a low, uniform inspection/testing fee for every shipment entered (AQIS, 2008). Each importer must also obtain a permit to import food. When importers apply for the permit, the government uses that opportunity to ensure that the importer knows the food safety and animal and plant health requirements of the country. All countries must meet the FSANZ standards.

Australia rarely requires export certificates. The exception is when the certificate requirement is being used as a tool to deal with a specific problem. In such cases, the issue is usually one of animal health rather than food safety.

Unlike Australia, New Zealand requires official certificates from exporting countries. Consignment-by-consignment certificates are seen as a useful tool in the regulation of imports for a number of reasons. First, a certificate gives the importing country a handle on the composition of the shipment at export, so it is useful in identifying the consignment and ensuring that it is not confused with another shipment on import. The description of the product on export also helps in indicating whether the product was tampered with during shipment, and thus is useful in monitoring security on import. The attestations in the certificate are helpful in ensuring that

the exporting party and its government are aware of and complying with New Zealand's requirements. New Zealand sees certificates as quite useful in tracing shipments when something goes wrong as, for example, in the Chinese melamine case.

INTERNATIONAL FOOD STANDARDS: CODEX ALIMENTARIUS

The Codex Alimentarius Commission is an international body comprised of governments as its members. Its dual role in developing international food standards and guidance is to (1) protect the health of consumers and (2) ensure fair trade practices in food trade (FAO/WHO, 2008). The Codex was formed in 1962 by the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Its Secretariat is housed at FAO in Rome, and it has more than 180 member governments. Since its inception, Codex standards have been utilized as voluntary standards that countries may choose to incorporate into national legislation. The standards are based on evaluations of scientific data and other necessary information. They address food safety hygiene, analytical methodologies, maximum limits for residues of pesticides and animal drugs in foods, nutrition issues, food labeling, limits for contaminants, product identity standards, and food inspection and certification, among other things.

Since the advent of WTO in 1995, Codex standards and guidance have served as reference standards in trade challenges before WTO. The SPS Agreement specifically recognizes the Codex Alimentarius Commission (WTO, 1995). The Codex standards can be used in challenges involving foods under the WTO Technical Barriers to Trade (TBT) Agreement as well. The SPS Agreement requires countries to base their national measures on international standards, guidelines, and recommendations, or provide the scientific basis for doing otherwise. Countries with limited resources can rely on Codex food safety standards instead of developing their own standards to protect public health and facilitate trade.

The FDA has participated in Codex Alimentarius since its inception and devotes a significant amount of resources to Codex work. The FDA does not have a procedure to adopt Codex standards and texts as national requirements. However, in partnership with the U.S. Codex Office (located in FSIS, under the Office of the Under Secretary for Food Safety in USDA) and the other federal agencies engaged in Codex activities (USDA agencies, the Departments of State and Commerce, the Office of the U.S. Trade Representative, and EPA), the FDA endeavors to ensure that all Codex standards, guidance, and other texts are consistent with U.S. national measures.

WTO: FOOD SAFETY AND TRADE OBLIGATIONS

In 1994, the Uruguay Round of Multilateral Trade Negotiations concluded with the Ministerial Meeting, where countries signed off on the Final Act of the Uruguay Round and the Marrakesh Agreement Establishing the WTO. The SPS and TBT Agreements are the two WTO agreements that focus on nontariff trade barriers, and both can apply to foods in different respects. The U.S. Congress enacted all the WTO agreements as U.S. law in the Uruguay Round Agreements Act of December 1994, just prior to the January 1, 1995, the date on which the agreements entered into force.

The FDA participated actively on the U.S. negotiating team for the Uruguay Round negotiations, especially on the SPS negotiations. The eventual text provided a balance between preserving a country's sovereign right to protect its citizens from public health hazards in imported food (among other things) and enabling agricultural trade to flow. Generally, under the General Agreement on Tariffs and Trade (GATT) and the SPS Agreement, WTO Members are not allowed to discriminate arbitrarily or unjustifiably among imports from WTO Members, meaning that all Members should be treated equally with respect to trade; nor can Members give less favorable treatment to a WTO Member's goods than they do to their own; unless there is a reason based in science (recognizing, however, that each Member's country has the right to set its own appropriate level of protection). These principles are called Most Favored Nation Treatment (WTO, 2009a) and National Treatment, respectively (WTO, 2009a).

For its part in the negotiations, the FDA wanted to ensure that the trade agreement would not impinge on its ability to protect public health, and it was successful in this regard. For purposes of this appendix, only sanitary measures are discussed, as phytosanitary, or plant health, measures are not at issue. The SPS Agreement states the right of WTO Members to establish sanitary measures to protect human or animal life or health, but places limits on this right. Some of these limits, or obligations, are mentioned below. A WTO Member or Members may bring a challenge against other Members they believe have violated these legally binding obligations. Such issues may first be raised informally at an SPS committee meeting in Geneva, generally held three times a year. A country may also raise a complaint formally and enter into the dispute settlement process, which may result in the establishment of a dispute settlement panel to assess the facts of the case and make a ruling.

It is useful to understand what exactly is a sanitary measure under the SPS Agreement. The definitions in Annex A indicate that they may include the following:

> Any measure applied . . .
> (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
> (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof. (WTO, 1995)

Measures can include laws and regulations, among other things, as well as operational measures, such as testing methods, sampling procedures, and methods of risk assessment.

A few of the SPS Agreement obligations are important to mention here (WTO, 1995). For example, under Article 2, WTO Members must ensure that measures are both applied only to the extent necessary to protect health and based on scientific principles. Members must ensure that their measures do not arbitrarily or unjustifiably discriminate between other Member States in which similar conditions prevail, including between their own territory and that of other Members.

Under Article 3, as mentioned in the previous section, Members must base their measures on international standards, guidelines, or recommendations, where they exist. Sanitary measures that conform to international standards, guidelines, or recommendations are deemed necessary to protect life or health and are presumed to be consistent with the SPS Agreement and GATT 1994. Thus, Codex standards become a "safe harbor" in the event of a challenge under the SPS Agreement. However, Members can still set sanitary measures that provide a higher level of protection if they are scientifically justified and based on the country's chosen level of protection.

Under Article 4, on equivalence, a Member is obligated to accept the sanitary measures of other Members as equivalent if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary protection.

Under Article 5, on assessing risk and determining a country's appropriate level of protection, WTO Members must ensure that their sanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to life or health, taking into account relevant scientific evidence, among other specified considerations, including economic factors.

Also included are other provisions pertaining to transparency in establishing measures and the rights and obligations of countries that have premarket approval systems for such things as veterinary drugs, pesticides, and food additives.

With regard to foods, the TBT Agreement applies to the extent that the issue, such as food labeling requirements not established to protect human or animal life or health, is not covered in the SPS Agreement. The TBT

Agreement is a wide-ranging agreement dealing with all kinds of nontariff trade barriers for all sorts of products, while the SPS Agreement is the primary agreement focused on national measures to protect agricultural and forestry products and food.

PRACTICAL CHALLENGES IN MEETING THE FDA'S IMPORTED FOOD PROGRAM OBJECTIVES

The goal of any imported food program is ensuring the safety of foods for consumption by the domestic population. The FDA has done a good job in achieving this goal, but there are a number of areas in which it might do better. This section explores some of these areas.

Stakeholder Buy-In

Margaret Hamburg, in her first testimony as FDA Commissioner, said, "A precondition for health is having access to safe food." She further stated, "A coalition of consumer groups is fighting for improvements in the food safety system so that more families do not have to suffer tragic consequences from foodborne disease. I am impressed that major sectors in the food industry also support and are advocating for fundamental change" (Hamburg, 2009).

It is essential that stakeholders understand and have buy-in and input into the FDA's imported food program to enable a strong, workable program; to establish incentives for compliance with requirements; and to promote common ground and backing for the program. The public, industry, and congressional dialogue that has taken place over the past few years as the FDA has lost almost a third of its food program resources is a healthy process and one that has helped in clarifying the reasons why the FDA's food safety program is important in both the domestic and global contexts. The current food safety bills in Congress are evidence that this dialogue process works. The FDA needs to do more to improve understanding of the issues it faces in promoting and regulating imported food safety, its import program objectives, and the reasoning behind these objectives with all its stakeholders, including other federal agencies, the Congress, foreign nations, states, and the general public. This can be done through dialogue, public meetings, brochures on the FDA's program and accomplishments, and other outreach efforts.

Teamwork, Clear Objectives, and Consonant Implementation

Because a number of offices in FDA headquarters and the field take part in establishing the objectives of the imported food program, it is important

that all these offices understand the various factors to be considered in setting up the program, including laws, resources, available mechanisms to ensure food safety, the global context of international trade agreement obligations, and international standards and guidance that bear on the operation of the program. It is imperative that the program and its policy staff that chart its overall objectives operate as a team with the offices that implement the program. Too often there have been conflicts in priorities or misunderstandings regarding program objectives that have hampered optimal achievement of these objectives.

For example, despite the FDA's goal of protecting public health from unsafe residues of pesticides in imported foods, the parallel goal of detecting as many violative shipments as possible led field offices in the past to oversample imported spices that often had violative residues. Sampling food products with higher per capita consumption rates might have provided greater public health protection, but the program had strong incentives to find violative products, and spices offered greater opportunity in this regard. Now sampling instructions for this program clearly state that only commodities of dietary importance should ordinarily be sampled (FDA, 2006).[9] These types of situations can easily be avoided by (1) establishing clear import program objectives, (2) ensuring that the spirit and rationale behind those objectives are well understood by field personnel, and (3) tracking the program accomplishments throughout the year to see whether adjustments need to be made to achieve the objectives.

Another example involving pesticides could provide a model for improving program design and implementation for imported foods. In the 1980s, FDA consumer surveys indicated that U.S. consumers saw pesticide residues as their top food safety concern. In response, the Office of Regulatory Affairs (ORA) and CFSAN decided to form Pesticide Coordination Teams (PCTs) in each district office, comprised of at least one representative from the laboratory, investigational, and compliance branches of the field office. These teams met regularly to coordinate and track their pesticide monitoring and compliance activities. Moreover, all the teams participated in regular conference calls with the headquarters' ORA and CFSAN program staffs, and often EPA staff, to be briefed on the latest pesticide issues, congressional hearings, U.S. Government Accountability Office (GAO) reports, press and consumer group reports, analytical improvements, or whatever brought greater understanding of why their work was so important to the

[9] *Pesticides and Industrial Chemicals in Domestic and Imported Foods FY 06/07/08* (7304.004), Part III, "Inspectional General Sampling Instructions": "Collect samples of commodities of dietary importance identified in Attachment B. Do not sample products such as parsley and spices that have little impact on total dietary intakes. Monitoring of these types of food will be directed by headquarters initiated surveys as needed."

U.S. consumer. All teams came together annually at a PCT meeting to compare notes, give presentations, and troubleshoot. The headquarters–field and field–field network in this program area was invaluable to the smooth and responsive operation of the program, which produced a full-color public report annually that often went through several printings because the public demand for it was so great. Although the public health importance of pesticide residues in the food supply has diminished—partly because of new, more protective pesticide legislation—the FDA's teamwork in giving this program the coordination needed at the time helped EPA and Congress obtain the data and knowledge required to develop the much-needed legislation.

Potential Use of Third-Party Certification

As the FDA's imported food program encounters a vast variety of foods from a broad spectrum of countries, companies, and importers, the challenges in ensuring imported food safety are considerable. The agency must have available tools that are best suited to the circumstances. One tool the FDA has placed on the table is third-party certification (see Chapter 8). This would involve the FDA's accrediting third parties to certify that its food safety requirements are being met. Currently, such certification is taking place on a private, commercial basis. In these cases, private standards, including end-product standards and production processes, are being established by a number of bodies. Developing countries have raised concerns to WTO and Codex regarding the use of private standards (Henson and Humphrey, 2009; WTO, 2009b), with the overriding concern that certification is very expensive and cost-prohibitive to small growers. Therefore, third-party certification may be useful only in limited situations where firms or governments can afford or choose to utilize it. Nevertheless, third-party certification can be a useful tool for gaining confidence in a country's exports when food safety problems have been found, and in other cases, it may enable the agency to shift enforcement resources to where they will do the most good.

Sampling: Surveillance, Compliance, and Hold and Test

Most of the sampling done under the FDA's imported food program is surveillance sampling. This means the agency does not have reason to believe the particular shipment will be violative. Compliance sampling generally occurs after a problem has been found. Samples are taken at the port of entry and are sent to a servicing laboratory for analysis. The shipment chosen for sampling, under 21 Code of Federal Regulations (CFR) 1.90, must be held intact until laboratory results are available and a decision can

be made on disposition of the shipment, that is, whether the consignment can be released into commerce or should be refused entry.

Surveillance sampling is done to gather information, to detect food safety problems, and to identify a violative shipment before it enters U.S. commerce. Other developed countries that carry out surveillance sampling of foods generally utilize such sampling to detect problems so they can act to stop future shipments of products that are found to be unsafe or misbranded. They allow the shipments that are randomly sampled to be distributed as they have no reason to hold them. This approach enables a more efficient sampling/analysis program with more sample throughput in the laboratory and more product coverage, but it also opens up the possibility for fault finding by political bodies and the public when a significant safety problem is uncovered. In practice, other countries say this rarely occurs and has not hampered their food protection safety net.

Inspection of Foreign Food Facilities

The FDA's inspection of foreign facilities with any regularity is impossible given that there are 200,000 such firms registered (Taylor, 2009). For this reason, it may be more appropriate for foreign facility inspections to be reserved for situations in which food safety problems have been detected in products from a facility. Especially given the high cost of foreign inspections, the FDA has recently stated (Taylor, 2009) that foreign inspections may not result in the best use of its resources, so it appears that the agency may be moving in that direction. A tool to obviate the need for individual foreign firm inspections is the recent guidance for Accredited Third Party Certification of firms and the FDA's recognition through auditing of the certifiers. This tool could provide increased confidence in particular firms, and the resulting data could then be fed into PREDICT (discussed below).

Incentives to Export Safe Food

There are a number of ways to encourage foreign companies to export safe food that could be incorporated into the FDA's imported food program. It has already been mentioned that the FDA could conduct more outreach to countries. The agency could also require import certificates attesting to food safety that in effect would put the foreign facility on notice that it needs to be aware of the safety status of food it exports to the United States. Licensing importers (or registering them as proposed in HR2749; see below) could be coupled with providing information and outreach to importers that they could convey to the food businesses they are servicing.

RECENT EFFORTS TO IMPROVE IMPORTED FOOD SAFETY

PREDICT

PREDICT is an electronic import screening tool that will automate many of the decisions currently made by import entry reviewers, utilize intelligence from numerous sources to guide automated decision making on the potential risk posed by imported food, and expedite the entry of more products that are not selected for examination. It will replace the admissibility screening portion of the FDA's existing electronic system (OASIS) for processing import entries.

PREDICT will apply to shipments of all products under FDA jurisdiction, not just foods, and will be used for both imported and domestic products. The focus here, however, is only on PREDICT as it applies to foods imported into the United States. This system holds great promise for enabling the use of almost any intelligence received and applying that intelligence in writing risk rules to establish a score for the particular entry line and importer. Such intelligence could include information pertaining to recalls, registration of low-acid canned food processes, agreements with other countries, data provided by governments on monitoring of their own products, information on government or third-party certification of facilities, and information from import certificates. Pilot testing for PREDICT began in June 2007 and was successful based on the evaluation criteria at the time. Now that user acceptance testing has been completed, PREDICT is expected to be beta tested in Los Angeles District in September 2009 and rolled out on a district-by-district basis thereafter.

The current OASIS is the only system in the federal government that exchanges import admissibility data with CBP in real time (ORA, 2009). OASIS receives data on products under FDA jurisdiction from CBP. It then electronically screens entry lines based on certain criteria and generates notices regarding admissibility decisions. OASIS will be supplanted by PREDICT, which has the capability and flexibility to mine data sources and integrate a vast amount of information in arriving at a risk score that can be used to decide whether an entry line may proceed into commerce or should be more closely reviewed. Thus, food entry data will flow from (1) the entry filer (importer, exporter, or broker); to (2) the CBP database; to (3) OASIS for prior notice (bioterrorism screening, which is done on 100 percent of entry lines); and then either to (4) the Prior Notice Center for review if, for example, the entry has no registration number or affirmation of compliance, or (5) straight to PREDICT for admissibility screening. Figure E-3 shows the process (ORA, 2009). The Prior Notice Center can decide to detain the shipment based on terrorism criteria or can release the entry line back into PREDICT admissibility screening. If PREDICT scoring rules determine that

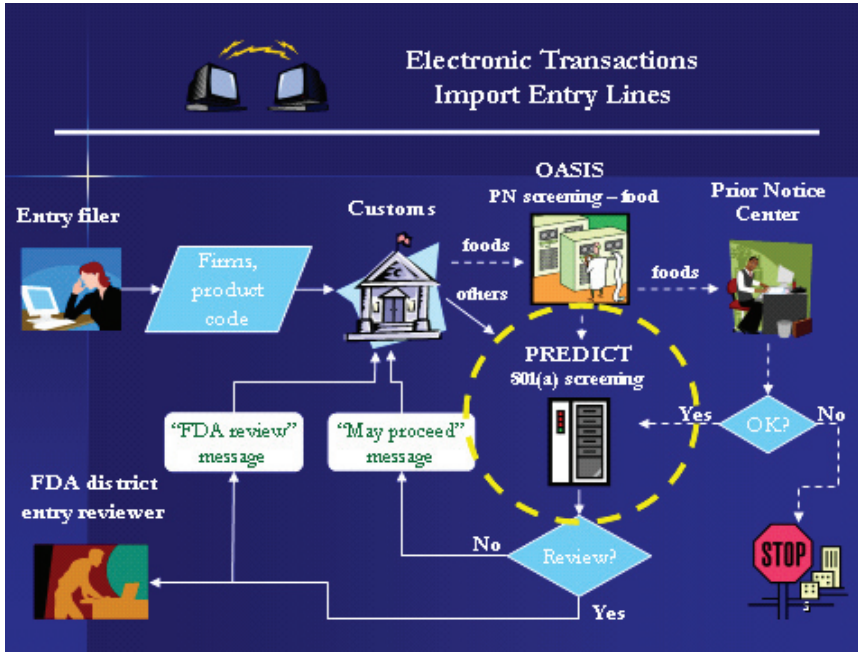

FIGURE E-3 Electronic transactions for import entry lines.
NOTE: FDA = U.S. Food and Drug Administration, OASIS = Operational and Administrative System for Import Support, PN = prior notice, PREDICT = Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting.
SOURCE: ORA, 2009.

the product may proceed into commerce, then that information is supplied to CBP. Otherwise, PREDICT sends the entry line to an FDA district entry reviewer, with results also being communicated automatically to CBP. The district entry reviewer then has the option to request additional information from the importer to make an admissibility decision, examine the product in the field, collect a sample for analysis, detain the product without a physical exam, or allow it to proceed into commerce.

PREDICT will utilize automated data mining and pattern discovery, open-source intelligence such as news reports, and existing CFSAN databases, including low-acid canned food scheduled processes and registration, to make admissibility decisions. For example, if a new food product is coming from a country, or if a usual product is valued at a significantly diminished amount or is shipped during a different time of year, the entry line may receive a higher score for review because the pattern is different from the usual. News reports of typhoons or hurricanes with significant environ-

mental damage may be added to the PREDICT rules for a country to flag reviews of the country's food products. Similarly, if a country is willing to provide the FDA with data on its domestic food testing programs and if the FDA finds the data compelling, the agency can create a rule in PREDICT that reduces the risk score associated with the information provided by the country. The rule created will provide the entry reviewer with the reason for the reduction in score. On the other hand, if a trusted country shares its findings on illegal drugs being found in imported fish from particular countries, that information can be utilized as intelligence that may lead to flagging fish shipments from those countries. Firms that have been inspected by accredited third-party certifiers and found to produce products in compliance with U.S. food safety requirements can also be given a score that reduces the risk associated with the products.

PREDICT will work by scoring each entry line on the basis of risk factors and surveillance requirements. The pilot testing on a small sample of 32,696 lines of seafood entering at five ports within the Los Angeles District found that PREDICT was better than OASIS in predicting violations for field exams and sample analyses (ORA, 2009). It also enabled a higher "may proceed" rate—39.1 percent versus 5.7 percent—by utilizing the wide range of intelligence data entered into the PREDICT system for the products. This more accurate prediction of violations and "may proceeds" should reduce workload for the FDA reviewers as well.

PREDICT and OASIS are both part of the Mission Activity Reporting Compliance System (MARCS), which is the overall integration system for a number of interfaceable databases. This is significant because for all the systems to work together, they must have high-quality, accurate data entered. This has been a problem, although inaccurate data entry may now cause PREDICT to flag an entry for review. Importers have been advised of this fact and the fact that their product entries may suffer if data mistakes are made. Another issue with PREDICT is the CBP Manufacturer Identification (MID) system. In the past, manufacturers have provided multiple, inconsistent MIDs for the same foreign facility (ORA, 2009). PREDICT will recognize each MID as a separate facility, and a new MID/facility may be flagged and have a higher risk score. To correct this problem, there are plans to utilize a unique, reproducible identifier for each facility. Nevertheless, importers will need to work closely with filers to ensure data quality, as poor-quality or missing data will increase the risk scores for entry lines. Filers' data error rates will be available to the public through FOIA.

The Import Trade Auxiliary Communications System is also part of the MARCS system and will interface with OASIS and PREDICT. It is an Internet portal for entry filers. The importance of this interface cannot be overemphasized as entry filers will have instant access to information on the status of their entries. At present, importers must phone FDA district offices

and talk to a person to determine whether a product has been released or whether the agency is waiting for them to provide further information. This interface will also allow filers to submit additional information electronically. Therefore, this system, which is also being beta tested in Los Angeles, has the potential to streamline communications and save resources and effort for FDA field staff and importers alike.

FDA data systems have never had the flexibility to utilize all the information that can affect whether a particular shipment should be examined in some manner. Also important is whether safe products can move unimpeded and without deterioration through trade channels. As better intelligence is generated and received through multiple sources, PREDICT holds the promise of being able to manage field resources and direct them to where they can do the most good in protecting consumers from unsafe products. Achieving this goal, however, is dependent on the decisions and information utilized in setting the rules for PREDICT, and these decisions and rules will surely be the subject of future debate. It is important, however, that in developing the PREDICT criteria, the emphasis be on public health criteria in deciding on admissibility. Given the number and volume of food shipments to the United States and the FDA resources needed to examine them, the criteria should focus on whether consumers are significantly at risk, not on whether examination/sampling of a product will simply result in a violation that may be of negligible health concern. As efficient use of public health resources is one of the purposes of PREDICT, it is hoped that this system can live up to its full promise.

Food Safety Working Group

On July 7, 2009, the Food Safety Working Group (FSWG), established by President Obama, issued its key findings on how to upgrade the nation's food safety system for the 21st century (FSWG, 2009). The FSWG recommended a new public health–focused approach to food safety based on three core principles: (1) prioritizing prevention, (2) strengthening surveillance and enforcement, and (3) improving response and recovery. Although the FSWG's initial key findings say little that pertain to the FDA's imported food program, it is understood that the full report, yet to be released, may contain such recommendations.

Food Protection Plan and Import Safety Action Plan

Both of these documents were produced under the previous administration, and while they have not explicitly been supplanted, the work of the cabinet-level FSWG and work on food safety legislative proposals (see below) have generally taken priority. Many of the recommendations of the

Food Protection Plan (FDA, 2007) and the Import Safety Action Plan (Interagency Working Group on Import Safety, 2007) pertaining to imported foods have, according to FDA contacts, been incorporated or addressed in the FSWG report, although until the full report is released by the White House, this cannot be confirmed.

Food Safety Legislation

Several pieces of food safety legislation have been proposed in the current Congress, including S510, HR875, HR759, and HR1332. On August 3, 2009, a comprehensive bill was passed by the House of Representatives and referred to the Senate Committee on Health, Education, Labor, and Pensions. This legislative proposal, HR2749, pertains to the FDA's overall food safety program but focuses primarily on the domestic portions of the program (U.S. sovereignty cannot easily extend into the territories of other countries). Nevertheless, it would provide for some major and potent new authorities in the food import and export areas (see also Appendix D):

- **Registration of facilities**—Under section 101, all facilities, domestic or foreign, that produce, pack, or hold food for consumption in, or for export from, the United States must submit an annual registration and pay a registration fee, which is set at $500 for 2010 but may be revised thereafter. Registration may be suspended if the registrant is found to have violations that could result in serious adverse health consequences or cancelled if registration is not updated annually or inaccurate information is submitted. This fee certainly would not be adequate to sustain the FDA's imported food program but would put registrants on notice that they need to avoid violations of U.S. law or risk losing their registration and no longer be able to export to the United States. Imported food will be considered "misbranded" if it comes from an unregistered facility. The bill authorizes collection of fees only until 2014.
- **HACCP requirement for all registered firms**—Under section 102, all facilities that are required to be registered annually, whether domestic or foreign, must have a food safety plan with a full HACCP program in place. The FDA will have to issue guidance or promulgate regulations to establish science-based standards. The bill explicitly states that international HACCP standards will be reviewed in issuing the guidance or regulations to ensure consistency.
- **Inspections based on risk**—Each registered facility must be inspected. Foreign facilities can be inspected by an agency or representative of a country recognized by the U.S. Department of Health and Human Services (HHS). The frequency of inspections

is based on whether the facility is Category 1, high risk (inspect every 6–12 months); Category 2, low risk (inspect every 18–36 months); or Category 3, holds food (inspect every 3 years). A facility's category depends on the type of food, its compliance history, whether it is "certified" by a quality entity, and other relevant factors. This provision requires notice and comment before a categorization is established or modified, which will be difficult and extremely resource intensive to implement, especially for foreign facilities. There is also a requirement to provide an annual report and a 3-year assessment to Congress on the costs and success of the program.

- **Finished product testing from Category 1 facilities**—Finished product test results must be provided by the owner, operator, or agent of each Category 1 facility (beginning after public notice/comment, pilot projects, and a feasibility study to be completed within 2 years). The firm must also have a food defense plan to prevent contamination throughout the supply chain. The testing must be done in accordance with science-based performance standards, to be established under section 103. Every 2 years, HHS will review and evaluate epidemiological data to identify the most significant foodborne hazards and apply performance standards to foods/food classes for compliance with these standards.
- **Mandatory Good Agricultural Practices (GAPs)**—Under section 104, there is a new provision for a determination of adulteration under the FDCA whereby raw produce not grown, harvested, processed, packed, sorted, transported, or stored under required standards can be considered adulterated under the law. The Secretary of HHS will determine for which foods mandatory standards/GAPs are necessary.
- **Records access**—Each person who manufactures, processes, packs, or holds an article of food in the United States or for importation into the United States must give inspectors access to records, including the food safety plan. This provision does not generally apply to farms, but in fact does if the food is a fruit, vegetable, nut, or fungus. Records must be retained for 3 years. Restaurants must keep records of suppliers only, so the current restaurant exclusion is modified. The most important change with this provision is that the FDA does not have to demonstrate that the food hazard poses a serious threat to life. Access to records can simply bear on whether such food is adulterated, misbranded, or otherwise in violation of the FDCA.
- **Traceability**—In section 107, the FDA is asked to hold two public meetings before putting this provision into effect, as this subject

has stirred great controversy in the past. The provision foresees maintenance of a full pedigree of origin and previous distribution of the food. The provision applies to food within or for importation into the United States.

- **Certification and accreditation**—Within 3 years after the date of enactment of the legislation, if a shipment requires but lacks certification of compliance, it will be considered misbranded in violation of section 801(q) and will be refused admission into U.S. commerce. Section 801(q) imposes an additional condition for admission of foods whereby a qualified certifying entity must provide certification that the food complies with the FDCA. Thus, if the Secretary has found that a food from a particular country, territory, or region is not subject to adequate government controls to ensure that it is safe and that certification would assist in this regard, a certificate of compliance can be required. The risk concern must be based on science. A qualified certifying entity is defined as a government or other entity recognized by the Secretary.
- **Disclosure of information**—Section 112 allows for disclosure of nonpublic information to bodies if they can protect the information.
- **Importation facilitated**—Under section 113, a program can be established, in coordination with CBP, to facilitate the movement of food through the importation process if the importer (1) verifies that each facility is in compliance with food safety and security guidelines, (2) ensures that appropriate controls are in place through the supply chain, and (3) provides supporting information to the Secretary.
- **Country-of-origin labeling for all foods**—Foods will be considered misbranded under the law if (1) labeling of processed food fails to identify the country in which final processing occurred, or (2) for nonprocessed food, if the country of origin of the food is not given.
- **Export certificates**—While not part of the import program, CFSAN currently issues thousands of official export certificates annually since some countries demand such certificates as a condition for entry of imported foods. Section 203 simply adds foods to section 801(e)(4) and allows the FDA to collect fees in appropriate amounts to support the issuance of certificates.
- **Registration for commercial importers of food**—Section 204 considers a product misbranded if the importer is not registered. Maintenance of registration is conditioned on compliance with Good Importer Practices (GIPs) (in January 2009, cross-cutting GIP guidance was published; this section anticipates regulations rather than guidance). The importer should have information about the

imported food, its hazards, and requirements of the FDCA, as well as the ability to take corrective actions. Further, the Secretary may incorporate "certification of compliance" under section 801(q) and participation in the safe and secure food importation program under section 805. Registration can be suspended or cancelled so that the importer has an incentive to follow the rules and not allow the firms it represents to skirt current regulatory sanctions. Regulations must be written for all aspects of this section.

- **Annual fee for importer registration**—Importers of food are required to pay an annual fee, initially set at $500 and to be adjusted in subsequent years.
- **Registration of customs brokers**—Customs brokers can have their registration cancelled and be subject to civil penalties under section 205. There is no fee associated with this registration.
- **Unique ID for food facilities, importers, and customs brokers**—As noted above, currently there can be multiple names for a particular firm, making it very difficult to track shipments and problem firms.
- **Prohibition against delaying, limiting, or refusing inspection**—The FDA conducts very few foreign inspections as they are expensive, and thus it generally limits them to high-risk firms or situations in which violative products or illnesses have occurred. In those cases where a foreign firm refuses or delays inspection (or, presumably, when a country refuses a visa to FDA inspectors), this provision allows the FDA to consider products coming from the firm to be adulterated, and entry of further products from that firm will be prohibited.
- **Dedicated foreign inspectorate**—The FDA will have a dedicated cadre of foreign inspectors. For the most part, this is the case now, but a system that facilitates travel for this cadre is needed.
- **Lead in ceramic ware**—Ceramic ware with glazes containing lead must be labeled as such, per section 216.
- **Extraterritorial jurisdiction**—This provision establishes as a prohibited act "the production, manufacture, processing, preparation, packing, holding, or distribution of an adulterated or misbranded food with the knowledge or intent that such article will be imported" into the United States. This is a significant provision that allows the FDA to stop a product from entering the United States based on inspection of a facility. It is comprehensive in capturing every portion of the supply chain.

OPPORTUNITIES TO IMPROVE THE IMPORTED FOOD PROGRAM

The following are some opportunities for improving the FDA's imported food program beyond those identified above:

- **Establish a sizable, flexible, and separate set of best-practice tools that can be utilized to regulate, negotiate, and take appropriate and proportional actions to deal with imported food safety issues.** Although the overarching goal of the FDA's domestic and imported food programs is safe food, the imported food program poses unique challenges and requirements. Further, the imported food program, unlike the domestic program, must have the appropriate linkages to the larger context of global food safety if it is to function in an optimal manner. In dealing with a multitude of countries, food products, and conditions of production, the imported food program requires the flexibility to use the right tool for the job. Some of the tools needed are included in the opportunities for improvement that follow.
- **Study other developed country and U.S. agency programs to determine whether their philosophies, practices, and techniques might have utility in FDA programs.** A recent GAO report (GAO, 2008) provides some of the foundation for such a study. Still it would be useful for the FDA to expend the resources to see and better understand how these systems work in practice. An experienced team of FDA representatives from the commissioner's office, CFSAN, ORA, and the Center for Veterinary Medicine (CVM) could carry out such a study within a short time frame (2–3 months) and report back on regulatory and other best-practice tools that might be added to the FDA's existing mechanisms for ensuring the safety of imported foods.
- **Open up for input, publicize, and promote the FDA's imported food program, its elements, its goals, and its accomplishments.** More public meetings; brochures on the values, challenges, and benefits of the program activities; meetings with agencies, industry groups, and congressional staff; and outreach to embassies will foster understanding of the program goals, garner input on the program, and enable constructive buy-in for program objectives and mechanisms.
- **Establish a tiered food import monitoring system that drives the level of examination/sampling rate based on (1) the FDA's knowledge, experience, and confidence with an exporting country's food safety system; (2) the exporting country's (or in some cases, private industry's) ability to ensure that the imported food meets FDA**

requirements; and (3) the known level of food safety risk associated with the product type. Generally, other countries have established their lists of high-risk foods around foods derived from animals. For example and as noted earlier, the EU focuses on animal-derived foods and requires that countries have equivalence agreements with the European Commission in order to ship products to EU countries. The EU then audits the other countries' programs just as it internally audits the programs of its Member States. While this system was a logical one for the EU as it was engaged in ensuring consistent food safety programs among the growing number of Member States and needed to demonstrate that "third countries" had to meet equivalent requirements, this system is not being suggested for the FDA. Instead, the FDA needs to have a multifactorial risk-ranking system, and with the advent of PREDICT should be able to implement high, medium, or low levels of examination upon entry of a product.

- **Establish an importer licensing program, such that importers are responsible for ensuring compliance with U.S. food safety laws, and licenses may be withdrawn based on set criteria.** HR2749 contains an importer registration program whereby the registration can be cancelled for cause, which is similar to this suggestion. A number of countries utilize importers as their point of control for food imports and work closely with them to ensure that they understand national food safety requirements and their responsibilities in making certain that these requirements are met. These countries believe these programs are effective and give importers an incentive to be stewards for the products and companies they represent. Implementing this suggestion would require legislation. It should be noted that in January 2009, the FDA issued draft guidance on GIPs (FDA, 2009e) for comment. HR2749 requires that importers observe these practices. HR2749 also establishes fees for registration that should help support the FDA's imported food program.
- **Give priority to negotiating agreements with countries including, but not limited to, those having comparable food safety systems for which products could be examined/sampled at a low frequency.** The FDA needs to have ORA, Office for International Programs, CVM, and CFSAN teams of skilled negotiators who can work regularly with other countries to resolve problems with noncompliant foods, using the various tools available to address the problems. Perhaps countries are willing to address problems by using an accredited third-party certifier or by issuing export certificates for firms in which they have confidence, or they may not have an

adequate food safety system to deal with the problems and need guidance or technical assistance. In any case, expert teams that can conduct country negotiations need to be seen as a routine part of the FDA's public health regulatory armamentarium. Priority also needs to be given to negotiating agreements with countries with comparable food safety systems to reduce the use of FDA resources for product examination to the lowest level appropriate to the food risk. Maintenance of comparability assessments could be achieved through accredited third-party audits (governments could qualify as the accredited third party), similar to what is done for maintenance of equivalence by FSIS.

- **Provide training in foreign negotiations for appropriate FDA staff.** As stated above, the FDA needs to work with other countries, still as a regulatory agency, to find ways to resolve problems, promote food safety, and minimize the risk of unsafe foods coming into the United States. Training in negotiations for qualified staff would ensure effective negotiations.
- **Consider limiting ports of entry for FDA products, ensuring that the FDA has adequate staff to cover all ports of entry.** Entry points for imported foods number in the hundreds. A study of the cost/benefit of limiting these points of entry or limiting them for imports of high-risk products is needed. Whereas CBP is now able to take samples on behalf of the FDA, limiting ports of entry for food products is a tool used by FSIS and other countries for high-risk imports.
- **Work with countries on import alerts to ensure that they are fully aware of how to successfully address the issues involved in those alerts.** Not only countrywide import alerts but also regular import alerts involving multiple firms may remain in place for a decade or longer. In bilateral discussions with countries, many are mystified as to how such import alerts remain in place for so long and what corrective actions they can take. The FDA needs to provide greater outreach to countries to clarify both procedures and FDA expectations for safe imports.
- **Take affirmative steps to provide outreach to foreign governments and industry on FDA food safety programs and requirements.** The FDA provides a vast amount of information on its website on its requirements and procedures. The agency could make a commitment to conducting more international outreach through its newly established FDA foreign posts, in partnership with the World Bank, the Foreign Agricultural Service, Washington embassies, and other federal agencies. Such outreach could include written materials for handouts, scripts and PowerPoints for speakers, foreign lan-

guage flyers, appearances at international food conferences, and videoconferences.

- **Allow long listings of DWPE products/manufacturers/importers to enable time to negotiate with countries on regional or importing country solutions to avoid countrywide import alerts.** Countrywide import alerts command the attention of other countries and relieve the FDA of having to sample products from all suppliers of similar products when multiple suppliers have already been found with the same type of violations. Nevertheless, there are other ways to command this same attention (e.g., raising the issue at an SPS Committee meeting in Geneva) without placing an entire country on DWPE. Good companies receive the same punishment as the companies that caused the food safety problem. Countrywide detentions should be a tool, but utilized in extremely rare circumstances.
- **Require that importers pay for food safety examinations.** Other countries charge for food safety examinations at the border. Australia's system is a possible model. HR2749 requires fees for registration of both domestic and foreign firms, thus providing a portion of the support for the imported food program, albeit paying for the registration rather than the services themselves.
- **Develop a policy statement(s) recognizing the importance of adhering to obligations under the Agreement on the Application of SPS Measures under WTO and clarifying the FDA's stance on the Codex Alimentarius standards and guidance.** The FDA, as part of the federal government, is required to adhere to WTO obligations under the U.S. Uruguay Round Agreements Act. Nevertheless, although many countries modified their food safety programs and requirements to ensure compliance with the trade obligations, the FDA did not see a need to do so. As a public health agency, the FDA exists to protect public health, not to promote or enhance food trade. Still, a policy statement to clarify this posture and the FDA's recognition of the necessity and intention to comply with SPS obligations (e.g., by continuing to base sanitary measures on scientific principles, to use risk assessment in developing the measures, to base measures on international standards and guidance or state the scientific rationale for doing otherwise) would go a long way toward defining the standing of the U.S. Uruguay Round Agreements laws in relation to the FDA's public health obligations. Similarly, this same or another policy statement could clarify the FDA's stance on Codex Alimentarius standards and guidance.
- **Amend 21 CFR 1.90 to eliminate the requirement that food products randomly selected for testing be held until test results are avail-**

able. This regulation states that when a product offered for import is sampled, the owner of the product should hold and not distribute the product until results of the sample analysis are known. This provision is necessary for products suspected of food safety violations, but not those sampled on a random, or not-for-cause, basis. With less than 1 percent of foods sampled and with many of these products being raw and somewhat perishable, it does not make sense for the FDA to have to rush to have them analyzed so their quality will not diminish.

- **Use surveillance sampling of food products solely to gather data and intelligence to identify and prevent future problems.** Targeted/compliance sampling requiring bonding of shipments and prohibition of distribution needs to be limited to situations in which the FDA has sufficient reason to suspect violations of the FDCA. Utilizing surveillance sampling solely for information gathering would free up laboratory and inspectional resources that could be utilized to examine/sample a greater percentage of imported foods, providing improved protection of consumers. If violations are found, future shipments of the same food can be stopped, and, of course, follow-up on the initially sampled shipment is warranted if there is a significant acute health concern.
- **Find means to effectively utilize confidentiality agreements with other countries to share data (1) on food products from their own countries and (2) on food products from third countries when such data can be used collaboratively to improve food safety oversight.** The FDA currently has confidentiality agreements with a number of countries whereby there is mutual agreement to protect nonpublic information of the other party. Food safety information has been exchanged in foodborne outbreaks, and this should continue. Additionally, some countries could share regular monitoring data that could provide intelligence on new problems being found or, when combined with FDA findings, could confirm an emerging food safety problem.
- **Determine an appropriate and nondiscriminatory means to enable other countries to import shellfish and Grade A dairy products under state–federal cooperative programs—the Interstate Shellfish Sanitation Commission and National Conference of Interstate Milk Shippers, respectively.** These solidly run regulatory programs, carried out primarily by the states, ensure appropriate sanitation for these high-risk products. Unfortunately, other countries cannot export shellfish or Grade A products to the United States without following these programs to the letter, including paying for state inspections. Despite some inroads with these organizations regard-

ing the obligation to recognize equivalence in Article 4 of the SPS Agreement, in practice it has been difficult to evaluate equivalence when these two programs are so prescriptive in order to guarantee consistency across the 50 states.

- **Provide for recognition of third-party audits of firms (by accredited certifying bodies), and require import certification for food products when appropriate.** The FDA has previously recommended these tools for improving imported food safety and specifically published guidance on certification of foreign facilities/systems by accredited certifying bodies. HR2749 also contains provisions that specifically authorize such systems. It should be noted, however, that third-party audits and so-called private standards are most useful in situations where foreign parties can afford to utilize such systems.
- **Establish more direct line authority and/or performance metrics between CFSAN and ORA headquarters and field staff conducting the imported food program.** CFSAN establishes food programs and policies, but often must compromise on the optimal implementation of its programs because of the ORA operational culture and organization, which cover both medical products and foods. Options could be explored that might include a designated and separate field food staff, food teams in each district that would report to CFSAN, CFSAN having its own field offices, having CFSAN policy/program staff work within ORA headquarters offices on food programs, CFSAN designating operational metrics for field staff performance plans, or any combination of such mechanisms.
- **Consider an FDA policy on proportionality.** Some countries see proportionality as an obligation of countries under the SPS Agreement, which in fact does say that sanitary measures should be no more trade restrictive than necessary. In FDA parlance, the agency may occasionally refer to its use of regulatory discretion in ignoring, say, a minor misbranding violation. Nevertheless, the FDA in the past has expended considerable energy in taking regulatory action on residues and products presenting a negligible health concern. Such a statement of policy could provide much-needed guidance for explaining to Congress, stakeholders, and FDA staff the agency's priorities in choosing to actively pursue public health violations, certainly for any imported food associated with illnesses, significant sanitation problems, pathogens, pesticide residues exceeding a legal tolerance, or in the absence of a tolerance, a Codex Maximum Residue Level. The policy would urge that common sense prevail in suiting the action to the seriousness of the violation.

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Appendix F

Food Safety Research at Intramural and Extramural U.S. Food and Drug Administration Research Centers, by Topic

TABLE F-1 Intramural Research Centers

Topic	Project
Center for Food Safety and Applied Nutrition (CFSAN)	
Additives	Development of Methodology to Detect and Quantitate Intermediates and Unsulfonated Impurities in Certifiable Color Additives
	Use of Migration Models for Indirect Food Additive Approval
Allergens	Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food
	The Detection of Food Allergens Using Rapid Immunology–Based Detection Devices
	Direct Detection, Confirmation, and Measurement of Allergens in Food Matrices
	Effects of Cleaning on Removal of Allergenic Foods from Food-Contact Surfaces
	Food Allergen Research
	Prevalence of Self-Reported Food Allergy in American Adults and Use of Food Labels
Filth and Spoilage	Assessment of Seafood Decomposition with Electronic Sensors
	Evaluation of the 2-Day Hydrophobic Grid Membrane Filter, Simplate Yeast and Mold Color Indicator, and Petrifilm Dry Dehydratable Film Methods for the Enumeration of Fungi from Foods
	Filth and Extraneous Materials in Foods

continued

TABLE F-1 Continued

Topic	Project
Food Defense: Control	Chemical and Thermal Inactivation of Ricin
	Thermal Characterization of Botulinum Neurotoxin Using Scanning Differential Calorimetry
Food Defense: Detection	Counter Terrorism for Proteinaceous Toxins: Ricin, *Clostridium botulinum*, and *Staphylococcal enterotoxin B*
	Detection of *Clostridium botulinum* Neurotoxins in Foods
	The Detection of Proteinaceous Toxins and Biomarkers of Select Agents Using Multianalyte (Multiplex) and Agent Specific Technologies
	Determination of the Characteristics in Foods of *Bacillus anthracis* in Comparison to Other Bacillus Species
	Development of Rapid, Multiplexed Methods for Detection and Confirmation of Protein Toxins and Allergens in Food Using Matrix Assisted Laser Desorption/Ionization and Electrospray Mass Spectrometry
	Isolation and Identification of Non-Traditional Pathogens from Food
Foodborne Pathogens: Detection, General	Alternative Molecular Subtyping Methods for Microbial Foodborne Pathogens
	The Application of Deoxyribonucleic Acid (DNA) Microarray Technology in Bacterial Identification Using Different Food Matrices and the Detection of DNA Hybridization Constructs Using Infrared Spectroscopy
	The Application of Interferometric Biosensor Technology to the Analysis of Food Matrices for Multiple Bacterial and Viral Pathogens, Allergens, and Toxins
	Characterization of the Zinc-Containing Metalloprotease Encoded by zpx and Development of a Species-Specific Detection Method for *Enterobacter sakazakii*
	Development and Validation of Methods for Species Identification of Potentially Hazardous Fish Species Based on DNA Bar-Coding
	Development of Liquid Chromatography/Mass Spectrometry Protein Profiling as a Tool for Bacterial Differentiation
	Diagnostic Methodology for Foodborne Illness (Bacteria and Virus)
	Evaluation of Bioluminex Test Methods and Application to the Analysis of Foods
	Evaluation of Direct Analysis in Real Time Ionization and Application to the Analysis of Foods and Food Contact Substances
	Infrared Detection of Label-Free DNA Hybridization on a Microarray Platform for Use in the Identification of Virulence Genes in Foodborne Microorganisms
	Molecular Applications for Identifying Microbial Pathogens in the Post-9/11 Era

TABLE F-1 Continued

Topic	Project
	Prevalence of Pathogens in Imported Product
	Pulsed-Field Gel Electrophoresis (PFGE) of Microbial Foodborne Pathogens
	Surface Plasmon Resonance Detection of Foodborne Pathogens and Toxins
	Use of Gas Chromatography-Flame Ionization Detector and Gas Chromatography-Mass Spectrometry (GC-MS) for Identification and Classification of Foodborne Bacteria and Spores
Foodborne Pathogens: Emerging Pathogens	Genomic Analysis of *Cyclopsora cayetenensis* and *Cryptosporidium* spp: Methods Development for Viability and Molecular Epidemiological Applications
	Identification and Analyses of Invasion Gene Targets for Use as Diagnostic Probes to Detect Virulent *Enterobacter sakazakii*
	Molecular Characterization of Foodborne Pathogens and the Development of Virulence Factor
Foodborne Pathogens: Foodborne Viruses	Effects of Food Processing on Viruses in Foods
	Microarray Based Identification of Foodborne Viruses
	Viral Survival During Produce Processing and Storage: Determined by Cellar Infectivity and Real-Time Polymerase Chain Reaction (PCR)
Foodborne Pathogens: Gram-Negative Bacterial Pathogens (*E. coli, Salmonella, Shigella, Yersina*)	Development of a Method to Enrich and Detect *Salmonella enteritidis* in Whole Eggs
	Ecology and Control of *Salmonella Newport* on Tomatoes
	Genetic and Phenotypic Differentiation of *Salmonella enteritidis* Strains Derived from Poultry
	Genetic Factors Regulating *Salmonella* Stress Response
	Identification of *Shigella* Species by GC-MS/MS and Two-Dimensional Gas Chromatography-Time of Flight
	Modification of *Shigella* Isolation and Detection Methods
	Molecular Characterization of Atypical Strains of Enterohemorrhagic *Escherichia coli*
	Molecular Evolution of Enteric Pathogens
	Recurrent Multistate Outbreak of *Salmonella Newport* Associated with Tomatoes from Contaminated Fields
	A Systems Approach to Minimize *E. coli* O157:H7 Food Safety Hazards Associated with Fresh and Fresh-Cut Leafy Greens
	Thermal Resistance of *Yersinia* Species in Milk and Other Liquids Related to Food Composition
Foodborne Pathogens: *L. monocytogenes*	Comparative Genomic Analysis of *Listeria monocytogenes* for Survival in Food Processing Environments
	Effect of Solids Levels on the Thermal Resistance of *Listeria* Species

continued

TABLE F-1 Continued

Topic	Project
	Efficacy of Mitigation Techniques Against *Listeria monocytogenes* on Seafood and Seafood Processing Surfaces
	Growth Modeling and Assessment of Technologies for Pathogen Reduction or Elimination of *Listeria monocytogenes*
	Identification and Characterization of Factors Associated with the Virulence of *Listeria monocytogenes* Involved in Human Gastroenteritis
	Optimization and Validation of Real Time PCR Most Probable Number Enumeration of Foodborne *Listeria monocytogenes*
Foodborne Pathogens: Processing	Decontamination of Dry Ingredients
	Inactivation of *Clostridium botulinum* Spores Using High Pressure Processing
	Post-Harvest Practices to Enhance the Safety of Fresh Tomatoes
	Validation of Microwave Pasteurization of Multiple Shell Eggs
Foodborne Pathogens: Risk Assessment	Development of a Risk-Ranking Framework to Evaluate Potential High-Threat Microorganisms, Toxins, and Chemicals in Food
	Development of Bacterial Pathogenesis Models Using *Ceanorhabditis elegans* as Host Organism to Study Bacterial Virulence and Host Defense Factors
	Framework for Establishing Extended Shelf-Life Processes Using the Food Safety Objective Approach
	Joint U.S. Food and Drug Administration (FDA)/Health Canada Public Health Risk Assessment of *Listeria monocytogenes* in Cheese
	Risk Assessment for the Public Health Impact of Highly Pathogenic Avian Influenza Virus in Poultry Meat, Shell Eggs, and Egg Products
	Risk Assessment to Determine Potential of Chronic Wasting Disease in Infected Cervids as a Human Health Risk
Foodborne Pathogens: Seafood Toxins	Biomarkers of Neurotoxic Shellfish Poisoning
	Ciguatera Fish Poisoning
	Detection Methods for Paralytic Shellfish Poisoning Toxins
	Development of Conjugates of Saxitoxins for the Production of Antibodies
	An Intervention Analysis for the Reduction of Exposure to Methylmercury from the Consumption of Seafood by Women of Child-Bearing Age
	Mussel-Associated Azaspiracid Intoxication in the United States
	Neurotoxic Shellfish Poisoning
	Non-Traditional Vectors for Paralytic Shellfish Poisoning

TABLE F-1 Continued

Topic	Project
	Paralytic Shellfish Poisoning: Link Between Surface Algal Blooms and Deep Water Shellfish Toxicity in Federal Waters
Foodborne Pathogens: Surveys	Indicator Microorganisms and Viruses in Shellfish in Harvest Waters
	Microbiological Survey of Raw Oysters Collected at Retail Across the United States
	Survey of U.S. Raw Milk Supply for Pathogens
Toxicology: Detection	Analysis of Total Mercury in Foods by Compton Suppression Instrumental Neutron Activation Analysis
	Determination of the Thyroid-Interactive Anions Iodide, Perchlorate, and Thiocyanate in Food
	Development of Tuna Reference Material for Toxic Elements
	Impact of Processing on Detection of Melamine and Cyanuric Acid
	Methodology for Determination of Volatile Contaminants in Foods
	Two-Dimensional Gas Chromatography and Time-of-Flight Mass Spectrometry for the Determination of Pesticides and Persistent Organic Pollutants in Foods
	Validating the Predictive Performance of *Caenorhabditis elegans* as an Animal Model for Toxicity Testing
Toxicology: Mechanisms	Cellular and Cytokine Biomarkers for Infectious and Inflammatory Models
	Denaturation/Renaturation Kinetics of Staphylococcal Enterotoxin in Acidic Foods
	Evaluation of the Mass Transfer Properties of Perfluoro Chemicals from Paper Food Packaging
	Hepatotoxicity—Role of Gender, Species and Inflammation on In Vitro and In Vivo Biomarkers of Liver Toxicity
	Interaction of Combined Exposure to the Microbial Toxin Lipopolysaccharide (and Deficient or Graded Dietary Vitamin D Level
Toxicology: Monitoring	Acrylamide Testing at CFSAN: Exploratory Survey Results
	Aquaculture Drugs and Chemicals
	FDA Toxicity Databases and Real-Time Data Entry
	FDA's Total Diet Study: Dietary Intake of Perchlorate and Iodine
	Health Care Provider Survey—re the Methylmercury Advisory

continued

TABLE F-1 Continued

Topic	Project
Center for Veterinary Medicine (CVM)	
Animal Feed Safety	Antimicrobial Susceptibility of Native *Enterococcus faecium* from Chickens Given Feed Containing Virginiamycin
	Detecting Animal Tissues in Feed and Feed Ingredients
	Evaluation of Two Commercial Lateral-Flow Test Kits That Detect Animal Proteins in Finished Animal Feed
	Validation of a PCR-Based Method for the Detection of Various Rendered Materials in Feedstuffs Using a Forensic DNA Extraction Kit
Compliance*	Develop Needed Enforcement Methods for Drug Residues
	Evaluate Screening Test Performance
	Perform Method Trials to Determine Drug Residues from Unapproved Uses
	Use Tissue-Fluid Correlations to Predict Drug Residue Levels in Edible Tissues from Food-Producing Animals
Premarket Drug Review: Antimicrobial Resistance Mechanisms	The Clonal Spread of Multidrug-Resistant Non-Typhi *Salmonella* Serotypes
	Determine Microbial Ecology of Antibiotic Resistance Development and Dissemination in the Food Animal Production Environment
	Genetic Diversity and Antimicrobial Susceptibility Profiles Among *Staphylococcus aureus* Isolated from Bovine Mastitis
	Interrogate Salmonella Diversity Using a Novel 35 Genome Salmonella Species Microarray—A Critical Path Study
	Use Molecular and Biochemical Methods to Determine the Animal Origin of Foodborne Bacterial Pathogens
Premarket Drug Review: Microbiological Methods	Broth Microdilution Susceptibility Testing of *Campylobacter jejuni* and the Determination of Quality Control Ranges for 14 Antimicrobial Agents
	Conduct Molecular Characterization of Foodborne Bacterial Pathogens Isolated from Animals and Retail Meats by Microarray Technology
	Develop Antimicrobial Susceptibility Testing Methods and Interpretive Criteria for Aquatic Animal Microflora
	Develop Standardized In Vitro Antimicrobial Susceptibility Testing Methods for Bacterial Pathogens
	Salmonella Resistant to Extended-Spectrum Cephalosporins: Prevalence and Epidemiology

TABLE F-1 Continued

Topic	Project
Postmarket Approval and Monitoring: Analysis of Survey Data	Characterize Antimicrobial Resistance Among Bacteria Isolated from Retail Meats Characterize Antimicrobial Resistance Among Historical Isolates of Foodborne Pathogens Characterize Antimicrobial Resistance Mechanisms of Animal Bacterial Pathogens Determine the Prevalence of Pathogenic *Escherichia coli* Recovered from National Antimicrobial Resistance Monitoring System (NARMS) Retail Meats DNA Fingerprinting of Foodborne Pathogens by PFGE (in conjunction with PulseNet) Genotyping of *Campylobacter coli* Isolated from Humans and Retail Meats Using Multilocus Sequence Typing and PFGE Molecular Serotyping of *Salmonella* spp by Using the Luminex Multianalyte Profiling (xMAP) Technology Survey Susceptibility of Foodborne Pathogens from Humans, Food, and Animals in Mexico Use of Tissue-Fluid Correlations to Estimate Gentamicin Residues in Kidney Tissue of Holstein Steers
Postmarket Approval and Monitoring: Survey Programs	Center for Veterinary Medicine (CVM) Participation in the NARMS Program CVM Participation in PulseNet Targeted Surveys as Needed Veterinary Drug Residues
National Center for Toxicological Research (NCTR)	
Antimicrobial Resistance	Antimicrobial Resistance Genetics of "Emerging" *Salmonella enterica* Serovar Javiana Phenotypes Involved in Clinical and Food-Related Outbreaks Beta-Lactamase Resistance in *enterococci* Heteroresistance to Vancomycin and Novel Point Mutations in Tn1546 of *Enterococcus faecium* ATCC 51559 Molecular Characterization of Multidrug-Resistant *Enterococcus* spp from Poultry and Dairy Farms: Detection of Virulence and Vancomycin Resistance Gene Markers by PCR Substitutions of Amino Acids in Alpha-Helix-4 of Gyrase A Confer Fluoroquinolone Resistance on *Clostridium perfringens*

continued

TABLE F-1 Continued

Topic	Project
Methods Development	Biostatistical Modeling for Food Protection Plan
	Development of Public Toxicogenomics Software for Microarray Data Management and Analysis
	Evaluation of Certain Food Additives and Contaminants
	Genotoxic Effects of Acrylamide and Glycidamide in Mouse Lymphoma Cells
	In Vitro Antimicrobial Susceptibility, Genetic Diversity and Prevalence of Uridine Diphosphate-Glucose 4-Epimerase Gene in *Campylobacter coli* and *Campylobacter jejuni* from Turkey Production Facilities
	Innovative, Static, and Dynamic Chemical Sensors for Food Safety—Litmus Cooperative Research and Development Agreement
	Integrating Time-Course Microarray Gene Expression Profiles with Cytotoxicity for Identification of Biomarkers in Primary Rat Hepatocytes Exposed to Cadmium
	Isolation and Characterization of Tetracycline-Resistant *Citrobacter* spp from Catfish
	Mold2, Molecular Descriptors from Two-Dimensional Structures for Chemoinformatics and Toxicoinformatics
	Molecular Characterization of *Salmonella* spp and *Vibrio* spp Isolated from Seafood and Development of Microarray Detection Method
	Molecular Typing Methodologies for Microbial Source Tracking and Epidemiological Investigations of Gram-Negative Bacterial Foodborne Pathogens
	Physiologically-Based Pharmacokinetic/Pharmacodynamic Model for Acrylamide and Its Metabolites in Mice, Rats, and Humans
	Rapid Bacterial Identification with Subspecies-Level Specificity
	Real-Time PCR Assays for Ricin and Related Potential Bioterrorism Agents in Foods
	The Survivability of *Bacillus anthracis* (Sterne Strain) in Processed Liquid Eggs
Other	Chemical Inactivation of Protein Toxins on Food Contact Surfaces
	Effect of Egg White Addition to Milk and Ground Beef on the Survival of Sterne Strain of *Bacillus anthracis, Salmonella enterococci*, and *Staphylococci* at Different Temperatures
	Laboratory Studies in Melamine and Cyanuric Acid Biochemical Toxicology
	Mechanistic Evaluation of the Induction of Lymphoproliferation and Apoptosis Inhibition by Probiotic Bacteria in Mice Infected with *Salmonella enterica*

TABLE F-1 Continued

Topic	Project
Risk-Based Research	Anaerobic Metabolism of 1-Amino-2-Naphthol-Based Azo Dyes (Sudan Dyes) by Human Intestinal Microflora Approaches in the Safety Evaluations of Veterinary Antimicrobial Agents in Food to Determine the Effects on the Human Intestinal Microflora Identification and Characterization of Class 1 Integron Resistance Gene Cassettes Among Salmonella Strains Isolated from Imported Seafood Influence of Erythromycin A on the Microbial Populations in Aquaculture Sediment Microcosms
Surveillance	Prevalence and Characterization of *Salmonella enterica* Serovar Weltevreden from Imported Seafood Probiotic Bacteria Are Antagonistic to *Salmonella enterica* and *Campylobacter jejuni* and Influence Host Lymphocyte Responses in Human Microbiota-Associated Immunodeficient and Immunocompetent Mice
Office of Regulatory Affairs (ORA)	
Food Science and Technology	Liquid Chromatographic Analysis of Vitamin B6 in Reconstituted Infant Formula: Collaborative Study Potential Use of DNA Barcodes in Regulatory Science: Applications of the Regulatory Fish Encyclopedia
Foodborne Pathogens: General	Molecular Confirmation of Oyster as the Vector for Hepatitis A in a 2005 Multistate Outbreak Recovery of *Mycobacterium bovis* from Soft Fresh Cheese Originating in Mexico
Foodborne Pathogens: Gram-Negative Bacterial Pathogens (*Campylobacter*, *E. coli*, *Salmonella*, *Shigella*, *Yersina*)	Comparison of *Salmonella enterica* Serovar Heidelberg Susceptibility Testing Results

*Compliance functions focus on methods development and validation, which includes incursion services as needed.

TABLE F-2 Extramural Research Centers

Topic	Project
Joint Institute for Food Safety and Applied Nutrition (University of Maryland)	
Additives	Predicting Exposure Estimates: Experimental Food Additive Partitioning Studies and Model Development
Filth and Spoilage	Moulds and Yeasts in Fruit Salads and Fruit Juices
Food Defense: Control	Studying Nisin and Sublancin to Strategize Protection of U.S. Food Supply from Bioterrorism
Foodborne Pathogens: General	Enzymatic Degradation of Prion Surrogate Proteins Plant-Derived Vaccines Against Diarrheal Diseases Public Health Impact and Cost-Effectiveness of Implementing Good Agricultural Practices in Tomato Farming
Foodborne Pathogens: Gram-Negative Bacterial Pathogens (*Campylobacter*, *E. coli, Salmonella, Shigella, Yersina*)	*Campylobacter*-Induced Interleukin-8 Secretion in Polarized Human Intestinal Epithelial Cells Requires *Campylobacter*-Secreted Cytolethal Distending Toxin- and Toll-Like Receptor-Mediated Activation of NF-κB Detecting and Identifying *Shigella* in Foods Reducing and Controlling *Salmonella* and *E. coli* in Crops Role of Efflux Pumps and Topoisomerase Mutations in Fluoroquinolone Resistance in *Campylobacter jejuni* and *Campylobacter coli*
Foodborne Pathogens: Processing	Survival of *Enterobacter sakazakii* in a Dehydrated Powdered Infant Formula
Risk-Based Research	Emotion Regarding a Food Crisis and Predicting Consumers' Hesitancy to Eat the Food After the Crisis Evaluation of the ALERT (Assure, Look, Employees, Reports, Threat) Campaign Impact on Audience Attitudes and Behaviors of Risk Messages about Act of Bioterrorism on U.S. Food Supply
Toxicology: Detection	Characterizing and Predicting Drug Residues in Fish
National Center for Food Safety and Technolog (Illinois Institute of Technology)	
Allergens	Cleaning and Other Control and Validation Strategies to Prevent Allergen Cross-Contact in Food-Processing Operations—A Review Purification, Crystallization, and Preliminary X-Ray Characterization of Amandin, A Major Allergen in Almonds (*Prunus dulcis*)

TABLE F-2 Continued

Topic	Project
Filth and Spoilage	Factors Affecting Mycotoxin Production in Fruits Minimum Leak Size Determination, Under Laboratory and Commercial Conditions, for Bacterial Entry into Polymeric Trays Used for Shelf-Stable Food Packaging Stability of Picrotoxin During Yogurt Manufacture and Storage
Food Defense: Detection	Detection and Decontamination Methods for Food Defense
Foodborne Pathogens: Detection, General	Rapid Tests for Pathogenic Microbes in Food-Producing Animals
Foodborne Pathogens: Foodborne Viruses	Inactivation of Hepatitis A Virus, Poliovirus and a Norovirus Surrogate by High-Pressure Processing
Foodborne Pathogens: *L. monocytogenes*	Multi-Virulence-Locus Sequence Typing Identifies Single Nucleotide Polymorphisms Which Differentiate Epidemic Clones and Outbreak Strains of *Listeria monocytogenes*
Foodborne Pathogens: Processing	Modeling the Inactivation of Bacterial Spores New Kinetic Models for Inactivation of Bacterial Spores
Western Institute for Food Safety and Security (WIFSS, University of California, Davis)	
Foodborne Pathogens: General	U.S. Food and Drug Administration Rapid Response Teams (to Enhance, Complement, Develop, and Improve State Manufactured Food Protection Regulatory and Surveillance Programs) Food Safety Risks and Mitigation Strategies for Feral Swine (*Sus scrofa*) Near Agriculture Fields
Foodborne Pathogens: Gram-Negative Bacterial Pathogens (*E. coli, Salmonella, Shigella, Yersina)*	*Escherichia coli* O157:H7 in Feral Swine Near Spinach Fields and Cattle, Central California Coast Incidence and Tracking of *Escherichia coli* O157:H7 in a Major Produce Production Region in California A Multi-State Outbreak of *Escherichia coli* O157:H7 Linked to Consumption of Beef Tacos at a Fast-Food Restaurant Chain *Salmonella* in Almonds
Funded by WIFSS	
Foodborne Pathogens: General	Attachment, Uptake, Dissemination and Inactivation of Foodborne Enteric Caliciviruses in Vegetables Fresh Express—Determining the Environmental Factors Contributing to the Extended Survival or Regrowth of Foodborne Pathogens in Composting Systems

continued

TABLE F-2 Continued

Topic	Project
	Survival and Transmission of Pathogenic Viruses in an Agricultural Environment
Foodborne Pathogens: Gram-Negative Bacterial Pathogens (*E. coli*, *Salmonella*, *Shigella*, *Yersina)*	Ecology and Epidemiology of *E. coli* O157:H7 in Fresh Produce Production Regions of the Central California Coast
	Effect of Wilting and Tissue Infiltration on the Behavior of *E. coli* O157:H7 on Leaf Lettuce Directly After Harvest
	Evaluation of Growth Kinetics of *E. coli* O157:H7 on Bagged Spinach, Crisp Head Lettuce, and Romaine Lettuce in Relation to Consumption Decisions Based on Visual Quality and Off-Odors
	Infiltration of Edible Plants by *E. coli* O157:H7

Appendix G

U.S. Food and Drug Administration Food Protection Plan

An integrated strategy for protecting the nation's food supply

November 2007

U.S. Department of Health and Human Services
U.S. Food and Drug Administration

"Americans enjoy unprecedented choice and convenience in filling the cupboard today, but we also face new challenges to ensuring that our food is safe. This Food Protection Plan will implement a strategy of prevention, intervention and response to build safety into every step of the food supply chain."

Michael O. Leavitt
Secretary of Health and Human Services
U.S. Department of Health and Human Services

A MESSAGE FROM THE COMMISSIONER

As a physician and the Commissioner of Food and Drugs, protecting America's food supply is extremely important to me.

American consumers have one of the safest food supplies in the world, but the world is changing and we know it can be safer. New food sources, advances in production and distribution methods, and the growing volume of imports due to consumer demand call for a new approach to protecting our food from unintentional or deliberate contamination. The U.S. Food and Drug Administration (FDA) must keep pace with these changes so that the safety of the nation's food supply remains second to none.

In the past few years, FDA has introduced several initiatives that address microbial and other food safety hazards with domestic or imported produce and that guide industry practices in the safe production of fresh-cut fruits and vegetables. FDA has also worked hard to raise awareness about food defense issues and preparedness. These are just a few things we are doing to improve food safety and food defense.

Recent nationwide recalls remind us how devastating foodborne illness can be. In the past year, contaminated peanut butter led to illnesses in more than 300 people and at least 50 hospitalizations. Contaminated spinach resulted in 206 illnesses, three deaths, and more than 100 people hospitalized. Reports of kidney failure and deaths in cats and dogs prompted a recall of more than 100 brands of pet food.

For every one of these emergencies, the FDA responded immediately to minimize harm. FDA investigators traced each problem's source and worked without delay to remove the affected products from market shelves. FDA staff continue to work diligently to protect our food supply, by containing outbreaks and preventing further illnesses.

With this FDA Food Protection Plan we are going even further. It is a forward-oriented concept that uses science and modern information technology to identify potential hazards ahead of time. By *preventing* most harm before it can occur, enhancing our intervention methods at key points in the food production system, and strengthening our ability to respond immediately when problems are identified, FDA can provide a food protection framework that keeps the American food supply safe.

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

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I. EXECUTIVE SUMMARY

FDA is implementing a Food Protection Plan (the Plan) that addresses both food safety and food defense for domestic and imported products. The Plan is integrated with the Administration's Import Safety Action Plan. The Food Protection Plan operates through a set of integrated strategies that:

- Focus on risks over a product's life cycle from production to consumption
- Target resources to achieve maximum risk reduction
- Address both unintentional and deliberate contamination
- Use science and modern technology systems

FDA's Integrated Plan Provides Three Elements of Protection

PREVENT Foodborne Contamination
- Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses
- Identify Food Vulnerabilities and Assess Risks
- Expand the Understanding and Use of Effective Mitigation Measures

INTERVENE at Critical Points in the Food Supply Chain
- Focus Inspections and Sampling Based on Risk
- Enhance Risk-Based Surveillance
- Improve the Detection of Food System "Signals" That Indicate Contamination

RESPOND Rapidly to Minimize Harm
- Improve Immediate Response
- Improve Risk Communications to the Public, Industry and Other Stakeholders

FDA recognizes the need to partner with Congress to make the changes necessary to transform the safety of the nation's food supply. This plan identifies the administrative actions we are proposing to take within the Agency. This Plan also recommends legislative changes to strengthen FDA's ability to continue to protect Americans from foodborne illnesses.

ADDITIONAL PROTECTIONS THAT INVOLVE LEGISLATIVE CHANGES TO FDA'S AUTHORITY

PREVENT Foodborne Contamination

- Allow FDA to Require Preventive Controls to Prevent Intentional Adulteration by Terrorists or Criminals at Points of High Vulnerability in the Food Chain
- Authorize FDA to Issue Additional Preventive Controls for High-Risk Foods
- Require Food Facilities to Renew Their FDA Registrations Every Two Years, and Allow FDA to Modify the Registration Categories

INTERVENE at Critical Points in the Food Supply Chain

- Authorize FDA to Accredit Highly Qualified Third Parties for Voluntary Food Inspections
- Require New Reinspection Fee From Facilities That Fail to Meet current Good Manufacturing Practices (cGMPs)
- Authorize FDA to Require Electronic Import Certificates for Shipments of Designated High-Risk Products
- Require New Food and Animal Feed Export Certification Fee to Improve the Ability of U.S. Firms to Export Their Products
- Provide Parity Between Domestic and Imported Foods if FDA Inspection Access is Delayed, Limited, or Denied

RESPOND Rapidly to Minimize Harm

- Empower FDA to Issue a Mandatory Recall of Food Products When Voluntary Recalls Are Not Effective
- Give FDA Enhanced Access to Food Records During Emergencies

FDA plans to enhance its information technology (IT) capabilities to fully support the implementation of the FDA Food Protection Plan.

For More Information

For follow up information on this report, contact:
Kari Barrett
Senior Advisor, Food Protection Team
Room 14B-17
5600 Fishers Lane
Rockville, MD 20857
Phone 301.827.9831
Email: FoodProtection@fda.hhs.gov

To download a copy of this report, go to http://www.fda.gov/FDAgov/Food/FoodSafety/FoodSafetyPrograms/FoodProtectionPlan2007/ucm132565.htm or for a pdf version go to http://www.fda.gov/FDAgov/downloads/RegulatoryInformation/Guidances/ucm132573.PDF.

For more in-depth information on the many programs FDA has underway to protect the nation's food supply, go to the Food Protection main page at http://www.fda.gov/FDAgov/Food/FoodSafety/FoodSafetyPrograms/FoodProtectionPlan2007/default.htm.

II. INTRODUCTION

Every day across the country, people eat out, buy groceries, and cook meals for their families. Americans expect that all their food will be safe, and FDA plays a critical role in making sure this is true. FDA is responsible for the safety of the vast range of food Americans eat; about 80 percent of all food sold in the United States. This includes everything except for meat, poultry, and processed egg products, which are regulated by the U.S. Department of Agriculture (USDA).

In May 2007, Secretary of Health and Human Services Michael O. Leavitt and Commissioner of Food and Drugs Andrew C. von Eschenbach, M.D., charged FDA with developing a comprehensive and integrated FDA Food Protection Plan to keep the nation's food supply safe from both unintentional and deliberate contamination. Driven by science and modern information technology, the Plan aims to identify potential hazards and counter them before they can do harm. A cornerstone of this forward-thinking effort is an increased focus on prevention.

The Plan builds in safety measures to address risks throughout a product's life cycle, from the time a food is produced to the time it is distributed and consumed. The Plan focuses FDA's efforts on preventing problems first, and then uses risk-based interventions to ensure preventive approaches are effective. The Plan also calls for a rapid response as soon as contaminated food or feed is detected or when there is harm to people or animals.

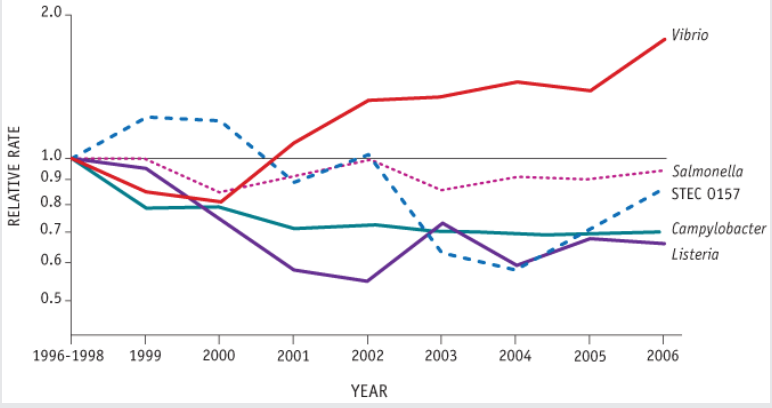
FDA's integrated approach, within the Food Protection Plan, encompasses three core elements: prevention, intervention and response.

- The *prevention* element means promoting increased corporate responsibility so that food problems do not occur in the first place. By comprehensively reviewing food supply vulnerabilities and developing and implementing risk reduction measures with industry and other stakeholders, FDA can best address critical weaknesses.
- The *intervention* element focuses on risk-based inspections, sampling, and surveillance at high risk points in the food supply chain. These interventions must verify that the preventive measures are in fact being implemented, and done so correctly.
- The *response* element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency. It also includes the idea of better communication with other federal, state, and local government agencies and industry during and after emergencies. Whether contamination is unintentional or deliberate, there is a

need to respond quickly and to communicate clearly with consumers and other stakeholders. The communication should emphasize identifying products of concern as well as assuring the public of what is safe to consume.

Under its FoodNet program (www.cdc.gov/foodnet), the Centers for Disease Control and Prevention (CDC) monitors foodborne microorganisms that cause illness and tracks trends.

Relative rates compared with 1996-1998 baseline period of laboratory-diagnosed cases of infection with *Campylobacter*, STEC O157, *Listeria, Salmonella* and *Vibrio*, by year.



This graph shows the progress that has been made in reducing foodborne infections. Other than recent increases in *Vibrio*- and Shiga toxin-producing *Escherichia coli* (STEC) O157-related illness, the incidence of illnesses associated with these foodborne microorganisms has mostly remained steady or gone down since the late 1990s, although further progress is needed. Note that the graph represents all illnesses associated with the five types of bacteria, not just that from contaminated food. The graph also represents illnesses from foods not regulated by FDA.

Source: Centers for Disease Control and Prevention

This graph shows the progress that has been made in reducing foodborne infections. Other than recent increases in *Vibrio*- and Shiga toxin-producing *Escherichia coli* (STEC) O157-related illness, the incidence of illnesses asso-

ciated with these foodborne microorganisms has mostly remained steady or gone down since the late 1990s, although further progress is needed. Note that the graph represents all illnesses associated with the five types of bacteria, not just that from contaminated food. The graph also represents illnesses from foods not regulated by FDA.

FDA is committed to strengthening the nation's food protection system through implementation of the FDA Food Protection Plan. The Plan's strategic and partnered activities are driven by science and incorporate the use of 21st-century technologies.

Scope of the Food Protection Plan	Three Core Elements
1. Applies to food for people and animals 2. Addresses domestic and imported products 3. Encompasses food safety (unintentional contamination) and food defense (deliberate contamination)	• Prevention • Intervention • Response

FDA Regulates Roughly 80 Percent of the U.S. Food Supply

- FDA regulates $417 billion worth of domestic food and $49 billion in imported food[1] annually.
- FDA has oversight of more than 136,000 registered domestic food facilities (including more than 44,000 U.S. food manufacturers and processors and approximately 113,000 U.S. food warehouses, including storage tanks and grain elevators).[2]
- FDA or state and local authorities regulate more than 2 million farms, roughly 935,000 restaurants and institutional food service establishments, and 114,000 supermarkets, grocery stores, and

[1] Based on FDA value-of-shipment information, 2003.

[2] Facilities that are engaged in more than one type of activity (e.g., manufacturing and warehousing) are counted in both categories; thus, the sum of the individual numbers of type of facilities exceeds the number of total registered facilities.

other food outlets.[3] FDA provides guidance, model codes, and other technical assistance to state and local partners.

- Approximately 189,000 registered foreign facilities manufacture, process, pack, or hold food consumed by Americans.

[3] Data from U.S. Department of Agriculture, National Restaurant Association, and U.S. Census Bureau.

III. CHANGES AND CHALLENGES

Increasingly, consumers want the convenience of opening up a bag of salad that's already prepared, and immediately serving it.

Current trends in the food industry promise better nutrition and wider choices for consumers. At the same time, multiple factors pose challenges. These include changing food production technology, patterns of human demographics and behavior, business practices, new threats, and communication issues.

Trends in Demographics and Consumption

Changes in demographics and consumption have increased consumers' susceptibility to foodborne illness. For example, by 2015, it is estimated that 20 percent of the population will be 60 or older. Older Americans are among those at highest risk for foodborne illness.

Also, the practice of a family buying a head of lettuce and preparing a salad at home is not as common. Increasingly, consumers want the convenience of opening up a bag of salad that's already prepared, and immediately serving it.

It used to be that when a single head of lettuce was contaminated, the resulting illness affected one family. Now, contaminated heads of lettuce may be processed with thousands of other heads of lettuce and placed into bags of convenience salad that many consumers can buy. These bags of salad end up in thousands of homes, potentially resulting in hundreds of illnesses.

The shifting demographics have increased the numbers of susceptible consumers, and the convenience factors have meant that small problems can lead to large outbreaks—both indications of the need to make changes to ensure a continued high level of food protection.

Shifting Demographics

Our population demographics are changing. Shifting demographics means that more of the U.S. population is, and increasingly will be, susceptible to foodborne illness.

- In 2007, 20–25 percent of the population is in a high-risk category (young, older, pregnant, immune-compromised). These Americans face a risk of serious illness or death from foodborne illness.*
- In 1980, 15 percent of the population was 60 or older. By 2025, the number will be 25 percent.
- Four percent of the population is immune-compromised (transplant patients, people who are HIV positive, people receiving chemotherapy or other immunosuppressive treatments, people with chronic diseases).

*For example in a joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) report on *Listeria monocytogenes* (LM) microbiological risk assessment, it was estimated that transplant patients had a 2,584 increased probability of becoming ill from LM, compared with a healthy adult less than 65 years old. The same report indicated that AIDS patients had an 865-fold increase and an otherwise healthy adult over the age of 65 had a 7.5-fold increase [ftp://ftp.fao.org/docrep/fao/007/y5394e/y5394e00.pdf].

Convenience Trends

Americans are consuming more convenience foods. Foods prepared outside the home may be subject to cross-contamination from other foods, as well as contamination from food workers.

- Ready-to-eat foods (bagged salad, cut fruit) and prepared foods (including hot bars with main and side dishes, as well as salad bars) and frozen dishes that can be cooked quickly are increasing in popularity.
- Cooking in the home is decreasing—people are eating out and bringing prepared foods home.
- Spending on foodservice items, such as supermarket deli foods, accounts for about half of all U.S. food spending.

Consumption Patterns

A greater variety of foods are eaten year round. Also, foods that are consumed raw or with minimal processing are often associated with foodborne illness.

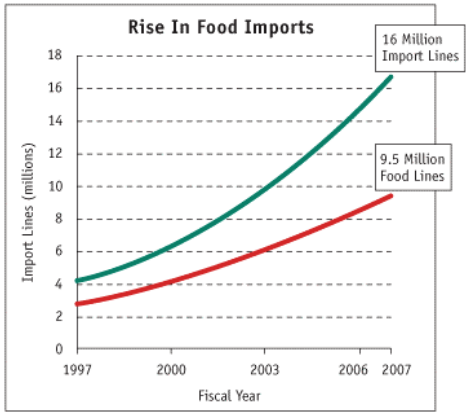
- Consumers are encouraged to make healthier food choices and increase consumption of fruits and vegetables (5–9 servings/day), including fresh produce.
- U.S. per capita consumption of fresh fruit and vegetables increased 36 percent from 1981 to 2000.
- A typical grocery store carried 173 produce items in 1987 and now carries 558 produce items.
- Produce items that were once considered seasonal are available on a year-round basis.
- Increased consumption of exotic foods whose safety hazards are not well understood.

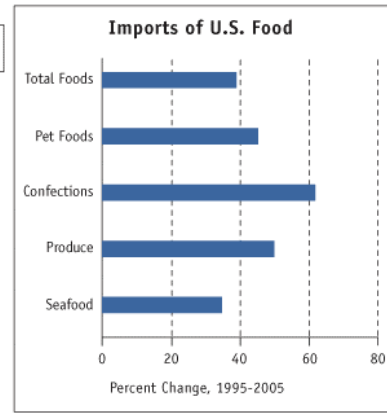
Sources: U.S. Census Bureau and USDA Economic Research Service

Global Food Supply

- There have been dramatic changes in the volume, variety, and complexity of FDA-regulated products arriving at U.S. ports. The United States trades with over 150 countries/ territories with products coming into over 300 U.S. ports. In the last decade, the number of food entry lines[4] has tripled. According to the USDA Economic Research Service, approximately 15 percent of the overall U.S. food supply by volume is imported. However, in certain food categories a much higher percentage is imported. For example, approximately 60 percent of fresh fruits and vegetables consumed in the U.S. are imported, which fills the gap when U.S. domestic production is inadequate or out of season (e.g., bananas, tropical fruits, etc.). Imports of seafood rose from less than 50 percent of U.S. seafood consumption in 1980 to more than 75 percent today.

[4] An entry line means each portion of an import shipment that is listed as a separate item on an entry document. Items in an import entry having different tariff descriptions must be listed separately.





The type of imported foods is changing. In the past, the bulk of FDA-regulated imports consisted of unprocessed food ingredients with subsequent processing of those ingredients covered by FDA domestic regulatory oversight. Today, foods that are inherently more likely to pose risks, such as ready-to-eat food products, fresh produce and seafood, account for an increasing proportion of imported foods.

This is not to suggest that food imported into the United States, as a whole, poses a greater food safety risk than domestically produced food. But increases in the volume and complexity of imported foods have taxed the limits of FDA's approach to handling imports. Currently, data on 100 percent of the shipments are submitted through the electronic systems of the U.S. Customs and Border Protection (CBP) and FDA. The data are screened electronically to determine whether the food appears to present a significant risk to public health. Some foods are then inspected physically based on perceived risk. Food products of greater concern are physically inspected more frequently.

Currently, FDA often has very limited information regarding conditions under which most food is produced in foreign countries. While many foreign countries have well-developed regulatory systems to ensure food safety, other countries have systems that are less well-developed and that may not be able to ensure food safety to the same degree.

Growth in Foreign Manufacturers Exporting Low-Acid Canned Foods

	1973	2004
Domestic LACF/AF Firms	742	1,300
Foreign LACF/AF Firms	34	6,700

One example of how the source of food has changed is in the import of canned or sealed fruits, vegetables, fish, and other products (collectively known as low-acid canned food/acidified food or LACF/AF). As the table shows, the number of domestic firms nearly doubled between 1973 and 2004. By contrast, there was close to a 200-fold increase in the number of foreign firms manufacturing these products for importation into the United States during the same period.

New Threats

New Foodborne Pathogens

Symptoms of foodborne illness range from mild stomach discomfort to life-threatening neurologic, liver, and kidney syndromes. In 1999, the CDC estimated that there were around 76 million cases per year of illness from foodborne agents, with 325,000 hospitalizations and 5,000 deaths in the United States each year. These data do not identify exactly how many are spread via foods (as opposed to person-to person contact or by some other means) nor do they indicate how the food became contaminated. However, we know that the most severe cases tend to occur in people who are very young, very old, or who have compromised immune systems.

Foodborne illnesses are caused by more than 200 different foodborne pathogens (agents that can cause illness) of which we are currently aware. These include viruses, bacteria, parasites, and toxins, plus a vast number of potential chemical contaminants and metals. The variety of agents associated with foodborne illness has steadily grown over the last few decades, and there is every probability that this list will continue to increase.

One example of a newer foodborne pathogen is *Enterobacter sakazakii*, which can cause serious illness such as sepsis (blood infection) and meningitis (inflammation of the membrane surrounding the brain and spinal cord). In 2002, FDA, working with CDC, discovered and subsequently alerted

health care professionals to clusters of *E. sakazakii* infections reported in a variety of locations among hospitalized newborns, particularly premature or other immuno-compromised infants who were fed powdered infant formulas.

The emergence of new foodborne pathogens requires updated technologies that can detect the presence of new agents in a variety of foods. Addressing these emerging hazards requires cooperation among industry, academia, and government to share information and establish testing protocols.

Pathogens Newly Associated with Foodborne Illness Since the Mid-1970s

- *Campylobacter jejuni*
- *Cryptosporidium parvum*
- Shiga toxin-producing *E. coli*
- Noroviruses
- *Salmonella* Typhimurium DT104
- *Vibrio cholerae* O139
- *Vibrio parahaemolyticus*
- *Campylobacter fetus*
- *Cyclospora cayetanesis*
- *Listeria monocytogenes*
- *Salmonella* Enteritidis
- *Vibrio vulnificus*
- *Yersinia enterocolitica*
- *Enterobacter sakazakii*

Intentional Contamination

We must also consider food as a potential vehicle for intentional contamination. Such intentional contamination of food could result in human or animal illnesses and deaths, as well as economic losses.

The stark possibilities are suggested by the recent incident in which vegetable protein products, which were represented as wheat gluten and rice protein concentrate, were contaminated with melamine and melamine analogues. Though not considered an act of terrorism, the incident appeared to be a deliberate act for economic gain. It resulted in the sickness and deaths of cats and dogs, the recall of hundreds of brands of pet food products, state quarantine or voluntary holds on livestock that consumed suspect animal feed, and concern regarding the possible associated human health risks.

FDA has no reason to believe any physical harm was intended, but the melamine event indicates the danger of attempts to deliberately compromise the U.S. food system.

Communication

Effective communication requires active collection and use of incoming information and timely communication to external groups. FDA uses the information it receives to make appropriate decisions about food safety. FDA also shares information and advice with consumers, news media, industry, and state, local, and foreign agencies. Providing information that is timely, useful, and easy to understand is critical.

FDA, states, and industry receive food safety information in various ways. Signals of potential problems come in the form of consumer complaints, inspection data, positive test results, adverse event reports, and other reports of illness. FDA is committed to improving information flow to improve detection and response to signs of trouble.

FDA collects data from several sources. Data from the testing of food, inspections, and reports of illnesses are collected in federal and state systems. Data from foodborne illness and pathogen identification are entered into systems maintained by the CDC, the lead federal agency for conducting disease surveillance and outbreak investigations. Data from imports are entered into specific import systems. Currently, states conduct 10,000 inspections under contract to FDA and another 40,000 inspections under state law. These inspections include the collection of 300,000 food samples each year.

Enabling FDA's information systems to communicate more effectively with internal and external data sources is essential. This will increase productivity of FDA staff and streamline response times during food emergencies. The overall success of the Plan depends on improving the integration and analysis of the vast amount of information collected.

Just as consumers and businesses have important roles to play in providing information to FDA, the FDA plans to improve communication with stakeholders during food emergencies. In the 2007 outbreak involving chili sauce contaminated with *Clostridium botulinum*, the recalled product remained on the shelves of small retailers weeks after the recall announcement. Improving outreach to all segments of the food industry will ensure that harmful products are removed from the market quickly.

IV. AN OVERVIEW OF THE APPROACH

Greater attention to prevention requires closer interaction with growers, manufacturers, distributors, retailers, food service providers, and importers.

Core Elements

While American consumers enjoy one of the safest food supplies in the world, growing challenges require a new approach to food protection at FDA—an increased emphasis on prevention.

Recent outbreaks linked to fresh produce, peanut butter, and pet foods show how FDA responds quickly to contain food safety problems. While this level of response needs to be maintained and even enhanced, there is also a need to focus more on building safety into products right from the start to meet the challenges of today. The FDA will work with the private sector to build on the actions of the food industry to ensure product safety. Building safety into products is described in one word: prevention.

It's critical to build safety into products right from the start.

This shift to an increased emphasis on prevention is at the core of FDA's Food Protection Plan, and will be evident immediately as the FDA begins an industry-wide effort to focus attention on prevention, from general best practices for all foods to the possibility of additional measures for high-risk foods. **Prevention** needs to be augmented by targeted **intervention** that focuses inspection and testing on the areas of greatest risk. This will reduce the likelihood that contaminated products will reach consumers. However, even the best system in the world cannot prevent all incidents of foodborne illness. Along with prevention and intervention, faster and more focused **response** is needed once a problem is detected.

- **Prevention—Build safety in from the start.**

FDA must strategically place greater emphasis on preventive measures for food safety and food defense. These measures will promote improved food protection capabilities throughout the food supply chain. This will require close interaction with growers, manufacturers, distributors, retailers and food service providers, and importers. These partners have the ability to implement preventive approaches and to require them of their suppliers. FDA will continue to work with industry, state, local, and foreign governments to further develop the tools and science needed to identify vulnerabilities and determine the most effective approaches. With regard to imports, FDA will also work with foreign governments, which have a greater ability to oversee manufacturers within their borders to ensure compliance with safety standards.

- **Intervention—Verify prevention and intervene when risks are identified.**

FDA, along with other federal agencies and state, local, and foreign governments, must undertake interventions in a coordinated and risk-based manner. Interventions, in the form of targeted inspections and testing, verify that preventive controls are working and that resources are being applied to the areas of greatest concern—either when the product is at the manufacturing facility, on its way to stores, or at a port of entry. Successful intervention will also require enhanced risk analysis, along with new detection technology to allow for faster analysis of samples. A successful and fully integrated food protection system will identify signals that indicate the need for intervention. Such signals may be a positive test for a harm-

ful contaminant following an inspection, an industry report, a consumer complaint, or a full blown outbreak.

- **Response—Respond rapidly and appropriately.**

Working with its food safety partners, FDA will improve its response system to more rapidly react when signals indicate either potential or actual harm to consumers. As part of an improved response system, the FDA will develop faster and more comprehensive ways to communicate with consumers and others during a food-related emergency.

Cross-Cutting Principles

Principles of the Food Protection Plan

- Focus on risks over a product's life cycle from production to consumption.
- Target resources to achieve maximum risk reduction.
- Address both unintentional and deliberate contamination.
- Use science and modern technology systems.

Four important cross-cutting principles will allow a comprehensive food protection approach along the entire production chain.

1. Focus on risks over a product's life cycle from production to consumption.

Comprehensive food protection requires considering the safety and defense risks associated with foods through their whole life cycle whether domestically produced or imported. Consideration must be given to areas that are potentially vulnerable to both unintentional and intentional contamination such as the point at which food is grown or produced, every processing or manufacturing step, points involved in distribution, transport, and warehousing, as well as all the points at the retail level through distribution to consumers. It is also important to consider the role that consumers play in safeguarding food once it is in their homes.

Consideration of the risks throughout a product's life cycle is a significant shift in the Agency's approach not only for domestic products but for imported foods too. A focus on prevention at the point of manufacture

based on risk will provide data to strengthen risk-based inspections domestically, at the border, and overseas. In particular, FDA plans to work with foreign governments and federal partners to ensure that foods produced in foreign facilities meet U.S. safety requirements. Risk-based targeted inspections at the border will serve as a second layer of protection, rather than the principal one.

2. Target resources to achieve maximum risk reduction.

A comprehensive risk-based approach must consider the many variables that define risk. Such variables include:

- the possibility that consuming a particular food will result in a foodborne illness due to contamination of the product, which depends on such factors as the number of microbes present or the level of a chemical or toxin present, the susceptibility of the person to the contaminating agent, and whether the food was properly handled and cooked;
- the severity of that illness, should it occur;
- the point in the production cycle where contamination is most likely to occur; and
- the likelihood of contamination and steps taken during the production cycle to reduce the possibility of contamination.

Foodborne illnesses range from distressing, but tolerable, symptoms to critical and life-threatening health problems. Illness due to *E. coli* O157:H7 can lead to kidney failure. Exposure to botulinum toxin can cause paralysis. Other, less severe illnesses may cause diarrhea and vomiting.

Some foods, such as those grown in the ground, may have little or no processing before they arrive in consumers' homes. Other foods are cooked to high temperatures (e.g., canned goods). Examining all aspects of the product life cycle helps define the areas of greatest risk. Implementation of the Food Protection Plan will involve acquiring the data to best address risk, or, where the data is unavailable, working with appropriate partners to determine those risks.

Those at highest risk for serious foodborne illness include young children, older adults, pregnant women, and people with weakened immune systems.

3. Address both unintentional and deliberate contamination.

Food safety, which traditionally refers to unintentional contamination, has been a cornerstone of public health for many years. The idea that someone may use food as a vehicle to deliberately cause harm is a risk that must be addressed. There is a heightened awareness of terrorism as a real possibility that could cause a major public health crisis. To this end, FDA has devoted significant efforts over the last six years to address food defense—defending the food supply against deliberate attack.

Whether dealing with intentional or unintentional contamination, the same regulatory experts, resources, and industry partners are involved. The best way to handle food safety and food defense is to develop approaches that appropriately address both. Although there are differences in how these events are addressed, there are also many overlaps and parallels between the two. For example, the concepts of prevention, intervention, and response apply equally to both.

4. Use science and modern technology systems.

A successful plan for food protection is based on science. FDA's Food Protection Plan emphasizes the need to know the science underpinning how and where food becomes contaminated and the associated risks. The Plan also highlights the use of science to determine optimal interventions to reduce the likelihood of contamination. If contamination does occur, then the priority is to minimize the likelihood that it will cause significant harm. For example, successful intervention relies in large part on the science of epidemiology to understand which foods pose risks and the science of modern detection methods to identify harmful agents quickly.

The Food Protection Plan also highlights the need to further integrate information systems. Too often, sophisticated data systems lack the ability to share information. A priority in the Plan involves creating interoperable data systems, along with making current systems more interoperable, to allow for the exchange of product information along the whole life cycle. The goal is to make the most of important data from all relevant systems, and to obtain easier access to critical information.

V. THE INTEGRATED PLAN

The Food Protection Plan is based on three integrated elements of protection:

- **Preventing** foodborne illnesses in the first place;
- **Intervening** with risk-based FDA actions at critical points in the food supply chain; and
- **Responding** rapidly when contaminated food or feed is detected.

Implementation of the elements will begin immediately, be phased in over time, and be integrated with the Administration's Import Safety Action Plan. All of the elements build on existing partnerships and direct resources to the areas of greatest risk.

But the FDA cannot take some key actions without new legislative authority. We summarize below in each element the new authorities needed to fully implement the Plan and strengthen our ability to protect Americans. We look forward to working productively with Congress to ensure understanding of the design of and need for these authorities.

CORE ELEMENT #1: PREVENTION

Prevention is the first essential step for an effective, proactive food safety and defense plan. FDA's Plan implements three key prevention steps, which will move forward concurrently. The prevention steps are risk-based and will be implemented as appropriate to particular segments of the industry, taking into account that some foods are inherently safer than others.

The Plan's Key Prevention Steps

- **Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses**
- **Identify Food Vulnerabilities and Assess Risks**
- **Expand the Understanding and Use of Effective Mitigation Measures**

FDA designed its Plan for the full life cycle of food—from production to consumption, whether it be domestic or imported. The prevention elements of the Plan emphasize the importance for FDA and corporations to work collaboratively to prevent food problems from occurring.

This will be accomplished through a comprehensive review of food supply vulnerabilities. FDA will work with industry and other stakeholders to develop effective tools and science to head off outbreaks of foodborne illness caused by unintentional and intentional factors.

Some examples of enhanced corporate responsibility might include:

- evaluating safety and security vulnerabilities and possible impacts
- when appropriate, implementing preventive measures—both required and voluntary—to ensure that food is produced safely and securely
- developing a contingency plan to aid in a response in the event of contamination

The Food Protection Plan builds on partnerships and directs resources to the areas of greatest risk.

1.1 PROMOTE INCREASED CORPORATE RESPONSIBILITY TO PREVENT FOODBORNE ILLNESSES

STRENGTHEN FDA ACTIONS

- Meet with states and consumer groups to solicit their input on implementing preventive approaches to protect the food supply.
- Meet with food industry representatives to strengthen science-based voluntary prevention efforts, including developing best business practices and food safety guidelines.
- Develop written food protection guidelines for industry to a) develop food protection plans for produce and other food products, and b) implement other measures to promote corporate responsibility.
- Issue in Spring 2008, a final regulation requiring measures to prevent *salmonella* in shell eggs and resulting illnesses.
- Meet with foreign governments to share results of domestic prevention efforts and develop approaches for improving food safety at the source.
- Provide foreign countries with technical assistance so that they can enhance their regulatory systems.
- Analyze food import trend data and integrate it into a risk-based approach that focuses inspection resources on those imports that pose the greatest risk.
- Focus foreign inspections on high-risk firms and products.
- Improve FDA's presence overseas.

ADDITIONAL LEGISLATIVE AUTHORITY NEEDED

Allow FDA to Require Preventive Controls Against Intentional Adulteration by Terrorists or Criminals at Points of High Vulnerability in the Food Chain

The FDA requests authority to require entities in the food supply chain to implement measures *solely* intended to protect against the intentional adulteration of food by terrorists or criminals. This authority would allow FDA to issue regulations requiring companies to implement practical food defense measures at specific points in the food supply chain where intentional contamination has the greatest potential to cause serious harm, such as requiring locks on tanker trucks transporting food. The specific points would be determined using vulnerability assessments such as CARVER+Shock,[1] and the authority would only apply to food in bulk or batch form, prior to being packaged, which have clearly demonstrated vulnerabilities (e.g., short shelf life), and where it would affect multiple servings and there is a high likelihood of serious adverse health consequences or death from intentional adulteration. These regulations will be developed taking into account the best available understanding of the uncertainties, risks, costs, and benefits associated with alternative options. The requirement would utilize industry best practices and would not apply to raw produce or food on farms, except for milk. FDA also proposes that firms be extended an affirmative defense in civil litigation if they comply with these controls.

Authorize FDA to Issue Additional Preventive Controls for High-Risk Foods

The FDA requests explicit authority to issue regulations requiring specific types of foods (those that have been associated with repeated instances of serious health problems or death to humans or animals from unintentional contamination) be prepared, packed, and held under a system of preventive food safety controls. Such authority would strengthen the FDA's ability to require manufacturers to implement risk-based Hazard Analysis and Critical Control Point (HACCP) or equivalent processes to reduce foodborne illnesses from high-risk foods.

Require Food Facilities to Renew Their FDA Registrations Every Two Years, and Allow FDA to Modify the Registration Categories

FDA requests statutory changes that would require facilities to register every two years and authorize the FDA to establish food categories within the registration system. These categories would allow FDA to tailor registration categories based on up-to-date food safety information. Under current law, FDA must use preexisting food categories that were not designed for registration purposes and therefore are of limited usefulness for evaluating potential threats to food protection. This change would ensure accurate, up-to-date registration data from facilities. Facilities whose registration remains unchanged would be able to file a simplified renewal registration or affirmation to that effect.

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[1]The CARVER+Shock model, explained in detail at http://www.cfsan.fda.gov/~dms/vltcarv.html), stands for Criticality, Accessibility, Recuperability, Vulnerability, Effect, and Recognizability, plus Shock. It is available as a software tool to evaluate the potential vulnerabilities of farm-to-table supply chains of various food commodities, as well as individual facilities or processes.

WHY THESE ACTIONS ARE IMPORTANT AND WHAT THEY WILL ACCOMPLISH

Those with the biggest stake in food safety, after the consumers who eat the food, are the people and companies who grow, process, and sell food. Their livelihood depends entirely on the confidence of their customers. A poor reputation for proper food handling can drive a company to bankruptcy. Promoting increased corporate responsibility is key in shifting FDA's food protection effort to a proactive rather than a reactive one. The FDA will seek partnerships with industry to enhance consumer confidence. FDA will continue to work with industry in a) developing food protection plans that address safety and defense vulnerabilities, b) implementing prevention steps, and c) developing contingency plans to improve response to an outbreak of foodborne illness.

The FDA will primarily focus on promoting the use of risk-based, preventive systems that companies can apply at all levels of food production and processing, when appropriate. Voluntary approaches may be as basic as good manufacturing practices to ensure proper equipment sanitation and employee safety training. Potentially high-hazard food categories may require additional control measures. FDA will work with industry, con-

sumer, and federal, state, local, and international partners to help model and promote preventive controls based on best industry practices.

FDA plans to acquire additional data to develop a better understanding of foreign country practices for food and feed. This may include the examination of best practices around the food safety control systems of other countries as well as increased understanding of the difficulties faced in implementing food protection measures. FDA will also seek to share U.S. food safety and defense best practices with foreign governments and provide technical assistance, when possible, to those countries exporting food products to the U.S. so they can enhance their regulatory systems. As part of its review of foreign systems and products, the Agency will analyze food import trend data and integrate it into a risk-based approach that focuses inspection resources on those imports that pose the greatest risk. This approach will also focus foreign inspections on high-risk firms. In the near term, a special emphasis will be placed on firms located in countries where imports into the United States have been refused repeatedly and import violations have threatened the health of U.S. consumers.

FDA's current and planned actions, along with the proposed legislative changes, would:

- Build safety and defense into the full food product life cycle—from production to consumption.
- Support work with industry, and state, local, and foreign governments to understand industry best practices and identify how and where preventive controls would work best.
- Promote the adoption of voluntary preventive controls throughout the food supply chain.
- Enhance relationships with trading partners and improve FDA's presence abroad.

1.2 IDENTIFY FOOD VULNERABILITIES AND ASSESS RISKS

STRENGTHEN FDA ACTIONS

- Work with the food industry, consumer groups, and federal, state, local and international partners to generate the additional data needed to strengthen our understanding of food safety and food defense risks and vulnerabilities.
- Use enhanced modeling capability, scientific data, and technical expertise to evaluate and prioritize the relative risks of specific food and animal feed agents that may be harmful.
- Establish a risk-based process to continuously evaluate which FDA-regulated products cause the greatest burden of foodborne disease.
- Work with CDC to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated.

ADDITIONAL LEGISLATIVE AUTHORITY NEEDED

None.

WHY THESE ACTIONS ARE IMPORTANT AND WHAT THEY WILL ACCOMPLISH

These FDA actions provide important tools to facilitate increased corporate responsibility to prevent food contamination. These actions also address the need for additional information to better understand food safety and defense vulnerabilities and possible impacts. FDA will continue its work in this area and further engage industry and other outside groups to identify and target the greatest risks.

FDA actions will include gathering data for risk assessments and to conduct risk evaluations of commodity-agent combinations and relative risk ranking of commodities. A comprehensive, risk-based approach allows the FDA to maximize the effectiveness of its available resources by focusing on food products that have the potential to pose the greatest risk to human and animal health.

By analyzing data collected throughout the food product life cycle, we are better able to detect risks posed by food products. We are also better able to recognize key junctures where timely intervention can reduce or avoid those risks. Working with CDC, FDA will also build the capacity to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated.

Once established and emerging risks have been identified, assessed, and ranked, we can more effectively allocate our available resources to manage these risks as addressed below.

FDA's current and planned actions would:

- Strengthen the FDA's risk assessment capabilities and capacity to provide risk evaluations efficiently and rapidly.
- Advance collaborative work with CDC, USDA, and other federal, state and local agencies to understand attribution data on the food commodities that cause foodborne illnesses.

1.3 EXPAND THE UNDERSTANDING AND USE OF EFFECTIVE MITIGATION MEASURES

STRENGTHEN FDA ACTIONS

- Focusing on higher-risk foods, develop and implement a basic research plan on sources of contamination, modes of spreading and best methods to prevent contamination.
- Research, evaluate, and develop new methods to detect food contaminants.
- Encourage outside development of new contamination detection and prevention technologies.
- Develop Web sites and other platforms for disseminating research results and new steps industry can use to address vulnerabilities.

ADDITIONAL LEGISLATIVE AUTHORITY NEEDED

None.

WHY THESE ACTIONS ARE IMPORTANT AND WHAT THEY WILL ACCOMPLISH

Building on risk assessments, FDA will initiate basic research to enhance our understanding of sources of contamination, modes of spreading, and how best to prevent contamination. This information in turn will inform FDA's efforts above to promote increased corporate responsibility to implement effective preventive steps.

Focusing on higher-risk foods, FDA—working with other agencies—will undertake basic research and leverage relationships with outside organizations. The FDA will also research, evaluate, and develop new methods to detect contaminants in foods, and seek to facilitate new technologies that enhance food safety.

FDA's current and planned actions would:

- Initiate risk-driven research about sources, spread and prevention of contamination.
- Develop new mitigation tools and implement appropriate risk management strategies.

CORE ELEMENT #2: INTERVENTION

Because no plan will prevent 100 percent of food contamination, we must have targeted, risk-based interventions to provide a second layer of protection. These interventions must ensure that the preventive measures called for are implemented correctly. These interventions must also identify contaminated food that either unintentionally or intentionally circumvent our prevention plan. The Plan includes three key intervention steps.

The Plan's Key Intervention Steps

- **Focus Inspections and Sampling Based on Risk**
- **Enhance Risk-Based Surveillance**
- **Improve the Detection of Food System "Signals" that Indicate Contamination**

These steps emphasize targeted interventions at the point of manufacture and during distribution. They allow FDA to safeguard domestic products while increasing protection against importation of unsafe food.

Using robust risk-based analysis, FDA will conduct high-priority inspections that rely on statistical sampling and advanced risk detection tools. The FDA will verify industry business practices across the food chain to ensure that effective preventive measures are in place. Gathering and analyzing test results, adverse event reports, consumer complaints, and other information will help the FDA track emerging food protection problems.

2.1 FOCUS INSPECTIONS AND SAMPLING BASED ON RISK

STRENGTHEN FDA ACTIONS

- Focus food and feed safety inspections and sampling based on risk.
- Identify, evaluate and, if appropriate, validate and implement innovative foodborne pathogen detection methods and tools capable of quickly and accurately detecting contaminants in foods, such as real-time diagnostic instruments and methods that allow for rapid, on-site analysis of a particular sample.
- Train FDA and state investigators on new, technically complex, and specialized food manufacturing processes, as determined by a risk-based needs assessment, and modern inspection strategies.
- Collaborate with foreign authorities to reduce potential risk of imported food.

ADDITIONAL LEGISLATIVE AUTHORITY NEEDED

Authorize FDA to Accredit Highly Qualified Third Parties for Voluntary Food Inspections

The universe of domestic and foreign food establishments subject to FDA inspection is immense and continuing to grow faster than the FDA's inspection resources. Even with the most sophisticated detection tools and laboratory capabilities, the FDA's inspection resources are finite. Therefore, legislation to authorize the FDA to accredit independent third parties, or to recognize entities that accredit, to evaluate compliance with FDA requirements would allow FDA to allocate inspection resources more effectively.

To establish such an accreditation program for voluntary food inspections, FDA would undertake a public process to determine best practices and solicit industry input in the design of the program. An FDA accreditation program would require FDA to accredit third-party organizations, or recognize an entity that accredits third parties. Third-party organizations could be, as appropriate, Federal departments and agencies, state and local government agencies, foreign government agencies, or private entities without financial conflicts of interest. FDA would also:

- Audit the work of these organizations to ensure that FDA requirements were consistently assessed;
- Review their inspection reports; and
- Provide ongoing training criteria to ensure they maintain their skills and knowledge, especially as technology and requirements change over time.

FDA would use information from these accredited third-party organizations in its decision making but not be bound by such information in determining compliance with FDA requirements. *Use of accredited third parties would be voluntary and might offer more in-depth review and possibly faster* review times and expedited entry for imported goods manufactured in facilities inspected by accredited third parties. Use of accredited third parties may also be taken into *consideration by the FDA when setting inspection and surveillance priorities.*

Require New Reinspection Fee From Facilities That Fail to Meet Current Good Manufacturing Practices (cGMPs)

As part of the 2008 budget process, the Administration proposed a new user fee requiring manufacturers and laboratories to pay the full costs of reinspections and associated follow-up work when FDA reinspects facilities due to failure to meet cGMPs or other FDA requirements. Where FDA identifies violations during an inspection or issues a warning letter, FDA conducts follow-up inspections to verify a firm's corrective action. The proposed reinspection fee ensures that facilities not complying with health and safety standards bear the cost of reinspection.

WHY THESE ACTIONS ARE IMPORTANT AND WHAT THEY WILL ACCOMPLISH

Effective FDA intervention means getting product risk information quickly to FDA investigators who oversee the regulated products, including a high volume of import entries. This information will allow the FDA to make better-informed decisions about what products should be examined more closely and tested. It also signals when to initiate further action such as additional surveillance or an enforcement action.

FDA will look to leverage the resources of outside parties to accomplish more in-depth review of food products. By improving product knowledge and communication with all of our partners, including foreign authorities and the import community, we also can identify lower-risk products requiring less FDA scrutiny at U.S. facilities and at the border. This would enable the FDA to shift more resources to evaluating more closely products that are more risky, less well known, or from unknown manufacturers.

Modern detection tools and methods are critical for effective inspections and sampling. Better detection tools will allow FDA and other partners involved in food testing to more quickly and accurately detect contaminants. Because of its relevant expertise and experience, the FDA has unique capabilities to develop these tools.

Such tools could include real-time diagnostic instruments and methods that allow for rapid, on-site analysis of a particular sample or entry, especially those that are considered high-risk. For example, rapid contamination detection technology could be expanded to cover new agents and new food types, such as produce and dairy products. This type of technology could reduce analysis time from days to minutes. Increasing the speed at which the FDA can detect problems will allow FDA to expedite import entry review decisions or provide critical health information to the public when a problem is identified.

In addition to modernizing detection tools using information technology, the FDA must modernize inspectional strategies. This means increasing the probability that investigators will observe and identify potential problems.

FDA's current and planned actions, along with the proposed legislative changes, would result in:

- Focused risk-based inspections and sampling across the food chain.
- Development of rapid detection and testing tools.
- Increased involvement of federal, state, local, and foreign governments, in coordination with other food safety partners.
- Greater product knowledge and oversight through the accreditation of independent third parties.
- Modernized inspectional strategies.

2.2 ENHANCE RISK-BASED SURVEILLANCE

STRENGTHEN FDA ACTIONS

- Further enhance FDA's ability to target imported foods for inspection based on risk and publish the *Prior Notice of Imported Foods* Final Rule in 2008 as part of Bioterrorism Act implementation.
- Conduct foreign food and animal feed inspections more efficiently using the tools designed to target high-risk firms.
- Use advanced screening technology at the border.
- Improve data quality and handling capacity for food imports.
- Enhance information sharing agreements with key foreign countries.

ADDITIONAL LEGISLATIVE AUTHORITY NEEDED

Authorize FDA to Require Electronic Import Certificates for Shipments of Designated High-Risk Products

For food imports, the burden falls primarily on FDA to inspect and detect contamination at the U.S. border. With the explosion in import volume, this burden has become a serious challenge. The FDA should have the option of moving the inspection of high-risk products of concern "upstream" by entering into agreements with the exporting country's regulatory authority for that authority (or an FDA-recognized third-party inspector) to certify each shipment or class of shipments for compliance with FDA's standards *prior* to shipment. FDA would apply this requirement for imported products that have been shown to pose a threat to public health for U.S. consumers and thus would be unlike other imports where there is no such showing of risk. Such import certificate programs would be used for designated products imported from countries with whom FDA has concluded an agreement on a certification program that provides a level of safety sufficient to meet HHS/FDA standards. FDA would implement the government-to-government agreement by requiring importers to provide certificates from either relevant government agencies or accredited third parties.

While FDA would retain the authority to verify the safety of imported products, this approach shares the burden of ensuring the safety of food products with the exporting country. Shipments that fail to meet requirements would be refused entry.

For such a system to be effective, FDA will have to establish an in-depth collaboration with the relevant foreign government authority to ensure that the standards, processes, and criteria the foreign authority or third party uses in certifying products are sufficient to ensure compliance with FDA food safety standards. The FDA will also have to take several steps to ensure a secure system that prevents counterfeiting of the certificates and takes into consideration transshipment of products as a way to avoid certification.

FDA would use non-discriminatory science and risk-based criteria to determine the focus of this proposed authority and would use the authority only to the extent necessary to protect human or animal life or health.

Require New Food and Animal Feed Export Certification Fee to Improve the Ability of U.S. Firms to Export Their Products

As part of the 2008 budget process, the Administration proposed a new export certification fee for the issuance of export certificates for foods and feeds to those situations where exportation is restricted without this type of certificate. Private sector exporters would bear the cost of the program, but would reap its benefits through the FDA's enhanced ability to facilitate product exports. Importantly, collection of these user fees will enable the FDA to issue certificates without redirecting resources from other critical food and animal feed safety programs devoted to protecting the public health. Such fees are currently collected by the FDA for export certificates for drugs and devices.

Provide Parity Between Domestic and Imported Foods if FDA Inspection Access is Delayed, Limited, or Denied

While FDA currently has the authority to obtain a warrant or initiate criminal proceedings if it is denied access to inspect facilities here in the United States, its ability, under the Federal Food, Drug, and Cosmetic Act, to enforce the inspection provisions for overseas sites is very limited. In particular, the FDA cannot refuse admission of food, even if its efforts to conduct a foreign inspection were unduly delayed, limited or denied at a facility where the product was manufactured, processed, packed or held. Having the authority to prevent entry of food from firms that fail to provide FDA access will enable the FDA to keep possibly unsafe food from entering U.S. markets. This authority provides strong motivation for firms to allow FDA to perform inspections, motivation similar to that provided to domestic firms. The authority would include several procedural safeguards, including an informal hearing if food is refused admission into the United States, such as is available for food that may be refused entry for other reasons.

WHY THESE ACTIONS ARE IMPORTANT AND WHAT THEY WILL ACCOMPLISH

FDA must prevent products that pose food safety and food defense threats from entering the United States. A targeted, risk-based approach to foreign product regulation is essential. Sampling the highest priority imports, especially those posing a significant public health threat, is critical and dependent on data related to the practices in the foreign facility. The activity will enhance FDA's import programs and focus these programs on the life cycle

of the imported product, through such means as enhanced use of information-sharing agreements with key foreign countries.

In addition, FDA will continue to look for enhanced ways to use risk-based screening technology to identify products that pose health risks at the border. For example, a screening technology prototype is currently being tested on imported seafood products in Los Angeles. If demonstrated successful, this technology could be extended to other imported products and ports, thus enhancing the FDA's ability to quickly screen products at the border.

FDA's current and planned actions, along with the proposed legislative changes, would:

- Better focus on the imported products' total life cycle.
- Improve data systems to monitor foreign-produced food products.

2.3 IMPROVE THE DETECTION OF FOOD SYSTEM "SIGNALS" THAT INDICATE CONTAMINATION

STRENGTHEN FDA ACTIONS

- Deploy new rapid screening tools and methods to identify pathogens and other contaminants.
- Improve FDA's adverse event and consumer complaint reporting systems, including capturing complaints made to food manufacturers and distributors.
- Work to create a *Reportable Food Registry* for reports of a determination that there is a reasonable probability that the use of or exposure to an article of food will cause serious harm or death to humans or animals [as defined in the 2007 Food and Drug Administration Amendments Act (FDAAA)]. Under FDAAA, industry is expected to report such situations to the FDA within 24 hours.
- Work to create an *Early Warning Surveillance and Notification System* to identify adulterated pet food products, outbreaks of pet illness and to provide notice to veterinarians and other stakeholders during pet food recalls (as defined in the 2007 Food and Drug Administration Amendments Act or FDAAA).

ADDITIONAL LEGISLATIVE AUTHORITY NEEDED

None.

WHY THESE ACTIONS ARE IMPORTANT AND WHAT THEY WILL ACCOMPLISH

FDA can better detect and more quickly identify risk "signals" in the food supply chain via two key approaches: 1) deploying new rapid screening tools and methods to identify pathogens and other contaminants; and 2) enhancing its ability to "map" or trace adverse events back to their causes (whether reported to FDA or the food manufacturer or distributor) by improving its adverse event and consumer complaint reporting systems. This additional information will serve as a supplemental warning indicator for trending emerging food protection problems.

To provide the information necessary to allow for early detection of, and intervention with, contaminated animal feed, FDA will develop a centralized database for veterinarians that captures data on food safety incidents and the causes of food-related illness. The FDA will populate the database with key information from the veterinary community, veterinary hospitals, and other private U.S. sources.

FDA's current and planned actions would identify:

- signals that may indicate a problem with food from routine testing, consumer complaints, industry reporting and documented illnesses.

CORE ELEMENT #3: RESPONSE

During the past year, FDA responded to food safety problems with contaminated spinach, lettuce, vegetable proteins, and peanut butter, among other foods. Whether contamination is unintentional or deliberate, there is a need to respond faster and communicate more effectively with consumers and other partners.

The following key response steps will increase FDA's ability to quickly identify food safety problems, better coordinate a rapid emergency response among FDA, state and local government response teams as appropriate,

and improve communications to the public, industry and other partners. This will better protect public health, help reduce the economic hardship affected industries face, and most importantly, maintain consumer confidence in the U.S. food supply following an incident.

The Plan's Key Response Steps

- **Improve Immediate Response**
- **Improve Risk Communications to the Public, Industry and Other Stakeholders**

3.1 IMPROVE IMMEDIATE RESPONSE

STRENGTHEN FDA ACTIONS

- Enhance the data collection, incident reporting and emergency response mapping capabilities of FDA's Emergency Operations Network Incident Management System.
- Work with stakeholders to develop an action plan for implementing more effective trace-back process improvements and technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients.
- Increase collaboration with foreign, federal, state, and local FDA partners to identify a contamination source, remove contaminated products, and implement corrective actions.
- Work with CDC and other selected federal, state, and local testing labs to communicate real-time testing results among FDA and lab members.

ADDITIONAL LEGISLATIVE AUTHORITY NEEDED

Empower FDA to Issue a Mandatory Recall of Food Products When Voluntary Recalls Are Not Effective

Although FDA has the authority to seize adulterated or misbranded food, this is not a practical option when contaminated product has already been distributed to hundreds or thousands of locations. And while the FDA has been able to accomplish most recalls through voluntary actions by product manufacturers or distributors, there are situations in which firms are unwilling to conduct a recall. In such situations FDA needs the ability to require a firm to conduct a recall to ensure the prompt and complete removal of food from distribution channels. This authority would be limited to foods that the Secretary has reason to believe are adulterated and present a threat of serious adverse health consequences or death. It would be imposed only if a firm refuses or unduly delays conducting a voluntary recall. An order to recall food could only be issued by the HHS Secretary, Deputy Secretary, or Commissioner of Food and Drugs, and would be accompanied by appropriate due process rights.

Provide FDA Enhanced Access to Food Records During Emergencies

During food-related emergencies, the FDA needs more complete and streamlined access to records necessary to identify the source of foodborne illness and take needed action. Improved access to information, including records related to an article of food or related articles of food that may present a threat, will enhance FDA's ability to identify problems, respond quickly and appropriately, and protect public health.

Currently, emergency access to records is limited to instances where, for an article of food, FDA has a reasonable belief that the food is adulterated and presents a threat of serious adverse health consequences or death. FDA proposes to expand access to records of *related* articles of food, such as food produced on the same manufacturing line. FDA also proposes, in food-related emergencies, to remove the adulteration requirement to allow its inspectors access to records in emergency situations where FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death. The recent melamine situation in which FDA had early clinical evidence that a specific food was causing illness in pets but did not have clear evidence of a specific adulteration is an example of such a scenario.

The records access would relate only to safety or security of the food and would not apply to records pertaining to recipes, financial data, pricing data, personnel data, research data, and sales data. The requirement would not impose any new recordkeeping burdens, and would maintain the current statutory exclusions for the records of farms and restaurants.

WHY THESE ACTIONS ARE IMPORTANT AND WHAT THEY WILL ACCOMPLISH

Recent food safety threats have demonstrated the importance of FDA's emergency response system. Contaminant tracing—or identifying where the contaminant has traveled within the food or feed supply—is critical in rapidly containing potential risks. Working with partners, FDA will pursue improvements to the current trace-back process and develop an action plan for implementing process improvements to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients.

As part of that effort, FDA will work with selected federal, state, and local testing labs to communicate real-time testing results among FDA and lab members.

FDA will also increase collaboration with foreign, state, and local regulators to identify the source of contamination, remove contaminated products as quickly as possible, and implement measures needed to prevent future contamination.

These improvements will allow FDA to quickly isolate problems, prevent contaminated products from reaching consumers, and ensure targeted recalls of products. Such steps aim to minimize the public health and economic impact from an outbreak.

FDA's current and planned actions, along with the proposed legislative changes, would:

- Enhance the nation's food emergency response system.
- Expand the FDA's trace-back process.
- Improve multi-partner collaborations, including with foreign regulators.

3.2 IMPROVE RISK COMMUNICATIONS TO THE PUBLIC, INDUSTRY AND OTHER STAKEHOLDERS

STRENGTHEN FDA ACTIONS

- Work with communications and media experts, including FDA's Risk Communication Advisory Committee, to design and conduct consumer communications and behavior response studies.
- Update the Food Protection Risk Communications Plan using the most effective strategies for sharing information with consumers.
- Build a consumer Web site to communicate relevant food protection information.
- In a food-related emergency, implement this communications plan, including utilizing all relevant media and technologies to reach consumers, retailers, industry, public health officials, and other stakeholders resulting in a better informed and thus more resilient population.

ADDITIONAL LEGISLATIVE AUTHORITY NEEDED

None.

WHY THESE ACTIONS ARE IMPORTANT AND WHAT THEY WILL ACCOMPLISH

Consumers protect themselves and their families from foodborne illness by responding promptly to FDA alerts. Important messages must be communicated clearly and through multiple forms of media to be effective, because different segments of the population use different technologies, ranging from television and newspapers to text messages and podcasts. In addition, major segments of the population do not use English as their primary language and rely on still other sources of information. This increases the challenge of implementing effective communication strategies.

Retailers, public health officials, industry and other key stakeholders likewise use an array of communications vehicles and sources. FDA's communication strategy during emergencies must use all such media to reach these different audiences and ensure that potentially harmful products are removed promptly.

FDA will enhance its risk communication program through aggressive, targeted food safety campaigns that disseminate clear and effective messages and regular updates through multiple venues to all targeted audiences. This program's designers will solicit input from the new FDA Risk Communications Advisory Committee, which is tasked with obtaining expert advice in the field of risk communications.

FDA's current and planned actions will enable the FDA to:

- Communicate more effectively with consumers.
- Provide more rapid alerts to all stakeholders, including retailers, industry, public health officials, and the consumers.

VI. ENHANCE INFORMATION TECHNOLOGY

In support of all three components of the Food Protection Plan, FDA plans to enhance its IT systems related to both domestic and imported foods. The focus will be to help the FDA more rapidly identify food importers, and maintain, update, and search records on food facilities and shipments more efficiently.

In particular, FDA will enhance collaboration with CBP on IT systems to more accurately identify firms involved in the food import supply chain during the import screening and review processes. These systems will allow for analysis of historical risk data about firms when making entry decisions for the firms' products.

A new systems approach can eliminate many problems with our current data. For example, assigning a unique identifier will eliminate duplicate records and make risk data about a firm easier to access. Policies for requiring the use of the new single national identifier will need to be established and agreed upon, recognizing the impact on industry worldwide.

Nearly all FDA business processes will benefit from more reliable and accurate information. Implementation of a new system will require a coordinated multi-agency effort that will benefit all federal agencies that process imported foods. CBP's existing data and ongoing activity will play a key role.

Finally, FDA will ensure that its infrastructure and disaster recovery system for IT systems and data are ready to deal with planned (maintenance and upgrades) and unplanned outages. This will provide the necessary support for import operations, which require the availability of multiple FDA systems around the clock. As an example, shipments arrive at U.S. ports day and night, and Prior Notice data are submitted at all hours. IT systems provide screening of the data as they are submitted, and Prior Notice Center (PNC) staff work around the clock to review the risk presented by shipments before their arrival. The PNC needs to review shipment data in as little as two hours from submission. Any interruption in the availability of the computer systems prevents the filing and timely review of information. This affects the flow of goods into the United States, and poses a safety risk to consumers.

An integrated, IT infrastructure—with data gathering, sorting, mining, and trending capability built into the systems—is critical to the success of FDA's food protection efforts.

VII. CONCLUSION

Ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission—to protect and promote public health. The FDA remains committed to working closely with its partners to protect the nation's food supply.

In the United States, market forces give companies a strong motivation to be vigilant and even innovative in ensuring food safety. The laws of regulation must encourage, not disrupt, these motivations. Rather than taking over responsibility from food companies, FDA wants to protect their flexibility to pursue it vigorously.

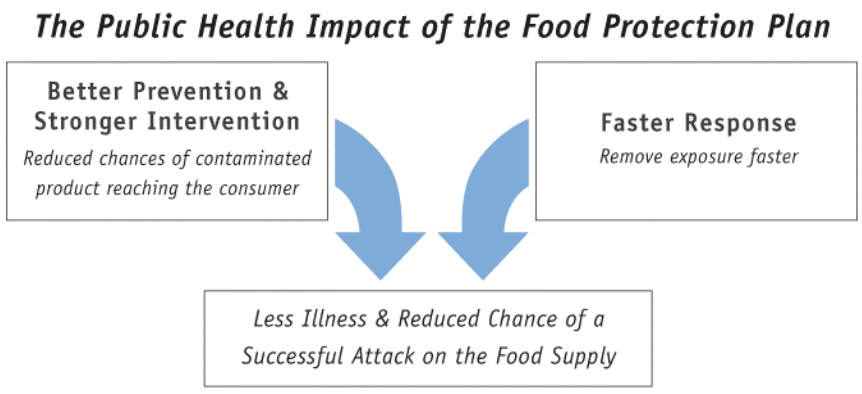
Although we have made progress, much remains to be done. Recent incidents of contaminated food and animal feed have highlighted the importance of a strong food protection system. Americans rightly expect to purchase food without having to worry about safety.

Rising food imports, increasing consumption of convenience foods, and new foodborne pathogens are among the challenges we face. To address these challenges, we must move toward a food safety and defense system that is more proactive and strategic.

FDA's Food Protection Plan contains three core elements—prevention, intervention, and response—with greater emphasis on preventive measures that keep contaminated food from ever reaching consumers. The Plan operates through a set of integrated strategies that address the product life cycle, a risk-based allocation of resources, the integration of food safety and food defense, and builds on a foundation of science and modern information systems.

FDA's Food Protection Plan complements the nation's strategic framework for import safety, which was released by the U.S. Department of Health and Human Services in September 2007. Both plans focus efforts on working smarter and better with importers, manufacturers, and other government agencies.

FDA will aggressively pursue the Food Protection Plan so that U.S. consumers can be assured that their food remains among the safest in the world.


The Public Health Impact of the Food Protection Plan
Better Prevention & Stronger Intervention
Reduced chances of contaminated product reaching the consumer
Faster Response
Remove exposure faster
Less Illness & Reduced Chance of a Successful Attack on the Food Supply

Appendix H

Glossary

Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) Agreement concerning the application of food safety and animal and plant health regulations as established by the World Trade Organization in 1995. Under these agreements, countries can set their own standards for safety as long as they are based on science.

Appropriate level of protection A way to express, on a population level, what level of risk a society is prepared to tolerate or considers to be achievable to protect human, animal, or plant life or health within its territory.

Biologics/biological products A wide range of products including vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. These products are regulated by the U.S. Food and Drug Administration (FDA).

Biomolecule Any molecule that is involved in the maintenance and metabolic processes of living organisms. Biomolecules include carbohydrate, lipid, protein, nucleic acid, and water molecules.

Biosecurity A strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) used in analyzing and managing risks in the sectors of food safety, animal life and health, and plant life and health, including associated environmental risk. Biosecurity covers the introduction of plant pests, animal pests and diseases,

and zoonoses; the introduction and release of genetically modified organisms and their products; and the introduction and management of invasive alien species and genotypes.

Bioterrorism The intentional release of viruses, bacteria, or other agents used to cause illness or death in people, animals, or plants.

Bottom-up data Data that model the path of pathogens from their source through the food supply chain to health outcomes.

CARVER+Shock A risk assessment tool that enables users to conduct assessments of the risks of, and vulnerabilities to, intentional contamination of a food production and distribution process. Its use by the food and agriculture sector and government agencies originates in its use by military special operations forces. The acronym stands for Criticality, Accessibility, Recuperability, Vulnerability, Effect, and Recognizability, which are the factors considered in assessing risk and vulnerability.

Class I recall A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

Classified information According to U.S. Code Title 18, any information or material that has been determined by the U.S. Government—pursuant to an executive order, statute, or regulation—to require protection against unauthorized disclosure for reasons of national security, and any restricted data, as defined in the Atomic Energy Act of 1954.

Cooperative Extension System A network of nationwide offices staffed by one or more experts who provide useful, practical, and research-based information to agricultural producers, small business owners, youth, consumers, and others in rural areas and communities of all sizes.

Decision analysis An applied branch of decision theory that offers individuals and organizations a methodology for making decisions; it also offers techniques for modeling decision problems mathematically and determining optimal decisions numerically. Decision models have the capacity for accepting and quantifying human subjective inputs, including judgments of experts and preferences of decision makers. Implementation of these models can take various forms ranging from simple paper-and-pencil procedures to sophisticated computer programs known as decision aids or decision systems.

Detention without physical examination (DWPE) An enforcement mechanism by which the FDA can detain shipments of imported products without having to actually analyze those shipments.

Electronic Foodborne Outbreak Reporting System (eFORS) A web-based reporting system used by the U.S. Centers for Disease Control and Prevention (CDC) to collect basic summary data from states on all reported foodborne illness outbreaks.

Electronic Laboratory Exchange Network (eLEXNET) A web-based information network that allows comparison of laboratory analysis findings and serves as a warning system for potentially hazardous foods.

Embargo authority When referring to food, the authority to issue and enforce a stop sale, stop use, removal, or hold for a food or processing equipment when there is probable cause to believe that it is dangerous, unwholesome, fraudulent, or insanitary.

Enterprise architecture A blueprint for organizational change and a foundation for information technology management, describing the current operation of an organization, how it intends to operate in the future, and how it plans to reach these goals.

Entry line Each portion of an import shipment that is listed as a separate item on an entry document. Items in an import entry having different tariff descriptions must be listed separately.

Epidemiology The study of the occurrence, distribution, and determining factors associated with the health and diseases of a population; the study of how often health events or diseases occur in different groups and why.

Etiology The cause or origin of a disease.

Food contaminant A substance that may be present in foods as a result of environmental contamination, cultivation practices, or production processes. If present above certain levels, these substances can pose a threat to human health. Some contaminants are formed naturally; carried over to food from water, air, or soil; or created as a by-product of the food production process itself.

Food defense A collective term used by agencies including the FDA, the U.S. Department of Agriculture (USDA), and the U.S. Department of Homeland Security to denote activities associated with protecting the nation's food

supply from deliberate or intentional acts of contamination or tampering. The term encompasses other similar verbiage, such as counterterrorism.

Food Protection Plan A plan issued by the FDA in 2007 to lay out the agency's integrated strategy for food safety and food defense. The three core elements of the plan are prevention, intervention, and response.

Food safety risk The likelihood of harm to health resulting from exposure to hazardous agents in the food supply.

Food Safety Working Group (FSWG) A group created by President Obama in 2009 to advise him on how to upgrade the U.S. food safety system. It is chaired by the Secretaries of the U.S. Department of Health and Human Services and USDA.

Foodborne illness An illness, usually either infectious or toxic in nature, caused by an agent that enters the body through the ingestion of food.

FoodNet A collaborative project of CDC, USDA, the FDA, and 10 Emerging Infections Program sites. It consists of active surveillance for foodborne illnesses and related epidemiologic studies designed to help public health officials better understand the epidemiology of foodborne illnesses in the United States.

FoodSHIELD A web-based platform whose mission is to support federal, state, and local regulatory agencies and laboratories in defending the food supply through web-based tools that enhance threat prevention and response, risk management, communication and asset coordination, and public education.

Functional genomics The study of genes, their resulting proteins, and the role played by the proteins in the body's biochemical processes.

Hazard A biological, chemical, or physical agent in or condition of food with the potential to cause an adverse health effect.

Hazard Analysis and Critical Control Points (HACCP) A production control system for the food industry. It is a process that identifies where potential contamination can occur (the critical control points) and strictly manages and monitors these points as a way of ensuring that the process is under control and that the safest possible product is being produced. HACCP is designed to prevent rather than detect potential hazards.

Information science The collection, organization, storage, retrieval, exchange, interpretation, and use of information.

iRISK A web-based risk-ranking prototype used to compare microbial and chemical hazards to support risk management decisions.

Iterative approach The repetition of a numerical or non-numerical process whereby the results from one or more stages are used to form the input to the next stage. Generally the recycling of the process continues until some preset goal is achieved, or the process result is constantly repeated.

Melamine A synthetic chemical with a variety of industrial uses, including the production of resins and foams, cleaning products, fertilizers, and pesticides. If ingested in sufficient amounts, melamine can result in kidney failure and death.

Memorandum of understanding (MOU) A document outlining the terms and details of an agreement between parties, including each party's requirements and responsibilities.

Metabolomics The science of measurement and analysis of metabolites, such as sugars and fats, in the cells of organisms at specific times and under specific conditions. The field of metabolomics overlaps with biology, chemistry, mathematics, and computer science.

Molecular surveillance Combines the methods of molecular biology with those of epidemiology in an effort to identify exposure to foodborne pathogens and subsequent disease. The use of molecular biology makes it possible to conduct pathogen surveillance at a genetic level and to determine the associations between contamination and disease when they are separated in space or time. PulseNet and VetNet are examples of molecular surveillance systems.

Multiple criteria decision analysis (MCDA) An approach used to systematically structure and model decision problems in multiple dimensions, with the goal of achieving a well-considered and -justified decision, and to provide a transparent explanation of the decision's basis.

Operational risk management A management approach used by the Departments of Defense and Transportation to identify risks and reduce them to an appropriate level, ensuring that benefits outweigh any risks.

OutbreakNet A network of foodborne disease epidemiologists from all states and CDC that works to improve communication among these partners.

Pathogen An agent causing disease or illness to its host, such as an organism or infectious particle capable of producing disease in another organism.

Phototoxicology Assessment of the toxic and/or carcinogenic potential of chemicals and agents when exposed to light or when applied to photo-treated skin.

Postmarket enforcement A process by which a regulatory agency determines the safety of a product only after it has entered into commerce. For example, manufacturers of foods and cosmetics in the United States generally do not have to submit evidence of safety to the FDA or obtain approval from the agency before putting their products on the market. If the FDA determines that a product is unsafe after it is on the market, the agency may take enforcement action against the product, but in any formal enforcement action, the burden is on the FDA to establish that the product in question is unsafe.

PREDICT (Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting) A screening tool that will automate decisions currently made by import entry reviewers by utilizing intelligence information from numerous sources. PREDICT will target higher-risk shipments for examination and will expedite the clearance of lower-risk cargo if accurate and complete data are provided by importers and entry filers.

Premarket Approval A process by which a regulatory agency determines whether a product is safe for the public before permitting it to enter into commerce. For example, manufacturers of food and color additives may put a product into commerce in the United States only if the FDA has already determined that the product in question is safe and has approved it for sale. In any formal enforcement action against an unapproved product, the FDA does not have to establish that the product in question is unsafe; rather, the agency will prevail simply by showing that the product has not received the requisite premarket approval.

Prior notice A requirement of the Bioterrorism Act of 2002 that the FDA receive advance notice of food to be imported into the United States before the food arrives.

Protected Critical Infrastructure Information (PCII) program A program established pursuant to the Critical Infrastructure Information Act of 2002 that provides a means for sharing private-sector information with the gov-

ernment while providing assurance that the information will be exempt from public disclosure and will be properly safeguarded.

Proteomics The large-scale study of proteins, particularly their structures and functions.

PulseNet A national network of federal, state, and local laboratories coordinated by CDC that uses standardized collection and sharing of pulsed-field gel electrophoresis (PFGE) molecular subtyping data to link isolates obtained from diverse sources. PulseNet allows scientists at public health laboratories throughout the country to rapidly compare the PFGE patterns of bacteria isolated from ill persons and determine whether those bacteria are similar.

Risk The possibility or probability of loss, injury, disadvantage, or destruction.

Risk analysis A transparent means by which to link the nature and extent of public health protection (risk reduction) achieved as a result of different risk management actions (or interventions). Risk analysis is composed of three activities: (1) risk assessment, (2) risk management, and (3) risk communication.

Risk assessment A process that provides information on the extent and characteristics of the risk attributed to a hazard.

Risk communication The exchange of information and opinions concerning risk and risk-related factors among risk assessors, risk managers, and other interested parties, stakeholders, and the public. In this report, risk communication is applicable when the message is directly related to specific risks (or benefits) of certain behaviors.

Risk management The activities undertaken to control risk.

Risk prioritization A multifactorial approach to ranking risks that considers a wide range of factors (in addition to public health) that might influence prioritization or decision making. Risk prioritization uses tools of both risk assessment and decision analysis to determine the importance of one risk over another, usually in relationship to mitigation. Risk prioritization is inherently used as a risk management tool.

Risk ranking A special form of risk assessment whose purpose is to compare hazards, commodities, or hazard–commodity pairs with respect to their degree of risk relative to one another.

Risk-based food safety system A systematic means by which to facilitate decision making to reduce public health risk in light of limited resources and additional factors that may be considered.

Sunshine laws State and federal statutes requiring that government meetings, decisions, and records be made available to the public.

Surveillance A key component of epidemiology, it can be defined as the ongoing collection, analysis, interpretation, and dissemination of health-related data. Surveillance is one of a number of methods used by epidemiologists to gather information on a disease.

Top-down data Surveillance-based data, such as epidemiological data on illnesses and deaths.

Toxicoinformatics Analysis and integration of genomic, transcriptomic, proteomic, and metabolomic databases with the objective of knowledge discovery and the elucidation of mechanisms of toxicity.

Traceability In the food arena, the ability to trace the history, application, or location of a food under consideration.

Trace-back/trace-forward activities In the food arena, activities performed to determine the origin (trace-back) or distribution (trace-forward) of a product, usually to identify contaminated food. The activities are conducted jointly with local health departments and appropriate federal agencies. They entail the review and analysis of records such as harvesting dates, specific field and product locations, number of packages within a lot, and packing and shipping dates.

User fee A charge for the use of a particular good or service, for example, an entrance fee to a state park or the rental of equipment at a pubic facility. Many government-operated facilities are financed by both tax revenues and user fees.

Viral communications/marketing Use of social networking to rapidly diffuse ideas, marketing campaigns, or other messages.

Zoonotic disease A disease of animals that may be transmitted to humans under natural conditions (e.g., brucellosis, rabies).

Appendix I

Acronyms and Abbreviations

ABI	Automated Broker Interface
ACS	Automated Commercial System
AF	acidified food
AFDO	Association of Food and Drug Officials
AFSS	Animal Feed Safety System
AIDS	acquired immune deficiency syndrome
ALERT	Assure, Look, Employees, Report, Threat
AMS	Agricultural Marketing Service (USDA)
APEC	Asia-Pacific Economic Cooperation
APFSL	Agricultural Products Food Safety Laboratory
APHIS	Animal and Plant Health Inspection Service (USDA)
APHL	Association of Public Health Laboratories
AQIS	Australian Quarantine and Inspection Service
ARS	Agricultural Research Service (USDA)
ASTHO	Association of State and Territorial Health Officials
AVMA	American Veterinary Medical Association
BATF	Bureau of Alcohol, Tobacco, and Firearms (USDOT)
BRC	British Research Consortium
BSE	bovine spongiform encephalopathy
BSL	biosafety level
CAERS	CFSAN Adverse Events Reporting System
CBP	U.S. Customs and Border Protection (DHS)
CDC	U.S. Centers for Disease Control and Prevention

CFI	Center for Foodborne Illness Research and Prevention
CFIA	Canadian Food Inspection Agency
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition (FDA)
CFU	colony forming units
CGMP	current good manufacturing practice
CHB	Customs House Broke
CIA	Central Intelligence Agency
CIFOR	Council to Improve Foodborne Outbreak Response
CIKR	Critical infrastructure and key resources
CRC	CFSAN Review Committee
CSPI	Center for Science in the Public Interest
CU	Consumers Union
CVM	Center for Veterinary Medicine (FDA)
DG SANCO	Directorate General for Health and Consumers (European Commission)
DHS	U.S. Department of Homeland Security
DLC	dioxin-like compound
DNA	deoxyribonucleic acid
DoC	U.S. Department of Commerce
DoD	U.S. Department of Defense
DoI	U.S. Department of the Interior
DOJ	U.S. Department of Justice
DVFA	Danish Veterinary and Food Administration
EFSA	European Food Safety Authority
EHR	electronic health record
EHS-NET	Environmental Health Specialists Network
eLEXNET	electronic Laboratory Exchange Network (FDA)
EPA	U.S. Environmental Protection Agency
Epi-X	Epidemic Information Exchange
ERS	Economic Research Service (USDA)
EU	European Union
FAO	Food and Agriculture Organization
FASCAT	Food and Agriculture Sector Criticality Assessment Tool
FASCC	Food and Agriculture Sector Coordinating Council
FBI	Federal Bureau of Investigation
FDA	U.S. Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FDCA	Federal Food, Drug, and Cosmetic Act
FEMA	Federal Emergency Management Agency (DHS)

FERN	Food Emergency Response Network
FMI	Food Marketing Institute
FMIA	Federal Meat Inspection Act
FNB	Food and Nutrition Board
FOIA	Freedom of Information Act
FoodNet	Foodborne Diseases Active Surveillance Network
FOUO	For Official Use Only
FPP	Food Protection Plan
FSA	Food Standards Agency (United Kingdom)
FSANZ	Food Standards Australia New Zealand
FSIC	Food Safety Information Council
FSII	Food Safety Information Infrastructure
FSIS	Food Safety and Inspection Service (USDA)
FSLC	Food Safety Leadership Council
FSQS	Food Safety and Quality Service
FSWG	Food Safety Working Group
FTC	Federal Trade Commission
FTE	full-time equivalent/employee
FVO	Food and Veterinary Office (European Union)
FWS	Fish and Wildlife Service (DoI)
FY	fiscal year
GAO	U.S. Government Accountability Office (previously U.S. General Accounting Office)
GAP	Good Agricultural Practice
GAqP	Good Aquacultural Practice
GATT	General Agreement on Tariffs and Trade
GCC	Government Coordinating Council
GC-MS	Gas chromatography-mass spectrometry
GFSI	Global Food Safety Initiative
GIP	Good Importer Practice
GIPSA	Grain Inspection, Packers, and Stockyards Administration (USDA)
GMA	Grocery Manufacturers Association
GMP	Good Manufacturing Practice
GPRA	Government Performance and Results Act
GRAS	generally recognized as safe
HACCP	Hazard Analysis and Critical Control Points
HC	Health Canada
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus

HSIN	Homeland Security Information Network
HSPD	Homeland Security Presidential Directive
IAC	Intertribal Agriculture Council
IEC	International Electrotechnical Commission
IFSS	Integrated Food Safety System
IFT	Institute of Food Technologists
IIT	Illinois Institute of Technology
IOM	Institute of Medicine
IRAC	Interagency Risk Assessment Consortium
IRB	Institutional Review Board
ISO	International Organization for Standardization
IT	information technology
JIFSAN	Joint Institute for Food Safety and Applied Nutrition
LACF	low-acid canned foods
LM	*Listeria monocytogenes*
MARCS	Mission Activity Reporting Compliance System
MCDA	multiple criteria decision analysis
MDP	Microbiological Data Program
MDVP	Methods Development and Validation Program
MHS	Meat Hygiene Service (United Kingdom Food Standards Agency)
MID	Manufacturer Identification
MOU	memorandum of understanding
NACCHO	National Association of County and City Health Officials
NAL	National Agricultural Library (USDA)
NARMS	National Antimicrobial Resistance Monitoring System
NASS	National Agricultural Statistics Service (USDA)
NCFPD	National Center for Food Protection and Defense (DHS)
NCFST	National Center for Food Safety and Technology
NCNPR	National Center for Natural Products Research
NCTR	National Center for Toxicological Research (FDA)
NEHA	National Environmental Health Association
NGO	nongovernmental organization
NIFA	National Institute of Food and Agriculture (USDA)
NIH	National Institutes of Health
NIMS	National Incident Management System
NIPP	National Infrastructure Protection Plan
NLEA	Nutrition Labeling and Education Act

NMFS	National Marine Fisheries Service (DoC)
NOAA	National Oceanic and Atmospheric Administration (DoC)
NORS	National Outbreak Reporting System
NRC	National Research Council or Nuclear Regulatory Commission
NRP	National Response Plan
NZFSA	New Zealand Food Safety Authority
OASIS	Operational and Administrative System for Import Support
OCI	Office of Criminal Investigations (FDA)
OCM	Office of Crisis Management (FDA)
OECA	Office of Enforcement and Compliance Assistance (EPA)
OHA	Office of Health Affairs (DHS)
OMB	Office of Management and Budget
OPA	Office of Public Affairs (FDA)
OPHEP	Office of Public Health Emergency Preparedness
OPPTS	Office of Prevention, Pesticides and Toxic Substances (EPA)
OR	Office of Research (CVM)
ORA	Office of Regulatory Affairs (FDA)
ORACBA	Office of Risk Assessment and Cost-Benefit Analysis (USDA)
ORAU	Office of Regulatory Affairs University
ORD	Office of Research and Development (EPA)
ORM	operational risk management
PART	Program Assessment Rating Tool
PCII	Protected Critical Infrastructure Information
PCR	polymerase chain reaction
PCT	Pesticide Coordination Team
PDP	Pesticide Data Program (USDA)
PFGE	pulsed-field gel electrophoresis
PFSE	Partnership for Food Safety Education
PN	prior notice
PNC	Prior Notice Center
PRA	Paperwork Reduction Act
PREDICT	Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting
PulseNet	National Molecular Subtyping Network for Foodborne Disease Surveillance
RACT	Risk Assessment Coordination Team
RCAC	Risk Communication Advisory Committee (FDA)

RIHSC	Research Involving Human Subjects Committee
RMF	risk management framework
SAHCDHA	serious adverse health consequences or death to humans or animals
SCC	Sector Coordinating Council
SEB	*Staphylococcal enterotoxin B*
SPPA	Strategic Partnership Program Agroterrorism
SPS	Sanitary and Phytosanitary
SQF	Safe Quality Food
SSA	Sector-Specific Agency
SSP	Sector-Specific Plan
TBT	Technical Barriers to Trade
TDS	Total Diet Study
UF	University of Florida
UK	United Kingdom
UMB	University of Maryland, Baltimore
USDA	U.S. Department of Agriculture
USDOT	U.S. Department of Treasury
WCFS	Western Center for Food Safety
WCL	Washington College of Law
WHO	World Health Organization
WIC	Special Supplemental Nutrition Program for Women, Infants, and Children
WIFSS	Western Institute for Food Safety and Security
WTO	World Trade Organization

Appendix J

Committee Member Biographical Sketches

ROBERT B. WALLACE, M.D. (*Chair*), is Irene Ensminger Stecher Professor of Epidemiology and Internal Medicine at the University of Iowa Colleges of Public Health and Medicine and Director of the University's Center on Aging. He has been a member of the U.S. Preventive Services Task Force and the National Advisory Council on Aging of the National Institutes of Health. He is a Member of the Institute of Medicine (IOM), past Chair of the IOM's Board on Health Promotion and Disease Prevention, and current Chair of the IOM's Board on the Health of Select Populations. His research interests are in clinical and population epidemiology and focus on the causes and prevention of disabling conditions of older persons. Dr. Wallace has had substantial experience in the conduct of both observational cohort studies of older persons and clinical trials, including preventive interventions related to fracture, cancer, coronary disease, and women's health. He is the site principal investigator for the Women's Health Initiative, a national intervention trial exploring the prevention of breast and colon cancer and coronary disease, and a co-principal investigator of the Health and Retirement Study, a national cohort study of the health and economic status of older Americans. He has been a collaborator in several international studies of the causes and prevention of chronic illness in older persons. Dr. Wallace received his B.S. and M.D. from Northwestern University and M.Sc. in epidemiology from the State University of New York at Buffalo.

DOUGLAS L. ARCHER, Ph.D., is Associate Dean for Research at the Institute of Food and Agricultural Sciences and a Professor in the Food Sci-

ence and Human Nutrition Department at the University of Florida (UF). He served as Chair of the department until 2001, when he stepped down to return to the faculty. Prior to his arrival at UF, Dr. Archer served as Deputy Director of the U.S. Food and Drug Administration's (FDA's) Center for Food Safety and Applied Nutrition (CFSAN), where he was charged with oversight of the research, regulatory, and policy activities of all food and cosmetic programs, including food additives, food labeling, special nutritionals, seafood, and cosmetics and colors. During his career with the FDA, Dr. Archer was a Commissioned Officer in the United States Public Health Service. He was appointed Assistant Surgeon General in 1990. He has received numerous awards, including three Meritorious Service Medals and the Distinguished Service Medal. His nongovernment awards include the J.C. Frazier Memorial Award from the University of Wisconsin in 1992 and the Ivan Parkin Lectureship in 2005 from the International Association for Food Protection. From 1984 until 1994, Dr. Archer served as Chairman of the Food and Agriculture Organization (FAO)/World Health Organization (WHO) Codex Alimentarius Committee on Food Hygiene, and since 1990, has been a member of the WHO Expert Advisory Panel on Food Safety. He is past U.S. Associate Editor for *Food Control* (and is currently an Editorial Board member) and member of the Advisory Board of the Academic Press Nutrition and Food Science Publications. He is a professional member of the Institute of Food Technologists (IFT) and serves on the Board of Directors of that organization. Dr. Archer is currently a member of the IFT Global Policy and Regulations Committee and is the subject expert for that committee on food hygiene. He has authored or co-authored more than 80 peer-reviewed scientific publications and given hundreds of presentations to scientific organizations, trade organizations, and consumer groups. Dr. Archer received a B.A. in zoology, an M.S. in bacteriology from the University of Maine, and a Ph.D. in microbiology from the University of Maryland.

KEITH C. BEHNKE, Ph.D., is Professor and Feed Technology Research Scientist in the Department of Grain Science and Industry at Kansas State University, where he has been a member of the faculty since 1977. He currently coordinates all feed-processing research and the production of all research feeds manufactured by the Department of Grain Science at Kansas State University. Dr. Behnke's research areas of interest are the effect of feed processing on animal and feed performance, the incorporation of feed additives into livestock feeds, and the utilization of food and nonfood coproducts in livestock feeds. Prior to his position at Kansas State University, he was Group Leader in Processing Research of the Food Division of Far Mar, Co., in Hutchison, Kansas. In 2007, Dr. Behnke was 1 of 15 invited attendees from around the world to the FAO/WHO Expert Meeting on Animal

Feed Impact on Food Safety. He is currently a member of several professional societies and associations, including the American Society of Animal Science, the Poultry Science Association, the American Feed Industry Association, and the Chinese Feed Manufacturing Association, of which he is an honorary member. Dr. Behnke served on the National Research Council's (NRC's) Committee on the Nutrient Requirements of Dogs and Cats. He received his B.S. in feed technology (1968), his M.S. in grain science (1973), and his Ph.D. in grain science (1975) from Kansas State University.

ANN BOSTROM, Ph.D., is Professor and Associate Dean of Research at the Evans School of the University of Washington, where she has been a member of the faculty since 2007. Her research focuses on risk perception, communication, and management and on environmental policy and decision making under uncertainty. Dr. Bostrom previously served on the faculty at the Georgia Institute of Technology from 1992 to 2007, serving most recently as Associate Dean for Research at the Ivan Allen College of Liberal Arts and Professor in the School of Public Policy. She co-directed the Decision Risk and Management Science Program at the National Science Foundation from 1999 to 2001. Dr. Bostrom is currently Associate Editor or Risk Communication Area Editor for *Risk Analysis*, the *Journal of Risk Research*, and *Human and Ecological Risk Assessment*. She has served on various science advisory and NRC and IOM committees, including the IOM Committee on Nutrient Relationships in Seafood: Selections to Balance Benefits and Risks and the NRC Committee on Review of the Tsunami Warning and Forecast System and Overview of the Nation's Tsunami Preparedness. She is a Fellow of the Society for Risk Analysis and the recipient of several awards and fellowships, including an American Statistical Association/National Science Foundation/Bureau of Labor Statistics Research Associateship for the 1991–1992 academic year and the 1997 Chauncey Starr award for a young risk analyst from the Society for Risk Analysis for her work on mental models of hazardous processes. Dr. Bostrom completed postdoctoral studies in engineering and public policy and her Ph.D. in public policy analysis at Carnegie Mellon University, and she holds an M.B.A. from Western Washington University and a B.A. in English from the University of Washington.

ROBERT E. BRACKETT, Ph.D., is Director and Vice President of National Center for Food Safety and Technology at Illinois Institute of Technology (IIT). Prior to his position at IIT, he was Senior Vice President and Chief Scientific and Regulatory Affairs Officer at the Grocery Manufacturers Association (GMA). As Chief Scientific and Regulatory Affairs Officer, Dr. Brackett oversaw all of the association's scientific and regulatory activity, including the operation of its in-house food safety laboratory. Prior to

GMA, he was Director of CFSAN. Dr. Brackett has served elected leadership positions in several professional associations and is a Fellow of the American Academy of Microbiology and the International Association for Food Protection. He serves on the Advisory Boards of the National Center for Food Protection and Defense, the National Center for Food Safety and Technology, Association of Analytical Comunities International, and the Food and Drug Law Institute. Dr. Brackett has won numerous awards, among them the CFSAN Leadership Award for his exceptional contribution in ensuring a "real world" perspective on the risk assessment of *Listeria monocytogenes* and the President's Appreciation Award, International Association for Food Protection, in July 2007. He has been a member of the IOM/Food and Nutrition Board (FNB) Food Forum. Dr. Brackett received his B.S. in bacteriology and his M.S. and Ph.D. in food microbiology, all from the University of Wisconsin.

JULIE A. CASWELL, Ph.D., is Professor and Chair of the Department of Resource Economics at the University of Massachusetts, Amherst. Her research interests include the operation of domestic and international food systems, analysis of food system efficiency, and evaluation of government policy as it affects systems operation and performance, with a particular focus on the economics of food quality, safety, and nutrition. Dr. Caswell has provided her expertise on food safety and labeling issues to the Organization for Economic Cooperation and Development and to FAO. She has held numerous senior positions with the Agricultural and Applied Economics Association and the Northeastern Agricultural and Resource Economics Association. Dr. Caswell has served on IOM committees including the Planning Committee on Future Trends in Food Safety: Changing Market Forces, Emerging Safety Issues, and Economic Impact (a workshop); the Committee on Implications of Dioxin in the Food Supply; and the Committee on Nutrient Relationships in Seafood: Selections to Balance Benefits and Risks. She is currently a member of the Food Forum. She held a Fulbright Distinguished Lectureship at the University of Tuscia in Viterbo, Italy, from April–June 2009. She received her Ph.D. in agricultural economics from the University of Wisconsin.

LEWIS A. GROSSMAN, Ph.D., J.D., is Professor of Law and Associate Dean for Scholarship at American University. He joined the faculty of Washington College of Law (WCL) at American University in 1997. He became Professor of Law in 2003 and Associate Dean for Scholarship in 2008. He teaches and specializes in food and drug law, civil procedure, and American legal history. Prior to joining the faculty of WCL, Dr. Grossman was an associate at the DC firm of Covington and Burling, where he is still employed on an "of counsel" basis and is a member of the food and drug

law practice group. Previously, he was clerk for Chief Judge Abner Mikva, U.S. Court of Appeals, D.C. Circuit. Dr. Grossman is co-author (with Peter Barton Hutt and Richard A. Merrill) of *Food and Drug Law: Cases and Materials*, 3rd ed. (Foundation Press, 2007). He is a member of the Food and Drug Law Institute, the American Society for Legal History, and the Supreme Court Historical Society. He has volunteered as a legal consultant for the IOM and NRC Committee on the Framework for Evaluating the Safety of Dietary Supplements. He earned his Ph.D. in history at Yale University, his J.D. at Harvard Law School, and his B.A. at Yale University.

LEE-ANN JAYKUS, Ph.D., is Professor in the Department of Food, Bioprocessing, and Nutritional Sciences and the Department of Microbiology at North Carolina State University. Her current research efforts are varied and include the following: development of molecular methods to detect foodborne pathogens (noroviruses, hepatitis A virus, and bacterial agents such as *Campylobacter* and *Salmonella*) in foods, including pre-analytical sample processing; investigation of persistence and transfer of pathogens in the food preparation environment; and the application of quantitative microbial risk assessment methods to food safety. Dr. Jaykus has collaborated on large, multi-institutional projects to investigate the prevalence and association of pathogens with domestic and imported fresh produce and to study the ecology of the pathogenic *Vibrio* species in molluscan shellfish originating from the Gulf of Mexico. Her professional memberships include the International Association for Food Protection (currently serving as President-Elect), the American Society for Microbiology, the IFT, the Council for Agricultural Science and Technology, and the Society for Risk Analysis. Dr. Jaykus recently completed a 6-year term as a member of the National Advisory Committee on Microbiological Criteria for Foods, and currently is a member of the NRC/IOM Standing Committee for the Review of Food Safety and Defense Risk Assessments, Analyses, and Data and the Committee for Review of the Food Safety and Inspection Service (FSIS) Risk-Based Approach to Public Health Attribution. She earned a Ph.D. in Environmental Sciences and Engineering from the University of North Carolina at Chapel Hill School of Public Health.

TIMOTHY F. JONES, M.D., is State Epidemiologist and Director of the FoodNet Program at the Tennessee Department of Health. In this position, he has been intimately involved in investigating foodborne disease outbreaks. Dr. Jones is nationally active in leading the FoodNet Outbreak Working Group, co-chairing the multiagency Council to Improve Foodborne Disease Outbreak Response, and serving as the liaison between the FDA and the Council of State and Territorial Epidemiologists. Formerly, he practiced medicine in Utah and then joined the U.S. Centers for Disease Control

and Prevention's (CDC's) Epidemic Intelligence Service in Tennessee. Dr. Jones has served as a consultant for WHO on foodborne disease issues. He has also been the Council of State and Territorial Epidemiologists's representative to the Association of State and Territorial Health Officials's Food Safety Committee and a participant in Trust for America's Health and Food Safety Research Consortium projects. Dr. Jones is an Associate Editor for the journal *Foodborne Pathogens and Disease*, and has produced over 100 publications and 110 posters and professional presentations. He obtained his M.D. from Stanford University and completed a residency in family medicine at Brown University.

BARBARA KOWALCYK, M.S., is Director of Food Safety at the Center for Foodborne Illness Research and Prevention (CFI). A biostatistician, she became involved in foodborne illness prevention in 2001 following the death of her 2½ year old son, Kevin, from complications due to an *E. coli* O157:H7 infection. Ms. Kowalcyk has volunteered extensively as a consumer advocate for food safety and co-founded CFI in 2006. In addition, she served on the U.S. Department of Agriculture's (USDA's) National Advisory Committee on Microbiological Criteria for Foods from 2005 to 2009 and serves on the Advisory Board for the Georgetown University Health Policy Institute's Produce Safety Project. Ms. Kowalcyk has given numerous presentations on food safety. In addition to her extensive experience in food safety advocacy, she has more than 10 years of experience as a biostatistician conducting clinical research in the pharmaceutical industry. She serves on the NRC Standing Committee on the Use of Public Health Data in FSIS Food Safety Programs. Ms. Kowalcyk earned her B.S. in mathematics from the University of Dayton and her M.S. in applied statistics from the University of Pittsburgh. She is currently pursuing a doctorate in environmental health with a focus in epidemiology/biostatistics at the University of Cincinnati and is a fellow in the Molecular Epidemiology in Children's Environmental Health Training Program.

J. GLENN MORRIS, Jr., M.D., M.P.H.&T.M., is Director of the Emerging Pathogens Institute at the University of Florida, Gainesville, and Professor of Medicine in the College of Medicine. Prior to assuming his current position, he served as Chairman of the Department of Epidemiology and Preventive Medicine at the University of Maryland School of Medicine, Baltimore (UMB), and interim Dean of the UMB School of Public Health. Dr. Morris was an Epidemic Intelligence Service officer at CDC, with responsibility for national foodborne disease surveillance. He played a key role in the development of the Pathogen Reduction/Hazard Analysis and Critical Control Points regulations at USDA/FSIS, where he also created and served as Director of the FSIS Epidemiology and Emergency Response Program. He was

instrumental in the creation of FoodNet while at USDA, and subsequently served as co-principal investigator of the Maryland FoodNet site. Dr. Morris maintains an active research program in the area of emerging pathogens and enteric diseases. He also has extensive experience in work with antimicrobial resistance and has served as a member of the National Advisory Committee on Microbiological Criteria for Food. Dr. Morris has authored more than 60 textbook chapters and symposium proceedings and more than 180 articles in peer-reviewed journals. His scholarly contributions were recognized by his election to the American Society for Clinical Investigation in 1996. He has served as a member or consultant on a series of National Academies expert committees dealing with food safety, including the Committee on the Public Health Risk Assessment of Poultry Inspection Programs (member), Committee on the Evaluation of Safety of Fishery Products (member), Committee on Evaluation of USDA Streamlined Inspection System for Cattle (consultant), Committee on Review of the Use of Scientific Criteria and Performance Standards for Safe Food (consultant), and Planning Committee on Foodborne Diseases and Public Health: An Iranian-American Workshop (member). He was also an advisor to the Subcommittee for the Review of FDA Science, FDA Science Board. Dr. Morris is currently a member of the FNB. He received his B.A. from Rice University in Houston and his M.D. and master's in public health and tropical medicine from Tulane University. His residency training in internal medicine was at the University of Texas Southwestern in Dallas and Emory University in Atlanta, with subspecialty training in infectious diseases at the University of Maryland.

MARTHA RHODES ROBERTS, Ph.D., is Special Assistant to the Director of the Florida Experiment Station and Dean for Research, UF, Institute of Food and Agricultural Sciences. She was formerly Deputy Commissioner of Agriculture at the Florida Department of Agriculture and Consumer Services and Assistant Commissioner of Agriculture (she was the first woman in the United States to hold this position). Dr. Roberts is a recipient of numerous awards, including the FDA Commissioner's Special Citation in May 2003 for outstanding leadership and cooperative support of joint regulatory responsibilities in advancing food safety and enhancing the public health mandate and the USDA Animal and Plant Health Inspection Service Administrator of the Year Award in 2003. She has received numerous awards from government and industry and serves on many committees regarding produce safety and agricultural and food policy. She was inducted into the Florida Agricultural Hall of Fame in 2003. Dr. Roberts' previous positions include Chairman of the 48-party Suwannee River Partnership; Co-chair of the Agriculture, Fisheries and Forestry Committee for the Mexico/U.S. Gulf of Mexico States Accord; President of the Association of Food and Drug Officials; Chairman of the Conference for Food Protection,

and Chair of Government Relations for IFT and Chair of the IFT Foundation. She served on advisory groups for the FDA (Microbiological Criteria for Foods, Food Advisory Committee), USDA, and other state and industry groups. Currently, Dr. Roberts also works as a private consultant in the food safety, government relations, and agricultural environmental areas and serves on the Farm Foundation Roundtable, Food Foresight food trend analysis group, and the Center for Produce Safety Executive Committee. She received her B.S. in Biology from North Georgia College and her M.S. and Ph.D. in microbiology from the University of Georgia, where she also completed postdoctoral studies in public health.

JOSEPH V. RODRICKS, Ph.D., is a founding principal of ENVIRON International, a technical consulting firm founded in 1982, and a Visiting Professor at the Johns Hopkins University School of Public Health. He is an internationally recognized expert in toxicology and risk analysis and in their uses in regulation, and he has consulted for hundreds of manufacturers, government agencies, and WHO. Dr. Rodricks has authored more than 150 publications on toxicology and risk analysis and has lectured nationally and internationally on these topics. From 1965 to 1980, he was Deputy Associate Commissioner for Health Affairs and Toxicologist for the FDA. Dr. Rodricks has served as a member of a number of NRC and IOM committees, including the Committee on Public Health Risk Assessment of Poultry Inspection Programs, the Committee on Institutional Means for Assessment of Risks to Public Health, the Committee on Scientific Evaluation of Dietary Reference Intakes, and currently the Committee on Decision Making Under Uncertainty; he also serves on the Board on Environmental Studies and Toxicology. He has been certified as a Diplomate of the American Board of Toxicology since 1982. Dr. Rodricks holds a Ph.D. in biochemistry and an M.S. in organic chemistry from the University of Maryland. He was a postdoctoral scholar at the University of California, Berkeley.