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Biosecurity

Origins, Transformations and Practices

Brian Rappert and Chandré Gould

Biosecurity

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Origins, Transformations and Practices

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List of Abbreviations

AHF	Argentine hemorrhagic fever
ANLIS	National Administration of Health Institutes and Laboratories (Argentina)
APHIS	Animal and Plant Health Inspection Service
ASM	American Society for Microbiology
ASSAf	Academy of Sciences of South Africa
BRCs	Biological Resource Centres
BSL	Bio-safety Level
BSP	Cartagena Biosafety Protocol
BW	Biological Warfare (or Weapons)
BWC	Biological and Toxin Weapons Convention
BWG	Biosecurity Working Group
CAS	Chinese Academy of Sciences
CBD	Convention on Biodiversity
CBM	Confidence Building Measures
CBRN	Chemical, Biological, Radiological and Nuclear
CBW	Chemical and Biological Warfare
CCS	Civil Contingencies Secretariat
CDC	Centers for Disease Control
CDSC	Communicable Disease Surveillance Centre
CEPR	Centre for Emergency Preparedness and Response
CfI	Centre for Infections
CIA	Central Intelligence Agency
CISAC	Committee on International Security and Arms Control
CITEFA	Armed Forces Scientific and Technical Research Institute (Argentina)
CONICET	National Scientific and Technical Research Council (Argentina)
CoW	Conference Committee of the Whole
CSGAC	Chinese Scientists Group for Arms Control
CSIS	Center for Strategic and International Studies
CW	Chemical weapons
CWC	Chemical Weapons Convention
DHHS	Department of Health and Human Services (US)
DHS	Department of Homeland Security (US)
DIGAN	Directorate of International Security, Nuclear and Space Affairs of the Foreign Office (Argentina)

DoD	Department of Defense (US)
ES	Embryonic Stem (cell)
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GM	Genetically Modified
GMO	Genetically Modified Organisms
HPA	Health Protection Agency
HPCSA	Health Professionals Council of South Africa
HSNO [Act]	Hazardous Substances and New Organisms Act (New Zealand)
IAEA	International Atomic Energy Agency
IAMP	InterAcademy Medical Panel
IAP	InterAcademy Panel
IBC	Institutional Biosafety Committees
ICGEB	International Centre for Genetic Engineering and Biotechnology
ICRC	International Committee of the Red Cross
ICSU	International Council for Science
IFP	International Futures Programme
IL	Interleukin
INEVH	National Institute of Human Viral Diseases (Argentina)
INTA	National Institute for Agricultural Technology (Argentina)
IRB	Internal Review Board (Japan)
ISP	Intersessional Process
ISU	Implementation Support Unit
IUMS	International Union of Microbiological Societies
IUPAC	International Union of Pure and Applied Chemistry
JDA	Japan Defence Agency
KNAW	Royal Netherlands Academy of Arts and Sciences
LMO	Living Modified Organisms
METI	Ministry of Economy, Trade and Industry
MEXT	Ministry of Education, Culture, Sports, Science and Technology (Japan)
MHLA	Ministry of Health and Labour Affairs (Japan)
MMA	Moscow Medical Academy
MoD	Ministry of Defence (UK)
MOFA	Ministry of Foreign Affairs (Japan)
NAM	Non-Aligned Movement
NAS	National Academy of Sciences
NATO	North Atlantic Treaty Organization
NDMC	National Defence Medical College (Japan)

NEA	Nuclear Energy Agency
NGO	Non-Governmental Organization
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NIID	National Institute of Infectious Diseases (Japan)
NPC	Non-Proliferation of Weapons of Mass Destruction
NPT	Non-Proliferation Treaty
NRC	National Research Council
NSABB	National Science Advisory Board for Biosecurity
OBA	Office of Biotechnology Activities
OECD	Organisation for Economic and Cooperation Development
OPCW	Organisation for the Prevention of Chemical Weapons
R&D	Research and Development
RAAS	Russian Agricultural Academy of Sciences
RAMS	Russian Academy of Medical Sciences
RAS	Russian Academy of Sciences
RISTEX	Research Institute of Science and Technology for Society (Japan)
RSA	Republic of South Africa
S&T	Science and Technology
SANDF	South African National Defence Force
SARS	Severe Acute Respiratory Syndrome
SCJ	Science Council of Japan
SENASA	Bacteriology and Exotic Diseases divisions of the National Service of Agri-food Health and Quality (Argentina)
SIFEM	Argentine Federal Emergency System (Argentina)
TRC	Truth and Reconciliation Commission (South Africa)
UK	United Kingdom
UN	United Nations
UNMOVIC	United Nations Monitoring, Verification and Inspection Commission
UNSC	UN Security Council
UNSCOM	United Nations Special Commission
US	United States of America
USAMRID	United States Army Medical Research Institute of Infectious Diseases
WHO	World Health Organization
WMD	Weapons of Mass Destruction

Notes on Contributors

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Chandré Gould is a senior researcher in the Crime, Justice and Politics Programme at the Institute for Security Studies, an African policy research institute. She has published widely on the apartheid chemical and biological weapons programme and on dual-use issues in the life sciences, with a particular focus on Africa. Over the past three years she has been engaged in various initiatives in South Africa, and elsewhere in Africa, to discuss dual-use issues with life scientists and to develop educational programmes on dual-use issues. In 2006 she obtained her PhD from Rhodes University. Her publications include *Secrets and Lies: Wouter Basson and the Apartheid Chemical and Biological Weapons Programme* (2002) with Marlene Burger, *The Apartheid Chemical and Biological Weapons Programme* (2002) with Peter Folb, and she edited a volume on small arms in Southern Africa with Guy Lamb titled *Hide and Seek: Taking Account of Small Arms in Southern Africa* (2004).

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1
The Definitions, Uses, and Implications of Biosecurity

Brian Rappert

Hope and fear

Biosecurity is a term with a rising currency. New streams of funding, national and international conferences, and policy initiatives are being launched to enhance the state of it. For instance, when the outline for this volume was initially formulated in early 2008, the editors benefited from attending three relevant major international conferences – meetings that indicated the intensifying but simultaneously disputed importance of this notion.

In February, the National Centre for Biosecurity at the Australian National University in partnership with the University of Sydney hosted a symposium titled 'Biosecurity Challenges facing Australia and its Region'.[1] Billed as the first meeting of its kind in Australia, it brought together under a common banner life scientists, government officials, social researchers, and others concerned about topics as diverse as the physical security of research laboratories, public and media reactions to outbreaks of disease, the potential for the deliberate spread of disease through biological weapons, the transmission of outbreaks within livestock rearing and slaughter, and techniques for the diagnosis of pathogens. The title for the event expressed the international composition of its delegates, as participants derived from more than a dozen nations in the Asia-Pacific region. Convening a symposium incorporating many hitherto individuals provided a basis for building a national network of those working under a shared label. For some the symposium was also a way of trying to influence outside audiences. Certain speakers used the opportunity provided to make the case for additional government funding and heightened recognition of particular areas (for instance, the convergence of nanotechnology and biosecurity).

And yet, while the symposium proved an occasion for fostering networks and advancing priorities, major differences in the basic framing of the issues at stake were also evident. These did not just pertain to the multiple notions of what should be included under the umbrella term of 'biosecurity'. Instead, they extended to whether it represented an unease or a goal. So, a keynote address 'Biosecurity: Upgrading the Web of Prevention' by Malcolm Dando employed a language of *risks and threats* to characterise the potential for advanced life science research to facilitate the development of bioweapons. In contrast, others spoke about the development of new diagnostics, sensors and surveillance procedures as means of *achieving* a state of security.[2] Such contrasting framings were not just abstract orientations, but unavoidably tied to determinations about what required attention and why.

On 11–12 March 2008, a second event held in Kampala, Uganda likewise exhibited diversity under a common heading. 'Promoting Biosafety and Biosecurity within the Life Sciences: An International Workshop in East Africa' was convened by the Uganda National Academy of Sciences. While not the first meeting held in the region primarily concerned with biosecurity, the principle audience for this one was practicing scientists rather than high-level policymakers. As stated in workshop background material, such an engagement was necessary since this group would 'ultimately be responsible for implementing and disseminating oversight procedures' (UNAS 2008: 6). As with the symposium in Australia, this meeting encompassed a wide range of topics. That included, for instance, the proper handling of common hazardous chemicals such as fertilisers. Yet, in the main, for the purpose of this workshop, biosecurity pertained to the implications of work conducted by scientists in laboratories. As contended during the workshop, this was a relatively new framing of a word that until then had been familiar to many participants in relation to controls over genetically modified food crops.

A recurring theme of many of the contributions from African participants was the novelty for practicing bioscientists to consider the security dimensions of their research. While at least the *policy framework* for lab safety was in place in a number of the countries in East Africa, the same did not hold for lab security. However, just what should follow from that existing low status was not a matter of agreement. Ben Steyn (Chemical and Biological Defence Advisor to the South African Surgeon General) for instance, argued that the risk to Africa from the deliberate spread of disease was dwarfed by the endemic diseases already prevalent throughout the continent. As such, the limited resources available should be spent to counter natural diseases rather than (largely hypothetical) threats associated with biological weapons (Steyn 2008). The further training of scientists to ensure they work safely would provide protection against the illegal diversion of pathogens from the laboratory in a matter proportionate to the human and financial resources at hand. Yet despite such sceptical interventions, much of the tone in the conference supported the suggestion that countries in East Africa and elsewhere should do more. This was particularly so for scientists from low biosafety level laboratories that work with viruses, including the hemorrhagic fevers, that reportedly kept no records of what the labs were working with or who worked with them.

The programmatic themes voiced during 'Promoting Biosafety and Biodiversity within the Life Sciences' were in line with the programmatic organisation behind the workshop. It was arranged through a joint collaboration between the Uganda National Academy of Sciences and the US National Academy of Sciences. Since the 2005 *Statement on Biosecurity* by the Inter-Academy Panel – the umbrella organisation for prestigious national academies of science around the world – a number of individual academies have initiated activities in relation to this subject, notably the one in the United States.

As part of efforts by national academies to bring more attention to biosecurity, a third major conference took place in early 2008. The 'Second International Forum on Biosecurity' was held in Budapest, Hungary between 30 March to 2 April.[3] A joint event between the US National Academies, the Hungarian Academy of Sciences, Inter Academy panel (IAP) and other scientific and medical organisations, this forum brought together high ranking professional representatives, practicing scientists, security analysts, and others. Following on the back of the Uganda workshop and with the inclusion of overlapping participants from Africa, the forum provided an opportunity to consolidate emerging attention to biosecurity in some parts of the world.

The 'Second International Forum on Biosecurity' was part of a wider programme of activities. The initial idea for it and the previous one held in Como, Italy in 2005 stemmed from a 2004 report by the US National Academies titled *Biotechnology Research in an Age of Terrorism* (NRC 2004). That report called for international meetings to ensure oversight measures developed in the US would be harmonised elsewhere.

And yet, while the 2008 forum brought together those that might well be regarded as leading biosecurity experts, many distanced themselves from the term. In one of the three breakout streams that dealt with the promotion of a research 'culture of responsibility', for instance, a proposal was mooted to establish a high level international working group that could clarify the meaning of the term. Participants acknowledged the confusion resulting from the contrasting definitions given to it throughout the world and even within the very deliberations of the second forum. The proposal for a clarifying committee was roundly rejected by those present though in favour of abandoning the term. In its place, attendees agreed on language that spoke to minimising the national, accidental, and deliberate spread of disease. Thus, a group of experts assembled under the heading of biosecurity concluded that it had enough drawbacks as to best be avoided. In a further twist, despite the many reservations expressed about the use of the term, the final report of the second forum frequently employed the term biosecurity (NRC 2008).

Other major international deliberations were later organised in 2008. This included a regional seminar in Indonesia (Indonesia and Norway 2008), a workshop about education and biosecurity in Italy,[4] a conference on biothreats in Jordan,[5] and (not least) the meeting of states parties to the Biological Weapons Convention. To this list of more policy-orientated conferences could be added many, many more dealing with the funding of research, the development of therapeutics and diagnostics, as well as first line responses to attacks. With each, questions can be asked about how biosecurity was defined and positioned.

Three premises underlining biosecurity: Its origins, transformations, and practice

However multiply conceived and fraught, 'biosecurity' is a topic of increasing prevalence in public policy in many quarters. In trying to understand its place, three premises underline this volume:

1. The meaning of biosecurity derives from its uses, not just the way it gets defined

As the previous section suggested and the next one elaborates, biosecurity is varyingly defined. As often noted, even at the basic level of wording, it is a source of some confusion. In Spanish and French, for example, the same word is used for both biosecurity and biosafety. This situation frustrates effective communication. As a result, various calls have been made to clarify the meaning of the term by establishing a precise and agreed definition (see Chapters 5 and 6).

And yet, while such points of language are valuable reminders for caution, to reduce the meaning of biosecurity to this or that specific definition is to discount the ways in which the term is made meaningful. In this regard it is worth remarking that, to date, much of its utility seems to have derived from its plasticity rather than its definiteness.

Moreover, the manner in which biosecurity is raised as a topic should be understood as a form of situated action. The evoking of 'biosecurity' can be part of bringing together previously disparate activities, assembling shared agendas for the future, empowering certain individuals and groups as vital experts, and advancing multiple organisational goals. Even the discussion of definitions can have this social action dimension, rather than simply being about clarity and precision. Take the previously mentioned proposal made during the 'Second International Forum on Biosecurity' to set up a high level definition working group. In a later discussion within this forum, it was proposed to the author that this suggestion was motivated as much by the desire to ensure those new to discussions (particularly those outside the West) had a forum for having their concerns heard as much as it was by the expected prospect for avoiding confusion by agreeing to word usage. Thus, in considering place of biosecurity today it is worth bearing in mind a classical sociological distinction between substantive (what something is) and functional (what something does) definitions of concepts.

2. Biosecurity is contestable because security is contestable

What should count as 'security' can be a matter of considerable disagreement. Security for who, security from what, and security defined by whom, are only some of the many points of contention. Is security a sense of well-being, an avoidance of risks and threats, a way of life, or the assurance that precautions have been taken to reduce the risk of harm? For whatever notion of security is used, how should it be prioritised against other goods? Is it something to be traded off against other political goals (such as liberty) or a fundamental prerequisite for achieving those goals?

As with other aspects of security then, the meaning of biosecurity should be approached as a matter of potential disagreement. Just what should be done in response, say, to high consequence but low probability events – such as mass deaths from the deliberate spread of a contagious agent – is a matter where contrasting appraisals are likely. If social fear of such attacks is considered disproportionate to likely threats, then should this be dismissed as irrational or should the prevalence of fear be treated as serious because it undermines a sense of well-being? Likewise, how much and in what way a country in East

Africa with limited resources for even basic healthcare and various endemic disease should concern itself with threats from bioweapons is the very stuff of politics. So too is the manner in which officials are enrolled into agendas through becoming made to feel uneasy with the *status quo*. Thus, within this volume, the negotiated emergence of 'biosecurity' offers the opportunity to chart the early formation and contestation of an identified challenge.

3. Current discussions would benefit from understanding rather than seeking to resolve differences

The '-security' portion of biosecurity is not the only contested element. Across the globe the place of the 'bio-' has been a matter of keen discussion. The conduct of research, the value of genetic manipulation, and the proper priorities for healthcare are just some of the many topics in such conversations. So as of 2008, while the language of biosecurity is now widespread, just what that interest does and should mean for practice is hardly straightforward. The elasticity of the term makes it useful in bringing together varied agendas, but it also can result in confusion.

This collection takes the varying definitions both within and between countries as its starting point for analysis. This is done, for instance, in contrast to working towards a single notion of what should properly be called biosecurity. No notionally unifying definition will be offered in this introduction for sifting the wheat from the chaff. As an intervention into current deliberations, this book seeks to sensitise, map, and index how the concerns associated with biosecurity are varyingly defined, their historical origins, and the implications for particular policy discussions today. The intent is to place future discussions on a more solid footing by flagging a range of issues at stake in what gets said.

In order to do this, the contributors come from varied national contexts and institutional backgrounds. With regard to the former, the authors are located in eight countries. This volume includes those from universities, research institutes, government ministries, professional science associations, and intergovernmental agencies. The wide range of national contexts and institutional affiliations are meant to convey a range of different experiences.

Bounds, framings and linkages

By way of prefacing the detailed analyses that appear in subsequent chapters, this section expands on the points previously raised regarding the alternative characterisations of biosecurity prevalent today. The goal though is not simply to convey a sense of diversity. Instead, the alternative framings provide the basis for asking wider questions about the governance of science and technology. This includes issues such as the regulation of research, the politics of hope and fear, and the relation between science and society.

Before doing so, it is worth making a few points about the bounds of this volume. Although the contributions to *Biosecurity* seek to convey a sense of difference, not everything labelled biosecurity today is equally addressed. In the past, this term was probably most frequently referred to measures designed to keep livestock and crops free from disease; largely transmitted from other livestock or crops. This sort of thinking, for instance, informed one of the keynote addresses at the 'Biosecurity Challenges facing Australia and its Region' symposium. Under the title 'The Social and Spiritual Dimensions of Biosecurity: The Collective Survival of Mankind', Dr. Suwit Wibulpolprasert spoke to wide ranging negative economic and social repercussions of recent attempts to prevent the spread of avian flu within duck and bird populations in southeast Asia.

More recently though, biosecurity has taken on additional dimensions aligned with national security agendas. Those security dimensions associated with the deliberate spread of disease provide the shared concern for the chapters in this volume. While attention to the inadvertent and so-called natural spread of disease also informs the chapters, biosecurity is addressed principally through attention to its intentional spread. In this sense, the bulk of this volume is in line with an Organisation for Economic Cooperation and Development (OECD) definition of biosecurity as measures to 'protect against the malicious use of pathogens, parts of them, or their toxins in direct or indirect acts against humans, livestock or crops'.[6]

Biosecurity: In the lab

Much of the concern about malicious use has related to the diversions of laboratory materials from legitimate facilities. The 2006 World Health Organisation (WHO) report *Laboratory Biosecurity Guidance* worked with this meaning. Biosecurity was said to pertain to 'reducing the risk of unauthorized access, loss, theft, misuse, diversion or intentional release of [valuable biological materials] to tolerable, acceptable levels' (WHO 2006: 11). The range of measures noted for enhancing biosecurity included: limiting access to certain materials, keeping records (for instance, about inventories), enacting approval procedures for those working with materials, undertaking biorisk assessments, disposing of materials, reporting security breaches, and fostering a positive culture of responsibility. Salerno and Gaudioso's (2007) *Laboratory Biosecurity Handbook* offers a detailed risk assessment guide for lab workers and managers.

This interpretation of the term biosecurity is perhaps most easily made sense of by contrasting it with more long-standing preoccupations about biosafety. If, in simple terms, biosecurity is about keeping biological agents safe from dangerous people, then biosafety is about keeping people safe from dangerous biological agents (see Chapter 6). WHO has defined laboratory biosafety as 'reducing the risk of unintentional exposure to pathogens and toxins or their accidental release' (WHO 2006: 11). In its *Laboratory Biosafety Manual*, it set out a four category tier classification for necessary equipment and procedures in working with particular agents. Incidents such as the laboratory acquired SARS infections of 2003–2004 in Singapore, Taipei and Beijing due to inadequate training and poor laboratory practices illustrate the types of concerns associated with biosafety. Organisations such as American Biological Safety Association and the European Biological Safety Association seek to promote international standards for practice.

Biosafety though is a term with its own history. Within the context of the agricultural applications of current biotechnology (as in the Cartagena Protocol on Biosafety), it has referred to ensuring biological diversity.

Even referring to laboratory-specific considerations, in practice the terms biosafety and biosecurity have been used interchangeably. For instance, the official inquiry into the outbreak of foot-and-mouth disease in August and September 2007 in the UK concluded that it was 'highly likely' to have originated from the Pirbright research site. This site includes the public Institute of Animal Health and the private company Merial Animal Health. Although there was no suggestion of intentional spread of the foot-and-mouth disease by those in or outside the research site, the *Final Report on Potential Breaches of Biosecurity at the Pirbright Site 2007* by the British Health and Safety Executive used a language of 'biosecurity' (instead of 'biosafety') to describe what happened (see Rhodes 2007).

The instances of the accidental release at Pirbright and the laboratory acquired SARS infections raise questions about the adequacy of procedures in place for biosafety and biosecurity (as in Gaudioso and BioInformatics 2006). While providing a detailed evaluation of these matters is beyond the scope of this introduction, grounds for concern about the adequacy of standards have been offered. To name but a few, countries such as Denmark, Israel, Japan, and Canada have introduced new national legislation and regulations in recent years to enhance the physical security of pathogens and other bioagents. Internationally, bodies such as the European Committee for Standardisation have sought to formulate standards for laboratories. Improving the security of laboratories has become part of government's assistance and development programmes. Again to name but a few, Australia, France, Norway, and Canada are among those countries that have initiated significant assistance programmes in recent years. By far the largest country funder of such activity is the US. The US Department of Defense's Biological Threat Reduction Program and the Department of State's Biosecurity Engagement Program are just two of the panoply on initiatives (US 2008). Yet, even in relation to relatively rich resource countries such as the US, the adequacy of biosafety measures and the variability of biosecurity measures have been topics of concern.[7]

Biosecurity: Beyond the lab

In recent years, attention to biosecurity has not just pertained to laboratory agents. Rather it has stretched to how the knowledge and techniques generated through advanced life science research might enable new destructive capabilities. In other words, focus is not simply with the *process* of research but its *products*. The latter requires attending to what sort of research gets done and what information is made available in the scientific literature.

The highly prominent 2004 US National Research Council (NRC) report *Biotechnology Research in an Age of Terrorism* argued that the problem that needed addressing was 'the intentional use of biotechnology for destructive purposes' (NRC 2004: 14–15). The chair of the committee responsible for the report – Professor Gerald Fink of the Whitehead Institute for Biomedical Research – summarised the issues at stake in this way:

> (...)[A]lmost all biotechnology in the service of human health can be subverted for misuse by hostile individuals or nations. The major vehicles of bioterrorism, at least in the near term, are likely to be based on materials and techniques that are available throughout the world and are easily acquired. Most importantly, a critical element of our defense against bioterrorism is the accelerated development of biotechnology to advance our ability to detect and cure disease. Since the development of biotechnology is facilitated by the sharing of ideas and materials, open communication offers the best security

> against bioterrorism. The tension between the spread of technologies that protect us and the spread of technologies that threaten us is the crux of the dilemma (NRC 2004: vii).

That dilemma of threat coinciding with hope raised by Professor Fink has since become referred to as the 'dual-use' potential of knowledge and techniques. On the back of the recommendations of *Biotechnology Research in an Age of Terrorism,* in 2005 the US federal government launched a National Science Advisory Board for Biosecurity (NSABB) to advise on needed policy responses. The NSABB set up a number of Working Groups to deliberate options and provide recommendations; including on the development of 'guidelines for the oversight of dual-use research, including guidelines for the risk/benefit analysis of dual-use biological research and research results'.[8] Related to this, since 2003 a number of scientific journals and funding agencies have enacted processes for weighing the risks and benefits of research manuscripts and applications (Rappert 2008).

As mentioned at the start of this chapter, one of the recommendations of *Biotechnology Research in an Age of Terrorism* was that the oversight measures undertaken in the US be paralleled elsewhere. The first and second international forums on biosecurity were efforts at realising this aim. In part following the US lead (and wording), the Israel Academy of Sciences and Humanities and the Israel National Security Council issued a report in 2007 titled *Biotechnology Research in an Age of Terrorism* (Friedman *et al*. 2008). Although addressing concerns about the 'dual use' potential of knowledge and techniques, it also made recommendations regarding the need for new regulatory measures regarding the physical control of pathogens, the security of laboratories, and the export of equipment.

The 2006 Institute of Medicine and NRC's report titled *Globalization, Biosecurity, and the Future of the Life Sciences* and the 2006 British Royal Society's report titled *Scientific and Technological Developments Relevant to the Biological & Toxin Weapons Convention* also attended to dual-use issues and thus an expanded notion of biosecurity. Reflecting a sense of biosecurity beyond the doors of laboratories, as part of the *Globalization, Biosecurity, and the Future of the Life Sciences* it was defined as:

> security against the inadvertent, inappropriate or intentional malicious or malevolent use of potentially dangerous biological agents or biotechnology, including the development, production, stockpiling or use

> of biological weapons as well as natural outbreaks of newly emergent and epidemic disease. Although it is not used as it is often in other settings, to refer to a situation where adequate food and basic health is assured, there may be significant overlap in measures that guarantee 'biosecurity' in either sense (IoM and NRC 2006: 25).

The report made use of rather stark terms to characterise forthcoming dangers. The report section titled 'Advancing Technologies Will Alter the Future Threat Spectrum' started with the statement:

> Although this Report is concerned with the evolution of science and technology capabilities over the next 5–10 years with implications for next-generation threats, it is clear that today's capabilities in the life sciences and related technologies may have already changed the nature of the biothreat 'space.' (ibid: 39)

Such conclusions were substantiated by examples such as the following:

> ...advances in technology have led to the possibility that, even if a new lethal influenza A virus does not emerge in nature within the near future, one could be artificially generated through reverse genetic engineering (...). Although not possible until recently with negative-strand RNA viruses, in October 2004, researchers from the University of Wisconsin used reverse genetic engineering techniques to partially reconstruct the highly virulent strain of influenza responsible for the 1918–19 pandemic and, the following year the complete sequence and characterization of the 1918–1919 influenza A virus was reconstructed. Although the knowledge, facilities, and ingenuity to carry out this sort of experiment are beyond the abilities of most non-experts at this time, this situation is likely to change over the next 5 to 10 years (ibid: 40).

One noteworthy aspect of the *Globalization, Biosecurity, and the Future of the Life Sciences* was that it made a case for the destructive potential of the life sciences beyond traditional areas of concern such as virology (for instance, through the use of bioregulator compounds). Synthetic biology was one of the areas that received considerable attention in the report in terms of how it might enable the widespread proliferation of capabilities for spreading disease (see Garfinkel *et al*. 2007). The 2007 Bio-preparedness Green Paper of the European Commission likewise expresses wide ranging and high-level policy concern with the developments in science and technology.

Such alarm about the potential for destructive application of research raises thorny questions about what should be done. Determinations of the wisdom of reviewing or even limiting research because of its security implications are inexorably tied to assessment of the severity and the probability of bioattacks – these by both state and sub-state groups, now and into the future.[9] Evaluations of the wisdom of encouraging widespread discussion of threats are tied to how security is conceived in the first place. If it is about enhancing the public's sense of protection or improving general state of well-being, then the extent to which biothreats are made matters of concern is as exactly important as it is problematic.[10]

There is no small irony in discussions about threats from science today. Over the last two decades, highly provocative metaphors (e.g., such as 'the Holy Grail', 'the book of life') and revolutionary promises have been attached to initiatives such as the Human Genome Project (see Nelkin and Lindee 1995). Indeed, it is not uncommon to hear that we are entering a new age. In this, genetics and related fields in the life sciences will revolutionise our understanding of the world this century as much, if not more, than physics did in the twentieth century. In short, many expectations for gene-based medical technologies as well as others have been fostered. Yet, the commercial therapeutic deliverables from genomics and biotechnology more generally have lagged far behind expectations and portrayals (see Nightingale and Martin 2004; Martin 2006). While there seems little room for doubt that the claims made on behalf of advanced life science research have been instrumental in securing significant funding in the past, with the contrast between 'hype' and deliverables comes the prospect for disillusionment.

The irony is that in relation to the themes of this book, the revolutionary therapeutic potential so often accorded to biotechnology has buttressed many of the fears about the scope for its destructive application. The logic of 'doom' and 'boom' share many of the same assumptions. With the concern about the link between life science research and bioweapons, any discrepancy between exceptions and possibilities threatens to bring untoward oversight responses. In short, an important question today is whether advanced research will be the victim of its own, somewhat inflated claims.

Biosecurity and public health

As what counts as 'biosecurity' expands, so too does the range of institutions that should take responsive action. So concerns with the dual-use aspects of life science research noted in the previous subsection suggest the need for many life scientists to incorporate security concerns within their research plans. Public health is another area that has more and more been infused with the language of security, thus raising questions about the work of clinicians, health managers, and others.

Fidler and Gostin (2008) have advocated for the increasing inclusion of security considerations within public health as well as a re-conceiving of what is meant by security by integrating in public health considerations. Thus, not only do health systems need to prepare for the deliberate spread of disease, but security agencies need to attend to the natural spread of infectious disease. Herein a robust view of national security (or the acceptance of the notion of 'human security' as opposed to 'national security') requires attending to far more than traditional preoccupations with military defences. For Fidler and Gostin, achieving the sought after transformation requires rethinking the existing place of the rule of law nationally and internationally. It also requires conceiving of biosecurity in a broad sense, to include the natural, accidental and deliberate spread of disease. They argue that the relatively new understanding given for biosecurity is needed to signal the novel agendas and practices required to the broadening threat. Past mechanisms are no longer sufficient.

Along the lines of asking how security thinking can be improved by contributions from public health, Robin Coupland (2005, 2008) of the International Committee for the Red Cross has outlined a public health approach for preventing casualties in armed conflict applicable in cases of the deliberate spread of disease.

While suggestions for reframing how security and public health should be conceived is sometimes disputed, the suggestion that the research agendas and funding patterns of public health agencies ought to incorporate security concerns more readily generates suspicion. Certainly on the public health side, voices have been raised about the creeping 'securitisation' of priorities. While the ability of those in public health and elsewhere to situate themselves under a security banner has facilitated access to additional sources of funding post 9/11, the danger for many is that this leads to improper priorities. In the US, for instance, the wisdom and effects of the massive multiple billion dollar growth in biodefence funding since 2001 has been questioned (Schuler 2005). Points of contention have turned on whether this funding is distorting research and health care priorities, whether the knowledge and materials being used pose their own security threats, and whether the funds are actually serving their stated aims (see, for instance, Choffnes 2002; Science 2005; Knight 2002; Center for Arms Control and Non-Proliferation 2008).

For those international agencies expected to ensure the health standards of some of the poorest communities while attending to the demands of diverse Member States – such as the World Health Organisation – the extent to which they incorporate concerns about the deliberate spread of disease within their portfolio of activities can be a rather fraught matter not readily understood through a blunt language of politics.

Yet, it would be far too simplistic to reduce debates about the proper place of biosecurity to geopolitical struggles between pro-security-orientated developed countries and those in the developing world antagonistic to it. So at both the Australian and Ugandan conferences mentioned at the start of this chapter ('Biosecurity Challenges facing Australia and its Region' and the 'Promoting Biosafety and Biodiversity within the Life Sciences'), some participants appropriated the language of biosecurity. The practice by corporations and health agencies centred in Europe and North America of obtaining disease samples from affected countries but then not enacting measures to enable these countries to receive significant benefits from subsequent innovations was said to undermine the state of 'biosecurity'. The decision in 2006 by Indonesia to forbid the transfer of H5N1 samples until concessions were made provides a vivid case of these sorts of concerns. By placing these issues under a biosecurity label, certain participants were aligning themselves with a stated theme of the conferences, but moved the discussion in a particular direction as well.

Yet, just as the pro and con splits are too easy, so too is the suggestion that the language of security is readily able to be marshalled towards different goals. The question needs to be asked of how couching concerns through the language of security and the accompanying rationales that follow construe the understanding of what is happening and what is possible.[11]

The last few paragraphs raise the questions of who defines priorities and how. These points are worth more detailed attention because they pertain to basic questions about the place of science in wider political processes. Much of the debate about what should be done in relation to biosecurity implicitly takes life science research as a given and asks what should be done to avoid future threats and opportunities. This way of conceiving of issues is particularly evident in relation to the dual use potential of advanced research. This framing has important implications for responses. These generally start with potential threats and then look to enact barriers to prevent them from being realised. That way of thinking has justified, for instance, putting in procedures for vetting individual grants and publications or limiting access to pathogens.

Yet, a different way of thinking about the issues at stake is to turn around the relation between science and society. Rather than asking how society ought to respond to science, science can be seen as needed to respond to societal needs. Through initiatives such as the *Kampala Compact: The Global Bargain for Biosecurity and Bioscience* and the *DNA for Peace* report,[12] Singer and colleagues have placed the question how science can be made to serve development as central in security discussions. That has entailed identifying the funding priorities in biotechnology that can aid international development (Singer and Daar 2001). As argued, only when such an orientation is taken alongside biosecurity-inspired controls can human security in its wider sense be realised.

Such an attempt to subordinate concerns about violence under a more encompassing notion of human security has a long past. The language of security is not only within the province of intelligence and military agencies. The introduction of Social Security in the US as a result of the Great Depression, for instance, speaks to the way in which security has been presented as a way of framing progressive reform. For some, however, any suggestion of trying to redefine security as it relates to the matters of biology examined in this chapter is misplaced (Cooper 2008).

The questions then are many. Do we need a notion of biosecurity, many notions of biosecurities or none at all? Who is the 'we' that should be part of this? How ought the strengthening of security be achieved – through organisations and agendas dedicated to this aim or through incorporating security within existing institutions dedicated to development, justice and health? Whatever goal is notionally placed top, how do things work in practice? Is the language of security a convenient label or does it imply a guiding philosophy?

The chapters

As is evident from the previous sections, the range of definitions given to and responses undertaken with regard to biosecurity are inseparable from basic geopolitical questions about the relative threats from the spread of disease, the priority of such threats against other health and security concerns, the acceptability of regulations on communications and movements, and the appropriateness of international standardisation.

All the contributors to this volume have contributed to debates surrounding the proper place of biosecurity – how, it might be said, security fears and hopes can be brought together. They have done so through various organisational capacities: as members of professional science associations, government agencies, research institutes, universities, and intergovernmental organisations. As such each has been engaged with the complex interweaving of expectations, uncertainties, fears, and promises. Those experiences provide the strengths and limitations of our contributions.

The chapters of this book address a number of questions:

- How is biosecurity varyingly defined?
- What are the premises about the nature of security embedded in such depictions? How might it be alternatively conceived?
- How are national and regional initiatives associated with preventing and mitigating the spread of disease aligned (and dis-aligned) with international discourse about biosecurity? What does the overall profile of alignments suggest for the uptake, development and impact of high-level policy discourse?
- To what extent have science and medical practitioners been engaged in biosecurity debates related to the conduct of their work?

In the main, Part I addresses these questions through the prism of activities undertaken by prominent international organisations. Before this though, Part I begins with Lentzos stepping back from current discussions to trace the shifting ways in which biothreats have been identified as problems requiring a response. As argued, the dominant way of discussing biosecurity today in North America and Europe is just one of many possible ways of thinking about the intersection of biology and security. She charts the rise and inter-relation over recent history of three 'security rationalities'. A central aim of this chapter is to assess how these rationalities of 'protection', 'preparedness' and 'resilience' both facilitate and limit responses because of manner they define threats as problems in the first place.

While the chapter by Lentzos provides something of a 'pre-history' to the most recent turn to the security dimension of biology, Revill and Dando detail international developments since 2001. Their specific interest is in the changing language and priorities within activities under the United Nations, primarily the Biological and Toxin Weapons Convention. As they maintain, within such high-level discourse, a predominant way of presenting issues of concern is event: biosecurity is thought of as laboratory security. Yet as they also argue, this narrow framing of the issues at stake is also contested by those forwarding a much wider notion of what counts as security. In reaction to the international framing of biosecurity outlined, Revill and Dando advocate bringing public health and security more closely in line with each other, but with a transformation in the functioning of international diplomacy.

Chapters 4–6 move on from these initial surveying chapters to consider how biosecurity has become defined within three organisations: the Royal Netherlands Academy of Arts and Sciences (by van der Bruggen), the Organisation for Economic Cooperation and Development (by Sawaya), and the US National Academy of Sciences (by Rusek). These chapters share many points:

- A broad sense of the types of concerns motivating current preoccupations;
- A starting apprehension of how to address biothreats without overinflating them;
- An assessment that while much of the impetus today derives from the US, the current attention to biosecurity should not be reduced to a strictly American agenda.

While this much is shared, owing in significant degree to the different remits of their respective organisations, how biosecurity has been used and the lessons drawn from those differ.

The chapters of Part II provide an elaboration of the main questions of this book through national comparisons of the policies and practices of biosecurity. In total, seven national contexts are examined; including countries from Africa, Asia, South America, North America, Europe and Australasia. Many of the authors collaborated under a grant from the Alfred P. Sloan Foundation project to enhance the awareness of those in the life sciences about the 'dual-use' applications of their research. The chapters share a focus on the relative importance of biosecurity (broadly defined) in their own countries and the way in which the state and scientific communities have (or have not) responded to the most prevalent international biosecurity discourse.

The chapters in this section highlight the extent to which the international discourse on biosecurity has been shaped by a single country's (the United States) threat perception and the limited extent to which this is shared in other continents. In line with the negotiation noted above, each uses a starting definition of biosecurity to identify relevant national activities, but each also seeks to be sensitive to the contrasting ways it is defined nationally. The authors also illustrate how the diversity mapped out by Revill and Dando becomes more pronounced as one moves away from high-level policy statements to local practices. While common features exist in the topics of debate and action, it would seem untenable to maintain a convergence of practices has taken place or could soon be realised.

The dominant theme emerging from the chapters in the second section is the view that naturally occurring disease presents a greater threat than deliberate disease (the exception of the United States). Indeed, the rejection of the bioterror threat perception as it exists in the United States is commonly expressed. What varies is the extent to which this rejection taints the national biosecurity discourse. Dunworth and Gould particularly refer to the close association the term has with the bioterror threat. In the case of New Zealand this appears to have resulted in the debate around dual-use issues being entirely ignored by the scientific community. Dunworth argues that New Zealands' need to preserve its natural biological resources is a far more pressing issue than the threat posed by dual-use research or biological weapons. Gould goes further to argue that the association between the term biosecurity and bioterror has resulted in a rejection of the term and a measure of resistance by the scientific community to dealing with the issues associated with the term. Both, however, demonstrate that rejection of the perception that biological terrorism presents a significant risk, has not impacted on state commitment to the BWC, or to fulfilment of the requirements of UNSC 1540. This is a theme that also emerges from the discussion of Argentina's approach to biosecurity issues, as presented by Lema, and Furukawa's discussion of Japan in relation to the biosecurity discourse.

Barr, whose chapter starts this section, concludes that China too shares the view that naturally occurring disease presents a greater threat than biological weapons use; however he discusses in some detail the factors that contribute to the need for China becoming engaged in the international biosecurity discourse.

Two additional issues emerging from the international comparison are the extent to which the level of attention that will be given by a state to the physical protection of pathogens and oversight of dual-use research is directly related to the perception of threat, and thus the priority given to the issue (Sawaya's reflection on the high cost of oversight and physical protection is instructive in this regard); and secondly that in most countries considered in this book, science communities often remain outside of the international biosecurity discourse. These are themes that those who advocate for more robust internationally applicable oversight systems of dual-use research should take heed of.

Through charting this diversity, the collection of chapters in this book do not try to forward one notion of biosecurity. Neither though is the aim simply to give an airing to many notions of biosecurities. Rather in examining the many ways in which biosecurity is advanced and contested, we hope to aid readers in thinking about how to approach its meaning and place.

Notes

1 Available from: http://biosecurity.anu.edu.au/index.php
2 This contrasting way of thinking is paralleled elsewhere. The later sections of this chapter detail how biosecurity has been identified with threats in the US. US Alliance for Biosecurity, for instance, is a collaboration among more than a dozen pharmaceutical and biotechnology companies who promote medical responses to deliberately initiated disease outbreaks. See http://www.upmc-biosecurity.org/website/special_topics/alliance_for_biosecurity/
3 Available at http://www7.nationalacademies.org/biosecurity/2nd%20International%20Forum%20on%20Biosecurity%20Agenda.html
4 Titled 'Fostering the Biosecurity Norm: An Educational Module for Life Sciences Students', 27 October 2008 (Como).
5 Titled 'Confronting Biological Threats: Biosecurity, Biological Weapons Nonproliferation, and Regional Cooperative Mechanisms', 27–29 October 2008 (Amman).
6 See http://www.biosecuritycodes.org/gloss.htm#biosec
7 See Sunshine Project (2004) and Gaudioso *et al*. (2006).
8 *Charter – National Science Advisory Board for Biosecurity,* 16 March 2006: 1. Available from: http://www.biosecurityboard.gov/revised%20NSABB%20charter%20signed%20031606.pdf
9 For contrasting appraisals of this see Kellman (2007) and Leitenberg (2005).
10 For a review of the risk communication and perception literature see Rodgers *et al*. (2007).
11 Related to this point, D'Arcangelis (2008) has examined how the language of threats infected US media coverage of the SARS outbreak. As she argued, such coverage was dominated by framings that reinforced long-time Western cultural caricatures of Chinese people as unhygienic, backward and inferior while, simultaneously, making Americans clean, modern and superior.
12 http://www.utoronto.ca/jcb/home/documents/DNA_Peace.pdf

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Part I

Biosecurity in the International Arena

2

The Pre-History of Biosecurity: Strategies of Managing Risks to Collective Health

Filippa Lentzos

Bioterrorism formed one of the Bush Administration's key security concerns over its two terms in office, and has, by one estimate, resulted in the expenditure of more than $50 billion on biodefence since 2001.[1] This emphasis appears set to continue. Indeed, Barack Obama seems committed to going even further than the Bush Administration with his statement: 'It's time for a comprehensive effort to tackle bioterror. …As President, I will launch an effort across our government to stay ahead of this threat.'[2] Obama has the backing of the leaders of the Commission on the Prevention of Weapons of Mass Destruction (WMD) Proliferation and Terrorism, established by Congress in 2007, who advocated during the Presidential elections that 'The next US president should put more emphasis on countering biological threats as part of a rethinking of national security strategy.'[3]

Echoing these concerns at an international level, the former UN Secretary General Kofi Annan noted in his address to the United Nations General Assembly in April 2006 that: 'The most important under-addressed threat relating to terrorism, and one which acutely requires new thinking on the part of the international community, is that of terrorists using a biological weapon.'[4]

Yet why is it that bioterrorism and biothreats have gained such prominence in the 'risk portfolios' of our political leaders when the limited historical examples available to us show that biological agents are difficult to weaponise and use with precision and with large-scale effects? Niklas Luhmann has pointed out that the world itself 'knows no risks, for it knows neither distinctions nor expectations, not evaluations, nor probabilities – unless self-produced by observer systems in the environment of other systems' (1993: 236). In other words, risk arises from particular ways of thinking about, seeing and practicing upon the world. This is a point also made, most famously, by Mary Douglas and Aaron Wildavsky: '[E]ach form of social life has its own typical risk portfolio' (1982: 6). A risk portfolio, then, is a way of selecting from all the possible, real or imagined threats and harms, the ones that shall be the focus of individual or collective attention. This selection is, inescapably, done in relation to moral evaluations pervaded by cultural norms.

I argue that the way in which biosecurity is 'problematised',[5] or the way in which biothreats are constituted as problems requiring policy responses, has changed significantly over the last few years and that the consequences of this are still not understood (Lentzos 2006; Lentzos and Rose 2009). Concerns with the security dimension of the life sciences have traditionally been related to practices and policies associated with national security, with military defence against the use of biological weapons by nation states and with disarmament efforts (Wright 1990; Lederberg 1999; Balmer 2001; Wheelis, Rózsa and Dando 2006). Since the early 1990s, but particularly post-9/11 and the anthrax letters, a new problematisation of biosecurity has emerged, one which incorporates the threat of biological weapons use by non-state actors (bioterrorism) and which links biosecurity with efforts to 'secure health' (Littlewood 2004; McLeish and Feakes 2008; Lakoff and Collier 2008; Fidler and Gostin 2008; Al-Rodhan 2008).

As illustrated in the Introduction to this volume, the new problematisation has brought in a much wider range of actors and now involves not only groups associated with war, defence, international order and strategy, but also groups concerned with crime, internal security, public order and police investigations as well as groups concerned with medicine, healthcare and the life sciences. While these groups share a concern with biothreats and the spread of disease, they frame 'the problem' of biosecurity differently and they advocate different response strategies. Some focus on biowarfare, or the deliberate spread of disease by one State in another's armed forces or civilian population, and tend to advocate for diplomacy, international treaties and dialogues between States. An increasing proportion of groups focus on terrorists and terrorist networks, some even on 'maniacs', 'diehard nihilists' or 'zealous lunatics' who 'could be anywhere on Earth' (Kellman 2007: 242) – including, it would seem, in American biodefence labs (where Bruce Ivins, named by the FBI as the anthrax letters perpetrator, worked). These groups tend to advocate investment in national defences and homeland security – in biosensors, high containment labs, vaccines and other countermeasures, scenarios and exercises, bioterrorism incident response guides, etc. Yet other groups focus on natural outbreaks of infectious disease and advocate greater investment in the public health system and in biomedical research. Others still focus on accidental outbreaks of disease and response strategies here tend to call for more effective regulations and oversight mechanisms.

Biosecurity today encompasses more than the practices and policies associated with military defence against enemy attack. It also includes the various technical and political interventions to secure health that have been formulated in response to new or newly perceived pathogenic threats.

The aim of this chapter is to put current biosecurity concerns into a broader historical context by outlining different strategies of managing risks to collective health and describing how these have been given different emphasis at different times. I aim to trace how governments and policymakers have understood and intervened in our polities to protect our 'national security' (in the broad sense of the word), how the parameters of their political decision-making have changed over time, and, as a result, how they have come to respond to biological threats in the way they are today. I will chart three approaches to uncertainty – what we call 'security rationalities' – through which potential dangers to collective health have been taken up as political problems. In so doing, I hope to demonstrate that in addition to the traditional 'rationality of protection' which assumes that it is possible to protect, the latter half of the twentieth century has seen a greater emphasis on other rationalities, more specifically on a 'rationality of preparedness' in the United States and on a 'rationality of resilience' in the United Kingdom.

The rationality of protection

The rationality of protection is characterised by both 'insurance' and 'precaution', the former of which can be traced to the beginning of the nineteenth century. The burgeoning science of microbiology, with its discovery of infection and its explanation of the causes of disease, made it possible to impose large-scale preventative behaviours like mass-vaccination for reasons of public health. It had been known for some time that a weak form of a disease causes immunity to the virulent version. Already in the late eighteenth century Edward Jenner had discovered vaccination using cowpox to give cross-immunity to smallpox. Yet, it was Luis Pasteur's discovery of artificially generated weakened versions of cholera and anthrax that revolutionised work in infectious diseases: naturally weakened forms of disease organisms no longer needed to be found.

Mass-vaccination programmes were introduced simultaneously with other programmes aimed at fostering the health and well-being of populations, such as urban water and sewage systems, guaranteed pensions, and health and safety regulations. These state-based social welfare programmes are still in operation today and work by collectivising individual risk through, amongst other means, insurance.

Insurance distributes risk by:

> first, tracking the occurrence of certain events over time across a population and, second, applying probabilistic techniques to gauge the likelihood of a given event occurring over a given period of time. Insurance is thus a way of reordering reality: what had been exceptional events that disrupted the normal order become predictable occurrences. In this way, insurance takes up certain kinds of external dangers and transforms them into manageable risks. The events that insurance typically takes up are dangers of relatively limited scope and statistically regular occurrence: illness, injury, accident and fire. When taken individually, such events may appear as contingent misfortunes, but when their occurrence is plotted over a population, they show a normal rate of incidence. Knowledge of this rate, gained through carefully plotted actuarial tables, makes it possible to rationally distribute risk. Thus, insurance removes accidents and other misfortunes from a moral-legal domain of personal responsibility and places them in a technical frame of calculability (Lakoff, 2007: 249–50).

In the protection rationality, risk is considered normal; it is not contested in and of itself. The only question is how to organise the apportioning of risk. Knowing the normal incidence rate of an illness and the occurrence of accidents enables planners to better manage the risks and to target intervention to improve collective well-being.

This 'social' form of security is based on the premise that technical rationality will be increasingly capable of managing collective risk. It is deeply rooted in science and technical progress, and in the belief that knowledge will manage uncertainty and that science itself will control any new risks arising from its progress. As new dangers are introduced, new possibilities of controlling and reducing them will be found. Francois Ewald elaborates:

> The nineteenth century's dream of security is tied to a scientific utopia ever more capable of controlling risks. While one cannot

> eliminate risks altogether (there is never zero risk), they will have been reduced sufficiently to be able to be dealt with collectively: accidents are the by-product, necessary although always more marginalised, of scientific and technical progress. These are special or abnormal risks, the responsibility for which should be spread over the community. Our concept of assured public health and safety involves prevention, the dream of an ever more complete reduction of risk (2002: 282).

Yet, the dream of an ever more complete reduction of risk, of the belief in science, probability and statistics to objectify and measure, to calculate and prevent, has been challenged by developments in the latter half of the twentieth century.

The challenge of uncontrollable risks

Ulrich Beck argues that the latter half of the twentieth century saw the introduction of a new kind of risk, one that cannot be managed through technical decision-making. Environmental and health hazards like global warming, mad cow disease and genetically modified food, ecological catastrophes such as Bophal and Chernobyl, global financial crises, and mass-casualty terrorist attacks constitute 'unnatural, human-made, manufactured uncertainties and hazards beyond boundaries' (2002: 41). He terms these 'uncontrollable risk' and explains that they do not differ from other risks because they have made everyday life more dangerous. Rather, they are different because they are 'de-bounded'. By this Beck means that uncontrollable risks do not take nation-state boundaries into account: climate change, air pollution, the ozone hole affect everyone.[6] By 'de-bounded' Beck also means that with uncontrollable human-made risks it is difficult to determine, in a legally relevant manner, who 'causes' environmental pollution or a financial crisis and who is responsible, since these are mainly due to the combined effects of the actions of many individuals. He also characterises uncontrollable risks as 'de-bounded' because of the potential delay between cause and manifestation of harmful effect. Think of nuclear waste and genetically modified crops in this regard. These hazards can cause global, irreparable damage and their effects may be of unlimited duration. They also escape the techniques of the protective rationality in dealing with social and industrial dangers. This is in stark contrast to the 'accidents' in the protective rationality, which are characterised precisely by the coincidence or the proximity of the cause and effect, and defined by their sudden or instantaneous nature.

Uncontrollable risks are non-quantifiable and go beyond rational calculation into the realm of unpredictable turbulence. One of the consequences of this is that 'the boundaries of private insurability dissolve, since such insurance is based on the fundamental potential for compensation of damages and on the possibility of estimating their probability by means of quantitative risk calculation' (2002: 41). In other words, the scale and incalculability of uncontrollable risks with catastrophic potential challenge the capacity of the insurance mechanism to provide adequate security and push such risks beyond the scope of insurability.[7] 'The speeding up of modernisation', Beck says, 'has produced a gulf between the world of quantifiable risk in which we think and act, and the world of non-quantifiable insecurities that we are creating' (2002: 40).

Responding through precaution

Drawing on Beck's analysis, Francois Ewald suggests that this new sense of vulnerability has led to the rise of 'precaution' as a way of responding to conditions of uncertainty.[8] The preventive strategies of the protective rationality were characterised by decision-making in contexts where there is certainty as to the consequences of an action. However, if the likelihood of the event is not measurable and its extent is not assessable, it is not a 'risk' in the technical sense of a danger that has been brought into the realm of calculative decision. Instead, decision-making in contexts where only a relationship of possibility, eventuality, plausibility, or probability between a cause and effect can be envisaged represents a new set of conditions within the rationality of protection that require a different response: precaution.

> Precaution starts when decisions must be made by reason of and in the context of scientific uncertainty. Decisions are therefore made not in a context of certainty, nor even of available knowledge, but of doubt, suspicion, premonition, foreboding, challenge, mistrust, fear and anxiety. There is to some extent a risk beyond risk, of which we do not have, nor cannot have, the knowledge or the measure (Ewald 2002: 294).

A prominent version of the precautionary principle was given in 1987 in the context of the Brundtland report on sustainable development. Another articulation of it constitutes the tenth major principle recognised at the Rio Summit in 1992. Precaution does not so much focus on individual injury, such as may be caused by an accident, but on collective 'catastrophic' injury. In the context of possible catastrophe, Ewald writes, calculation is no longer relevant, one must take into account not what is probable or improbable, but what is most feared: 'I must, out of precaution, imagine the worst possible, the consequence that an infinitely deceptive malicious demon could have slipped into the folds of an apparently innocent enterprise' (2002: 286). Under conditions of uncertainty, formulations of precaution can invite you to anticipate what you do not yet know, to take into account doubtful hypothesis and simple suspicions. In its most extreme versions it invites you to take the most far-fetched forecasts seriously and in the face of an incalculable threat enjoins against risk-taking. In this manner this approach seeks to keep the dangerous event from occurring. In some ways, precaution creates a world in which, in principle, compensation no longer has meaning, because the only rational attitude is to avoid the occurrence of a threat with irreversible consequences. Precaution, then, represents a different response to insurance and compensation, yet its overarching aim is still the same: protection.

The rationality of preparedness

A very different way of approaching uncertain but potentially catastrophic risks has been articulated by Andy Lakoff and Steve Collier (Lakoff 2007; Collier 2008; Collier and Lakoff 2008). They argue that a 'preparedness rationality' has emerged. Unlike the precautionary approach, it does not prescribe avoidance of uncontrollable risks, but rather, enacts a vision of the dystopian future that it is assumed will happen and develops a set of operational criteria for response. Preparedness, they say, does not seek to prevent the occurrence of a disastrous event but rather assumes that the event will happen, and as such turns potentially catastrophic threats into vulnerabilities to be mitigated: It 'provides security experts with a way of grasping uncertain future events and bringing them into a space of present intervention' (Lakoff 2007: 247). Intervention is achieved by organising a set of techniques – scenarios and simulations, stockpiling of relief supplies, early warning systems, training first responders, coordinating response among diverse entities, crisis communication systems, metrics for readiness assessment, etc. – for maintaining order in a time of emergency.

Lakoff and Collier trace the origins of these techniques of preparedness to the Cold War United States, where the techniques were initially assembled in response to the threat of a surprise nuclear attack by the Soviet Union: 'This was the context for the rise of the US national security state, in which a huge military build-up arguably took the place of what in Western Europe became the welfare state' (Lakoff 2007: 255). Techniques like scenario planning liberated security experts from reliance on prediction or probabilistic calculation familiar to us from the strategies of prevention and made it possible for them to think about the unthinkable, to plan for the unknowable. The end of the Cold War saw the techniques of preparedness becoming even more entrenched in US national security strategy. No longer was there a rational enemy whose likely actions could be calculated and managed. As Colin Powell said in 1991: 'We no longer have the luxury of having a threat to plan for.'

The key change in the nature of threat was from the stable enemy to the non-specific adversary. This shift became even clearer after the attacks of September 11. In a 2002 speech to the Council on Foreign Relations, Donald Rumsfeld counselled that the United States must vigilantly prepare for the unexpected: 'September 11 taught us that the future holds many unknown dangers, and that we fail to prepare for them at our peril.' He elaborated, using the language of anticipation and surprise familiar from scenario planning: 'The Cold War is gone and with it the familiar security environment. The challenges of the new century are not predictable. We will probably be surprised again by new adversaries who may strike in unexpected ways. The challenge is to defend our nation against the unknown, the uncertain, the unseen, the unexpected.'[9]

Since the probability and severity of catastrophic events cannot be calculated, the way to avert catastrophes is to have plans to address them already in place and to have exercised for their eventuality – in other words, to maintain an ongoing capability to respond appropriately. For example, in 2001 'Dark Winter' was performed, a scenario depicting a covert smallpox attack in the US. This was an 'executive level simulation' set in the National Security Council over 14 days. Current and former public officials played the roles of members of the Council, and members of the executive and legislative branches were briefed on the results. One outcome was the Bush Administration's decision to produce 300 million doses of smallpox vaccine. There have also been exercises jointly coordinated between two countries, and a few involve larger numbers of countries as well as intergovernmental organisations. The 'Top Officials Three' full-scale exercise – the third in the congressionally mandated Top Officials (TOPOFF) series simulating multi-point terrorist attacks using chemical and biological weapons – was jointly conducted by the US, the UK and Canada. It was the largest terrorist drill ever, involving simultaneous related exercises in the three countries, costing $16 million and including 10,000 participants.

'Atlantic Storm' – a table-top exercise convened in Washington in January 2005, a couple of months prior to 'Top Officials Three' – was designed to mimic a summit of transatlantic leaders forced to respond to a bioterrorist attack involving a smallpox attack on multiple nations of the transatlantic community. The transatlantic leaders were played by current and former officials from each country or organisation represented, and included the prime ministers of Canada, Italy, the Netherlands, Poland, Sweden, and the United Kingdom; the presidents of the European Commission, France and the United States; the Chancellor of the Federal Republic of Germany; and the Director General of the World Health Organisation. Questions of immediate response were posed: What kind of vaccination approach? Which countries have enough supplies of vaccine, and will they share them? Will quarantine be necessary? After the exercise, participants concluded that, first, there was insufficient awareness of the possibility and consequences of a bioterrorist attack, and second, no organisation or structure is currently agile enough to respond to the challenges posed by such an attack: Structures of coordination and communication of response in real time must be put into place. The rationality of preparedness means approaching risks like a bioterrorism attack, where the probability and severity of the event are not known, as if the worst-case scenario was going to occur – to act as though it is not a question of if, but when.

The preparedness rationality differs significantly from the protection rationality in its object of protection. Whereas insurance and precaution focus on individuals and groups, the vulnerabilities protected through preparedness are the operations of 'critical infrastructures' – such as information and communications, finance, transportation, and energy – whose continuous functioning is understood to be vital for economy and polity.

The rationality of resilience

Yet, precaution and preparedness are not the only means by which uncertain but potentially catastrophic risks to collective health have been responded to in our polities. In my work with others on the UK, for example, we have identified what we have termed a rationality of resilience, which aims to improve the nation's ability to handle any disruptive challenges that can lead to, or result in, crisis (Lentzos and Rose 2009).

'UK Resilience' is the name of a website which links together the various governmental initiatives aiming to 'reduce the risk from emergencies so that people can go about their business freely and with confidence'.[10] It brings together information on high profile risks such as Avian Influenza, on emergency preparedness, response and recovery, on the civil contingencies initiative and much more, linking together procedures for addressing severe weather, flooding, drought, human health, terrorism, transport accidents, animal and plant diseases, public protest and industrial action, international events, industrial technical failure, structural failure, industrial accidents and environmental pollution.

The Civil Contingencies Secretariat (CCS) at the Cabinet Office is the body responsible for coordinating emergency planning and for assessing, anticipating and preventing future crises. It aims to improve UK resilience through the Capabilities Programme, which concentrates on ensuring that a robust infrastructure is in place to deal rapidly, effectively and flexibly with the consequences of conventional or non-conventional disruptive activity. The programme consists of a total of 18 capability 'workstreams', one of which is on Chemical, Biological, Radiological and Nuclear (CBRN) Resilience.

Led by the Home Office, the CBRN Resilience workstream aims to ensure a quick and effective response from all parties concerned in the event of a terrorist incident to save lives and minimise the impact on property and the environment. To this end, the Home Office has provided: mobile decontamination units for nationwide use by ambulance and emergency departments; personal protection suits for key health workers and high performance gas-tight suits for fire-fighters; stockpiles of emergency medical equipment, strategically stored around the country and available within 24 hours; and special training for police officers to deal with CBRN incidents. The Home Office also runs a programme of major exercises that specifically deal with terrorist scenarios. It simulates three full-scale 'live' terrorist attacks and 12–15 'tabletop' or workshop exercises each year, the results of which feed into the UK Counter-Terrorism Contingency Manual – a classified document used by everyone involved in responding to terrorism incidents (UK 2003). The biggest CBRN exercise was Exercise Horizon, consisting of three separate exercises carried out in 2004 and 2005.

Another key institution involved in the UK's resilience to collective health threats is the Health Protection Agency (HPA). The HPA provides a comprehensive service in support of health protection for all types of emergencies, regardless of whether they are natural, accidental or deliberate, and irrespective of whether they are conventional or involve a release of CBRN substances. This includes preventing and controlling infectious diseases; reducing the adverse effects of chemical, microbiological and radiological hazards, and preparing for potential and emerging threats. The HPA is also responsible for: providing training in preparedness and response to potential bioterrorist incidents and in the diagnosis and recognition of symptoms of unusual dangerous microorganisms; carrying out and coordinating exercises at the local and national levels with the NHS, local authorities and the emergency services to improve national preparedness in the event of major bioterrorist incidents; and for maintaining surveillance of potential threats both nationally and internationally. In addition to this, the HPA is the sole manufacturer of the UK's licensed anthrax vaccine, it is responsible for the delivery of the Food, Water and Environmental Microbiology Testing Service, and it maintains the National Collection of Type Culture. Institutions under the responsibility of the HPA include the Communicable Disease Surveillance Centre (CDSC), the Centre for Infections (CfI), and the Centre for Emergency Preparedness and Response (CEPR).

So what, then, is the rationality of resilience? Initially referring to an act of rebounding, recoiling or springing back, in the nineteenth century the term became applied to the capacity of a property or a structure to regain its initial shape after compression, and then, later, to the mental state of being able to withstand stress or adverse circumstances or to recover quickly from their effects, and later still, to the capacity of systems, structures or organisations to resist being affected by shock or disaster, and to recover quickly from such events.[11] Significantly, resilience, today, has become something that can be engineered into systems, organisations, perhaps nations and persons. In the words of the Resilience Engineering Network:

> The term Resilience Engineering represents a new way of thinking about safety. Whereas conventional risk management approaches are based on hindsight and emphasise error tabulation and calculation of failure probabilities, Resilience Engineering looks for ways to enhance the ability of organisations to create processes that are robust yet flexible, to monitor and revise risk models, and to use resources proactively in the face of disruptions or ongoing production and economic pressures. In Resilience Engineering failures do not stand for a breakdown or malfunctioning of normal system functions, but rather represent the converse of the adaptations necessary to cope with the real world complexity. Individuals and organisations must always adjust their performance to the current conditions; and because resources and time are finite it is inevitable that such adjustments are approximate. Success has been ascribed to

> the ability of groups, individuals, and organisations to anticipate the changing shape of risk before damage occurs; failure is simply the temporary or permanent absence of that.

A rationality of resilience, then, is not merely an attitude of preparedness; to be resilient is not quite to be under protection, nor merely to have systems in place to deal with contingencies. Resilience implies a systematic, widespread, organisational, structural and personal strengthening of subjective and material arrangements so as to be better able to anticipate and tolerate disturbances in complex worlds without collapse – to withstand shocks and to rebuild as necessary. Perhaps the opposite of a Big Brother State, a logic of resilience would aspire to create a systematic state to enable each and all to live freely and with confidence in a world of potential risks.

Concluding remarks

The rationalities of protection, preparedness and resilience are not three views of the world that succeeded each other. Rather, they are different approaches to uncertainty and insecurity, developed under certain circumstances, applied within others, and each engendering a particular set of political responses. In the preventive world, risk is normal and the question is how to distribute its consequences. It is a world that is, in principle at least, amenable to calculation and of disciplining the future in probabilistic algorithms. Still operating within the rationality of protection, in the precautionary world catastrophic threats that seemingly cannot be calculated or mitigated lead decision-makers to avoid taking risks. In sharp contrast to precautionary strategies, preparedness does not seek to prevent the occurrence of a disastrous event but rather assumes that the event will happen. Instead of constraining action in the face of uncertainty, preparedness turns potentially catastrophic threats into vulnerabilities to be mitigated through techniques of preparedness. While these techniques also form a part of the rationality of resilience, the main emphasis in the world of resilience is instead placed on strengthening the ability of individuals and institutions to handle disruptive challenges that could lead to, or result in, crisis.

The different strategies of managing risks to collective health can co-exist within a government's set of policy responses. For instance, while the Bush Administration's use of scenarios and exercises as a response to potential bioterrorism attacks is part of a preparedness rationality, its development of vaccines against anthrax, plague and other bio-threat agents and its inoculation of military personnel and first responders form part of a preventive strategy. Moreover, it has been argued that its invasion of Iraq *vis-à-vis* concerns about the country's nuclear, biological and chemical weapons capability was justified as a precautionary measure (Stern and Wiener 2006).

Rationalities, or framings of a problem, exercise a 'power over men' (Foucault 1991: 102) in that they provide a language for talking about or a way of representing a particular kind of knowledge about uncertainties, risks, and threats. They construct security in a certain way and thereby limit other ways in which it can be constructed. As determinants of what can and cannot be thought, the rationalities of protection, preparedness and resilience thus delimit the range of policy options (Hacking 2001).

Under the rubric of preparedness, for instance, questions surrounding the social basis of vulnerability are not posed. Preparedness raises the question of what *kind* of governmental techniques are most salient for looking after the well-being of citizens, and what the goals of knowledge and intervention in the name of security should be. It emphasises questions such as hospital surge capacity, the coherence of evacuation plans, the resilience of the electrical grid, or ways of detecting the presence of *E. coli* in the water supply, but it does not consider the poverty rate or the percentage of people without health insurance as these are not salient indicators of readiness or of the efficacy of response. From the vantage of preparedness, the conditions of existence of members of the population are not a political problem. Not so in the rationalities of protection or resilience, where the physiological and psychological condition of the population are of paramount importance in managing risks to the health of the nation.

Foucault notes in his discussion of the political economy of truth that if one wants to change the world, one must change 'the political, economic, institutional regime of the production of truth' (1980: 133). It is by 'denaturalising' biosecurity – by analysing the forms of knowledge, the authority and the expertise that underpin different framings of security and by exploring the political, economic and social consequences of buying into them (both figuratively and materially) are – that we can highlight alternative policy options. Or as MacKenzie has argued in relation to nuclear weapons it could here be argued that 'to see the mundane social processes that form the [biosecurity] world is to see simultaneously the possibility of intervening in them, of reshaping that world' (1990: 4).

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Notes

1 http://www.armscontrolcenter.org/media/fy2009_bw_budget.pdf
2 Senator Barack Obama, speech on confronting new threats, 15 July 2008.
3 *The Wall Street Journal*, 'WMD Panel Urges Focus on Biological Threats', 9 Sept 2008.
4 Report of the Secretary-General 'Uniting against terrorism: recommendations for a global counter-terrorism strategy', A/60/825, p. 11.
5 Problematisation is a term that suggests a particular way of analysing an event or situation: not as a given but as a question. As Michel Foucault writes, 'a problematisation does not mean the representation of a pre-existent object nor the creation through discourse of an object that did not exist. It is the ensemble of discursive and non-discursive practices that make something enter into the play of true and false and constitute it as an object of thought (whether in the form of moral reflection, scientific knowledge, political analysis, etc' (1994: 670).
6 We should note, however, that, while global risks are deterritorialised, they do not equate with a homogenisation of the world. All regions and cultures are not equally affected by a uniform set of uncontrollable risks. On the contrary, global risks are *per se* unequally distributed: they unfold in different ways in every concrete formation, mediated by different historical background, cultural and political patterns.
7 Some commentators disagree with Beck's analysis. Ericson and Doyle (2004), for example, argue that what constitutes a catastrophic event is a matter of perception. An event whose extent would be catastrophic (and therefore outside of cost-benefit logic) for some may be manageable by others. The field of catastrophe modelling seeks to bring events of uncertain probability but potentially catastrophic extent – e.g. natural disasters, terrorist attacks and new epidemics – into a space of insurability.
8 Similar shifts have been identified in the broader security studies field. Didier Bigo and Tsoukala Anastassia (2006), for example, working on EU security agencies, argue that we are seeing a move away from traditional policing and a 'criminal justice logic focusing on acts already committed' towards proactive prevention and an 'intelligence logic focusing on anticipation'.
9 Donald Rumsfeld (2002) 'Transforming the Military' *Foreign Affairs*, 81(3).
10 http://www.ukresilience.info/
11 Interestingly, resilience, as a mental, psychological or neurobiological capacity, has recently become the subject of considerable research in the 1990s, especially in the United States: this research turned away from the usual focus on the reasons why individuals exposed to various forms of 'traumatic events' from childhood abuse to military conflict suffered unpleasant psychological

consequences, to concentrate instead upon the reasons why some, subjected to those same conditions, do not.

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3
The Rise of Biosecurity in International Arms Control

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Multilateral arms control and partial disarmament treaties – such as the Biological and Toxin Weapons Convention (BWC or BTWC) and the Chemical Weapons Convention (CWC) – are a product of their geostrategic context. They are constructed and reconstructed by the evolving interests and understandings of the States Parties. Thus, such treaties do not operate in a vacuum, rather they are sculpted by shifting perceptions of, *inter alia*, security and science. In the BWC and elsewhere, this has resulted in a degree of convergence in states' treatment of biosecurity.

This chapter firstly looks at how changing perceptions of science and security have impacted upon the perceptions of States Parties to the BWC. Subsequently, it traces the contestation and subsequent rise of 'biosecurity' through the BWC and UN Security Council Resolution 1540, addressing how the term has become entrenched in both the lexicon of national and international responses to dealing with biological and toxin weapons. This chapter concludes with an assessment of the limits of hegemonic conceptualisations of biosecurity-as-laboratory-security and the need for a broader understanding of the term, both in the BWC and in framing international security threats.

Biosecurity and the BWC

At least some notion of 'biosecurity' has been integrated into the BWC from its inception. Articles III and IV obligates states 'not to transfer, or in any way assist, encourage or induce anyone else to acquire or retain biological weapons' and to 'take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in article I' respectively (ISU 2008). Article IV is particularly important in terms of biosecurity, as the EU (2006a) has stated, it

> is not simply an obligation of conduct but amounts to an obligation of result. It will not be sufficient to introduce mere prohibitions into national law to meet the obligations included in Article IV since States Parties have to take 'measures to prohibit *and prevent*'.

Under the additional understandings for Article IV, successive Review Conferences have noted the importance of: 'Legislation regarding the physical protection of laboratories and facilities to prevent unauthorized access to and removal of microbial or other biological agents, or toxins' (UN 1991).[1] Thus the physical protection of laboratories and facilities has some precedent under the BWC. However, since the construction of the Convention in the early 1970s, both the security environment and the capacity and the control of the life sciences have undergone what many governments and others characterise as a significant change. Over the last decade this has affected, albeit in diverse ways, perceptions of threats from biological weapons and elevated the significance of biosecurity.

In terms of the changing capacity of science, a joint paper by the Depository States (the UK, the US and the USSR) at the First Review Conference was sanguine in its assessment stating that science and technological developments had 'not appear[ed] to alter substantially capabilities or incentives for the development or production of biological or toxin weapons' (UN 1980). By the Third Review Conference of 1991, there had been a notable shift in perceptions.[2] By the start of the twenty-first century, a palpable sense of concern is evident in BWC proceedings to the extent that in 2001 the UK (as cited in UN [2001]) remarked that, 'Given the accelerating pace in science and technology, the UK wonders whether it is prudent to maintain a five year gap between such assessments under the BTWC'. This change in capacity has been complemented with a change in the ownership and control of biotechnology and at the national level. Historically, significant research with both a benign civilian, but also a potential weapons application, has largely been the preserve of government-led or linked research academies. Increasingly, however, research with the potential to contribute to a biological weapon is being undertaken outside of government laboratories and in commercial enterprises.

In parallel with the advance of biotechnology, there has been an equally significant change in perceptions of security since the Cold War, particularly post-September 11 2001. On the one hand, the heightened importance of terrorism has starkly altered the language and conceptualisation of security and insecurity in the contemporary environment. This is not new *per se*, anxiety over the proliferation of weapons of mass destruction (WMD) and terrorism clearly predate 9/11. For example, concerns were heightened in the mid-1990s by the development and use of chemical weapons and the attempted development and use of biological weapons[3] by the cult Aum Shinrikyo (see the chapter by Furukawa). If Aum can be seen as generating greater consideration of some form of new terrorist threat, then the events of September 11 and the subsequent anthrax letter attacks have starkly elevated concerns over the threat of terrorism, particularly in the US.

On the other hand, there are also growing concerns over infectious disease as a threat to security. Indeed, as the process of globalisation has accelerated, the international transportation of goods and people has increased and the speed at which disease can be spread from one country to the next has quickened. This has been widely recognised by States Parties to the BWC but succinctly summarised by South Africa (2004) when it stated that, 'Disease outbreaks do not respect international boundaries and may spread extremely rapidly via modern travel methods.'

The importance of treating the issues often associated with biosecurity in the twenty-first century as a product of changing science and security is reflected in the selection of agenda items for the (first) BWC intersessional process. Constructed in the post-September 11 era, the intersessional process (ISP) was an attempt to salvage the BWC from the collapse of the Ad Hoc Group verification negotiations. The collapse of these negotiations effectively rendered a decade of work and thinking about controlling biological and toxin weapons moribund and destabilised efforts to deal with the problem of such weapons in an era when they have emerged as a clear focus of concern. Despite this collapse in 2001, states have not given up. As the UK (2002: 5) proposed:

> …efforts to strengthen the Convention must continue, and that a range of international and national measures can and should be taken, both to strengthen the Convention and to counter the threat from BW [Biological Weapons]. Some could be pursued at the national level only.

The reference to the 'national level only' is significant. In the twenty-first century there has been a palpable shift in the focus from inter-state compliance-mechanism towards intra-state compliance mechanism during the ISP. The agenda items included in its mandate were developed through a series of bilateral discussions between Tibor Tóth and States Parties, and they were presumably accepted by the US prior to presentation at the resumed Fifth Review Conference in 2002. All of the agenda items feed directly or indirectly into responding to the challenge of biological insecurity:

i. the adoption of necessary national measures to implement the prohibitions set forth in the Convention, including the enactment of penal legislation;
ii. national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;
iii. enhancing international capabilities for responding to, investigating and mitigating the effects of cases of alleged use of biological or toxin weapons or suspicious outbreaks of disease;
iv. strengthening and broadening national and international institutional efforts and existing mechanisms for the surveillance, detection, diagnosis and combating of infectious diseases affecting humans, animals, and plants;
v. the content, promulgation, and adoption of codes of conduct for scientists (UN 2002: 3, 4).

Over the course of 2003 items i and ii have been addressed at one Experts Meeting and one States Parties conference; in 2004 stipulations iii and iv were addressed using a similar format and finally, item v has been discussed over the course of two meetings during 2005. Under Article 18 (e) of the Final Report of the resumed Fifth Review Conference, it was agreed that '[t]he Sixth Review Conference will consider the work of these meetings and decide on any further action' (UN 2002: 4).

The rise of biosecurity in the BWC

The first intersessional process

All of the agenda items identified above fed into the emerging international concept of biosecurity. The purpose of this section is to outline how the concept of biosecurity has evolved in the BWC, beginning with what was effectively the introduction of the term itself into the BWC forum over the course of the 2003 meetings. Indeed, the discussion of what was labelled as 'biosecurity' during the 2003 BWC Meeting of Experts, was for some states 'their first exposure to such a concept' (Tóth 2003: 151). For other states previously exposed to biosecurity, it became clear that there were contrasting framings of the concept within the BWC context, which reflect perennial political machinations present in international arms control negotiations but also reflect the differing 'determinations about what requires attention and why' (see the Introduction to this volume).

For states such as the US, biosecurity – at least in the context of the BWC – was related to preventing the deliberate theft of dangerous pathogens. In 2003, the US stated that 'biosecurity practices and principles are designed to reduce the risk of unauthorised access to or diversion of dangerous pathogens and toxins – practises designed to keep pathogens and toxins safe and out of the hands of unauthorised or unsafe people' (US 2003). From the perspective of the US it was comprised of the following generic principles:

- Personnel Reliability
- Physical Security
- Information Technology Security
- Material Control and Accountability
- Material Transfer Security
- Program Management

This approach, which closely resembles the subsequent WHO definition of *laboratory* biosecurity[4] of 2006, was echoed by several other states not just from the West, but from across the globe. A statement by China (2003), for example, closely mirrored US proposals stating biosecurity measures should include that a 'risk assessment of microbe [sic] should be carried out, physical protection levels, design and operation guidelines of laboratories be established, the wrapping, storage, transfer of pathogenic microorganisms be strictly administered'.

A laboratory biosecurity orientated approach is logical for countries with relatively limited disease burden. It was also understandable given the then recent events in the US. However, such a laboratory biosecurity approach is of limited utility in other parts of the world where natural outbreaks of disease in humans, animals and plants is of far greater concern that bioterrorism. In this regard, the laboratory-orientated concept of biosecurity forwarded by the US and others in 2003 was contested over the course of the early intersessional meetings (see the chapters on the South Africa and New Zealand approaches to biosecurity in Part II of this book). Russia (2003: 3) addressed this in stating: 'Concern over the possibility of terrorists getting hold of biological agents is understandable. Other delegations insisted on a wider approach to the solution of the problem of bio-security in connection with the implementation of the BTWC.' Exactly what constituted a 'wider approach' in the BWC varied, Australia (2003: 125) remarked that biosecurity 'within Australian agriculture [it] also means protecting the country from exotic pests and diseases through quarantine, surveillance and early detection measures' adding that 'the FAO use it [read: biosecurity] in terms of securing food supplies'. A more pointed indication of a different perspective on biosecurity based on a differing prioritisation for less developed states is evident in Littlewood's (2005: 236) citation that in a country such as South Africa, 'spending $1 million on biosecurity still fails to prevent an individual going into Kruger National Park and digging up anthrax spores'. A review of the literature outside the convention, yet in security focused discussions, provides a further indication of this broader approach as Halim (2004: 13) has stated:

> Biosecurity is not limited to protecting laboratory-based pathogens and toxins from theft… such a narrow strategy has limited value in Indonesia, where dangerous pathogens are not only located in laboratories, but can also be found readily in nature.

In this regard, at the 2003 meetings biosecurity was somewhat disparately conceptualised or, as Russia (2003: 3) stated, the topic has 'produced a mixed impression'. It added that the way forward was for 'clear-cut definitions of biosecurity pursuant to which that problem could indeed be resolved'. No such 'clear cut definitions' emerged from 2003. However, with the focus of agenda items (i) and (ii) and the fixation in countries such as the US regarding the security of pathogens in the laboratory, a laboratory orientated approach understandably emerged as the dominant conceptualisation in 2003. The BWC discussions served as a useful awareness raising process *vis-à-vis* this way of thinking. Certainly a joint paper by the EU (2006b: 4) stated that, 'the discussion of the concept and meaning of biosecurity in 2003, and the identification of the types of measures required for biosecurity resulted in the recognition of the value of such measures'.

Whilst this may be indicative of the success of the 2003 meetings in fostering an appreciation of laboratory-orientated approach to biosecurity, there is considerably less in terms of concrete cohesive agreement between States on specific mechanisms to be undertaken to support this approach. In the substantive paragraphs of the *Report of the Meeting* *of States Parties* (UN 2003: 5) the States Parties agreed on the value of, *inter alia*:

> …The need for comprehensive and concrete national measures to secure pathogen collections and the control of their use for peaceful purposes. There was a general recognition of the value of biosecurity measures and procedures, which will ensure that such dangerous materials are not accessible to persons who might or could misuse them for purposes contrary to the Convention.

The failure to agree upon a more specific action plan for effective implementation lies in part because of the relatively new nature of the topic. Japan (2003) spoke of the novel nature of the topic, stating that the Experts Meeting served to clarify that many States Parties were 'exploring how best to address the issue of biosecurity'. However, the limited outcome at the BWC further reflected other issues. One, the continuing disappointment and allocation of blame over the collapse of the verification protocol discussions; two, a degree of uncertainty with regard to the relatively new working practices of the BWC during the ISP; and three, the limited utility of this approach to biosecurity in states with high disease burden.

In contrast to the 2003 meetings, the 2004 sessions were focused on dealing with challenges posed by infectious disease and can be linked to a much broader conceptualisation of biological security. Although seemingly incongruent with the BWC as understood from conventional security perspectives (see the introduction section to this chapter), there was wide acceptance of the agenda items of 'surveillance, detection, diagnosis and combating of infectious diseases' and 'capabilities for responding to, investigating and mitigating the effects of cases of alleged use'. Their importance of these topics *vis-á-vis* the BWC was made clear by the US (as cited in UN 2004a) when it stated, 'Improved national and co-operative international disease surveillance is consistent with the object and purpose of the Convention which is the elimination of biological weapons'. Such sentiments were reflected in the Final Report from the Meeting of States Parties in 2004 (UN 2004b: 4) in which States Parties recognised that, 'strengthening and broadening national and international surveillance, detection, diagnosis and combating of infectious disease may support the object and purpose of the Convention. It further added:

> States Parties' national preparedness and arrangements substantially contribute to international capabilities for responding to, investigating

> and mitigating the effects of cases of alleged use of biological or toxin weapons or suspicious outbreaks of disease.

Despite consensus recognition of the relevance of enhancing surveillance, detection, diagnosis and combating of disease, as well as national preparedness measures, these elements have not been explicitly encompassed under the rubric of biosecurity in the BWC arena. Nonetheless, this approach, which contributes to the advancement of the development dimension of the Convention[5] is important. It serves a role not just in the political appeasement of the hard-line Non-Aligned Movement (NAM) States, but, more significantly it acknowledges the linkage between what have traditionally been considered separate spheres in mainstream security thinking: public health and national security. Thus whilst this does not equate to consensus acceptance of a broader conceptualisation of 'biosecurity' which moves beyond the laboratory, it can be seen as reconstituting security thinking (or at least beginning the process of reconstituting such thinking) to include issues such as the surveillance, detection, diagnosis and combating of infectious disease.

The 2005 meetings added another dimension to laboratory biosecurity strategies through highlighting the limitations in scientists' awareness of the potential ramifications of dual-use research. Indeed, although the 2005 meetings are likely to have been considered of limited substance by many in the arms control community, the utility of discussing seemingly peripheral topics functioned to unlock synergies between traditional security approaches and other issues. This suggestion is reflected in a subsequent statement by the US (2008: 2) that:

> When the ...[ISP]... was being developed, the concept of codes of conduct seemed of peripheral importance...As the United States has discovered recently, personnel reliability programs and the establishment of norms of responsible conduct of research, in addition to laws and regulations for biosafety and biosecurity...are critically important.

Indeed the 2005 Meetings made both a substantive and procedural contribution to the BWC and indirectly, broadened the components recognised as being necessary to enhance biosecurity.

Procedurally, the nature of the topic necessitated that the arms control and disarmament community more closely engage with the life science community beyond those individuals directly advising delegations. As

Pearson (2005: 14) noted, 'over 280 scientific and other experts from capitals and international agencies' attended the 2005 Experts Meeting. For the BWC this has generated a precedent of engaging scientific and professional organisations on issues deemed relevant within the BWC forum which, in turn, paved the way for even greater scientific participation in subsequent meetings.

In terms of the substantive contribution, deeper engagement by States Parties with stakeholders and representatives of the scientific community highlighted the chasm that existed between science and security in the biological sphere and it underlined the limited awareness of the scientific community on security aspects of biological weapons. This latter point was reflected in the BWC's Conference Secretariat's press release which stated: 'many experts agreed on the general need to raise awareness and increase education amongst the scientific community' (UNOG 2005). In this context, the 2005 BWC meetings contributed the expansion of laboratory-orientated principles to biosecurity to include not just 'personnel reliability' but 'personnel awareness'. The latter is important, not least, because ensuring scientists have an understanding of laws enables them to follow such laws.

The Sixth Review Conference

By the Sixth Review Conference in 2006, the UN Secretary General (2006) suggested that '[T]he security of dangerous pathogens has been improved', signifying that key aspects of the laboratory biosecurity approach had been enhanced. Improvement remains a relative term though. It was clear that while several States Parties had reported back on new policies intended to enhance laboratory biosecurity, these states represented only a small percentage of the total number of States Parties to the convention. Moreover, in many cases the efficacy of the implementation of such policies remains open to question and the security of dangerous pathogens is still regarded as a particular cause of concern for some states.

Nonetheless, a much clearer consensus had emerged around the principles of what was understood by the concept of biosecurity within the BWC. This is reflected in the various proposals made to the Sixth Review Conference Committee of the Whole (CoW) (see UN 2006a) which essentially serves as a drafting committee which feels into and the final outcome document of the Conference. Under the additional understanding for Article IV, the document:

> ... calls upon States Parties to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and

> other measures, including penal legislation, designed to: …ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins. (UN 2006b)

Significantly, the Sixth Review Conference also agreed on much stronger language on the issue of education and awareness. Successive Review Conferences have made reference to 'inclusion in medical, scientific and military educational materials and programmes of information on the Convention and the 1925 Geneva Protocol'. Following the 2005 meetings, however, States Parties were able to go further and achieved a consensus agreement on the Additional Understanding linked to Article IV which stated:

> The Conference urges States Parties to promote the development of training and education programmes for those granted access to biological agents and toxins… in order to raise awareness of the risks, as well as of the obligations of States Parties under the Convention. (UN 2006b: 10)

Further adding that:

> The Conference encourages States Parties to take necessary measures to promote awareness amongst relevant professionals of the need to report activities… that could constitute a violation of the Convention or related national criminal law… the Conference recognises the importance of codes of conduct and self-regulatory mechanisms in raising awareness. (UN 2006b: 11)

Whilst this is indicative of a broadening of laboratory security, it is further notable that the Conference added a new paragraph under Article IV stating that, 'The Conference reaffirms the commitment of States Parties to take the necessary national measures to strengthen methods and capacities for surveillance and detection of outbreaks of disease at the national, regional and international levels' (UN 2006b: 11). The fact that an arms control and partial disarmament convention had produced a consensus agreement reaffirming their commitment to dealing with disease outbreaks underlines the increased linkages between disease and security.

The second intersessional process

Based on the agreement at the Sixth Review Conference, laboratory biosecurity has been revisited at the behest of *inter alia* the EU, New Zealand and South Africa (see CoW Report section on suggestions for a second ISP, UN 2006a) over the course of the second intersessional process meetings in 2008. Replicating the format of the first intersessional process, the Second ISP allocated one Expert and one States Parties meeting in 2008 to 'discuss, and promote common understanding and effective action on':

> 1. National, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins.
> 2. Oversight, education, awareness raising, and adoption and/or development of codes of conduct with the aim of preventing misuse in the context of advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention. (UN 2006b: 21)

By 2008 the concept of biosecurity within the BWC had clearly taken the form of what the WHO termed laboratory biosecurity, something evidenced in the BWC Implementation Support Unit's (ISU) background paper from 2008 stated:

> The term biosecurity is more complex as it can have different meanings in different contexts...In the setting of the BWC, it is most commonly used to refer to mechanisms to establish and maintain the security and oversight of pathogenic microorganisms, toxins and relevant resources, as discussed during the 2003 meetings of the Convention. (ISU 2008: 2)

The fact that the Chairman 'drew the attention of delegations to' this background paper and there was no evidence of States Parties contesting the document, arguably suggests that this understanding of biosecurity has been accepted within the BWC. Yet despite the persistence of a 'narrow strategy' that omits elements of protection from disease and the security of food stocks – as alluded to by Australia and the FAO (see FAO 2003) respectively – the BWC context has continued to witness efforts to expand on the mechanisms and practises of biosecurity. Indeed, the choice to link these two clusters of topics discussed in 2008 together as the focus of the year, reflects the perception amongst States Parties of laboratory biosecurity and life scientists' education/awareness as being linked. This was evident in the consensus Final Document from the 2008 Meeting of State Parties, in which the arms control and disarmament community states:

> States Parties noted that formal requirements for seminars, modules or courses, including possible mandatory components, in relevant scientific and engineering training programmes and continuing professional education could assist in raising awareness and in implementing the Convention. (UN 2008: 6)

In this regard the BWC forum can be seen as engendering a modest expansion of the conceptualisation of laboratory biosecurity in the twenty-first century, despite often treating the term as synonymous with this set of concerns. Whilst public health-related activities – specifically enhancing surveillance, detection, diagnosis and combating of disease – have taken place during the ISP, such topics have been separated from biosecurity within the BWC forum.

The consolidation of 'biosecurity' through UNSC 1540

If the BWC can be seen as defining and redefining laboratory-based biosecurity, then UN Security Council (UNSC) Resolution 1540 of 2004 can be seen as further consolidating such a perspective through the somewhat unprecedented exploitation of UN Chapter VII which makes 1540 legally binding upon all states. UNSC (2004) Resolution 1540 states that:

> States shall take and enforce effective measures to establish domestic controls to prevent the proliferation of nuclear, chemical, or biological weapons and their means of delivery, including by establishing appropriate controls over related materials and to this end shall:
>
> …(a) Develop and maintain appropriate effective measures to account for and secure such items in production, use, storage or transport;
> (b) Develop and maintain appropriate effective physical protection measures.

Although there were some initial concerns that UNSC 1540 could duplicate work being conducted in the BWC, it is now largely agreed that 1540 is a complement to the Convention and the Chair's reports indicate that there is a degree of cooperation and interaction between the BWC's ISU and the 1540 committee. Moreover, the successful adoption of UNSC Resolution 1540 can be seen as consolidating and entrenching a US-led model of laboratory biosecurity in the international system, and this to some extent serves to stifle definitional debates as was arguably occurring over the course of the 2003 meetings.

This adoption should not be seen as equating to the resolution of the wider issue of where biosecurity stops, particularly for states in the developing world faced by naturally occurring disease. However, a review of the activity undertaken across the world during the first ISP suggested there have been a range of activities undertaken by States Parties to the BWC to enhance biosecurity. Certainly the report of the 1540 committee (2008) notes that: 'From the data available for all States, the Committee notes that 38 States reported having measures in place to account for biological weapon-related materials, whereas *53 States reported having measures in place to secure them*.' Further adding that 'the Committee notes that only 25 States reported having measures in place to undertake reliability checks of personnel working with sensitive materials' (UNSC Committee 2008). In terms of the specific measures the UNSC 1540 report of 2008 points to measures to secure the transport of biological agents as being given particular attention, as indicated in Figure 3.1.

Whilst it is impossible to detail the activities undertaken by every State in this chapter, a review of the material reported to 1540 and the BWC suggests 'biosecurity' in the twenty-first century context has become synonymous with a laboratory centred conceptualisation.

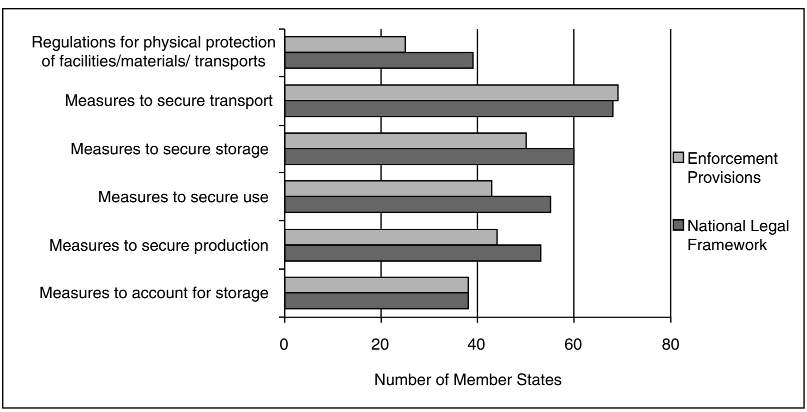

Figure 3.1 2008 Assessment of Implementation of UNSC Resolution 1540 Paragraph 3 (a) and (b) – biological weapons and related materials

The following section provides an illustrative, though not comprehensive, understanding of concrete national and regional developments in responses to the challenge of biosecurity in the twenty-first century that have been reported to the BWC or the UNSC 1540 commission.

The limits of laboratory biosecurity

As reports to the 1540 committee indicate, several States Parties to the BWC have outlined new policies, regulations and legislation devised in order to support laboratory security. Many of these policies are assessed in more detail in subsequent chapters of this book. The purpose of this section is not to encroach upon the content of subsequent chapters, but to provide some critical examples of the limitations in some attempts to implement this way of thinking *vis-à-vis* the BWC and assess the utility of it in the broader context. Concerning the limitations, several factors need to be taken into consideration.

Firstly, in order to be meaningful, laboratory biosecurity requires sustained political and economic support. For example, in Russia and the former Soviet states, this issue has been a major concern because of the legacy of the Soviet biological weapons programme (Kobyakov and Orlov 2005). Accordingly, post-2001, biosecurity has been afforded much interest by the Russian government, though the policies developed have produced ambiguous results. Daniil Kobyakov and Vladimir Orlov (2005: 15) noted that in 2005 the Russian government announced the creation of 'a special commission on biological and chemical security which will coordinate the activities of different state agencies'. This commission corresponded to the national focal point advocated by western commentators[6] to deal with biosecurity concerns and, as such, can be seen as a step forward. However, Kobyakov and Orlov (2005: 16) also report that 'Russia has effectively wound up its program to develop protection against pathogens. From 2005 onwards this program is not being further', adding that there is a 'lack of coherent Russian policy in the domains of biosecurity and biosafety'.

This example points to the sustained political and economic support necessary for improved laboratory security. Sustained political support in turn requires a degree of cohesion within a state's thinking about what requires attention and why. Over the long term there are no guarantees that such interest can be maintained as a priority over other issues. This is particularly important in relation to the issue of economic support. The continued funding of biosecurity mechanisms is by no means guaranteed.

Secondly if the laboratory biosecurity model is to be successful, the coverage needs to be global. As early as 1994, Milton Roemer (cited in King 2004) suggested that 'in the modern world, the claim that "disease knows no borders" has become a cliché'. He went on to argue that means and measures designed to keep pathogens and toxins safe and out of the hands of unauthorised or unsafe people may ultimately prove futile if pathogens can be accessed from laboratories with limited biosecurity. In this regard it is significant that none of the States Parties located in the Middle East contributed to the UN background documentation on compliance, nor the more recent BWC Compendium of National Approaches to Biosafety & Biosecurity. This situation renders any assessment of laboratory biosecurity provisions difficult. One could make the case that this is because of the limited biotechnological capabilities in the region. Yet it could also be noted that there are 15 States Parties and three Signatory States that reside in the region, many of which currently have some level of biotechnology infrastructure.[7]

The rate at which disease can be spread suggests it is important not to fixate on laboratory biosecurity to the detriment of looking at the broader challenges to security posed by disease. This is a more difficult topic to integrate into conventional approaches to security as defined by rationalist-materialist perspectives, as it is not an issue which necessarily affects military power. Indeed, dealing with the challenges to the security of humans, animals and plants requires broadening conceptualisations of security. As Chyba (2002) has suggested, '[E]ffective biological security demands that the United States act to improve global disease surveillance and response capacity—an element of "defense" that has no good nuclear or chemical analogue.' However, moving beyond a laboratory-orientated approach to biosecurity in the BWC context requires a further shift in States Parties' conceptualisations of security, which moves away from a national security-orientated perception of threats (such as military forces and terrorism) to one which integrates disease as a security threat. This is happening to some degree both in the BWC and more broadly, and there is evidence to suggest that 'health and security are intersecting with greater frequency' (Ban 2001: 8).

Despite this growing intersection, Fidler and Gostin (2008) have argued (in an otherwise fruitful contribution) that the traditional gap between foreign policy and security on the one hand and health security on the other negates the possibility of public health becoming more closely aligned with security. For Fidler and Gostin (2008: 59), this approach has resulted in a 'funeral for the traditional arms control approach' contending that 'primary reliance on the BWC's arms control approach for governing the problem of biological weapons is dead'. The approach of Fidler and Gostin appears to have fallen victim to the idea that foreign policy, security and public health are somehow fixed and unchanging. While multilateral arms control and partial disarmament agreements have a fixed central text to work from; they are reconstructed and updated through additional understandings which reflect changing concerns based on the perceptions by States Parties of the evolving geostrategic context. Similarly foreign policy and practise is not fixed, rather fluid and changes with context. In this sense, it is notable that a review of early historical records suggests that 'Some of the earliest international treaties dealt with the threat of communicable disease and the first embassies were established in medieval Italy to provide city states with information about outbreaks arising in neighbouring areas' (McKeea and Atunb 2006).

In this context, the challenge for the future is reconstructing and reconfiguring foreign policy, security and health to adapt to new challenges through converging and unlocking synergies. Although the BWC remains state-centric and focused on deliberate disease, this should not be equated with a 'funeral for the traditional arms control approach' but rather suggests that the BWC needs to continue to evolve to deal with new challenges – as it already has done during the intersessional process. Processes in the BWC should additionally give consideration to not only laboratory biosecurity and the security of pathogens in the laboratory context, but also to disease prevention and mitigation and security of biological organisms from biological events as is being discussed in BWC meetings in 2009.

Notes

1 Exact language varies between Review Conferences.
2 Certainly the UK stated '...in the period since the BTWC entered into force, the techniques of GM [genetic modification] remained the most significant development among the scientific and technological activities that have relevance for the BTWC...there has been a steady refinement of those biotechnology aspects other than GM that an aggressive nation could misuse in developing an offensive BW capability; important among the capabilities that could be misused are techniques for the large scale production of natural or modified micro-organisms or toxins...' (UN 1991).
3 Aum Shinrikyo is alleged to have been working on Botulinum Toxin and Anthrax. There have been further allegations in the US Senate Subcommittee (1995) claiming the cult dispatched members to Zaire under the pretence of humanitarian aid, to retrieve samples of Ebola Hemorrhagic Fever with the intention of culturing such samples for the purpose of biological terrorism.
4 According to the WHO's *Laboratory Biosecurity Guidance* (2006) 'laboratory biosecurity describes the protection, control and accountability for valuable

biological materials (VBM, see definition below) within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release'.

5 As embodied in Article X which deals with peaceful cooperation and exchange.

6 Certainly, William Potter has made this point 'What is badly needed is a focal point within the Russian government for biosecurity cooperation', see (Potter 2004).

7 Certainly UNIDO survey suggests *inter alia* the following institutions are active in biotech research: Guilan Science and Technology Park (GSTP), Iran; Mubarak City for Scientific Research and Technology Application (MUCSAT), Egypt; METU Technopolis (MUTP), Turkey; MRC Technological Free Zone (TEKSEB), Turkey; Pardis Technology Park (PTP), Iran; Sinai Technology Valley (STV), Egypt ; Sheikh Bahai Technology Park, Iran; Beirut Emerging Technology Zone (BETZ), Lebanon; DuBiotech – Dubai Biotechnology and Research Park, UAE; Dubai Technology Park (DTP) Mohammed Bin Rashid, UAE; iTeknoCity (ITC), Bahrain; Jeddah BioCity Science Park (JBC), Saudi Arabia; Technopark of Borj Cedria (TBC), Tunisia; Technopark El Boustène (EB), Algeria; Technopark Ibnou-Sina (IS), Algeria; Technopark of Sidi Thabet (TST), Tunisia. (UNIDO nd)

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4

Science of Mass Destruction: How Biosecurity Became an Issue for Academies of Science

Koos van der Bruggen

Introduction

The growing interest in biosecurity outlined in other chapters in this volume has reached the international academic arena. Many national and international scientific organisations are involved in these issues in a way they were not in the past; including national academies of sciences. This chapter concentrates on the role of the InterAcademy Panel (IAP) on International Affairs and on the debates and discussions in the Netherlands where the Royal Netherlands Academy of Arts and Sciences (KNAW) developed a national Code of Conduct for Biosecurity.

The initial background in the first part of the chapter will serve as a springboard for addressing two questions in the second part:

- Is the interest from growing parts of the life science community in biosecurity fuelled by a growing risk of misuse of life sciences or more by a growing political and societal concerns on (bio)security?
- How are relevant political and military developments incorporated in the life sciences discussions on biosecurity?

The chapter concludes with some recommendations for the future involvement of scientists and their organisations in the debate about biosecurity.

The Inter Academy Panel and biosecurity

The Inter Academy Panel on International Affairs was launched in 1993 as a global network of science academies. Its primary goal is 'to help member academies work together to advise citizens and public officials on the scientific aspects of critical global issues'.[1] Since its inception, IAP has issued statements on urgent social and scientific issues such as population growth (1994), sustainability (2000) and human reproductive cloning (2003). By issuing these statements and other activities, IAP has the intention to help academies to develop 'the tools they need to participate in science policy discussions taking place beyond university classrooms and research laboratories'. These tools will help 'to raise both their public profile among citizens and their influence among policymakers'.[2]

Since 2004, IAP has been active on the issue of the relation between security and life science research. In that year a Biosecurity Working Group (BWG) was established with the Academies of China, Cuba, Nigeria, the Netherlands, the United Kingdom and the United States. This BWG was inspired by activities on the field of biosecurity that had already been developed in the United States and that resulted in the now famous 'Fink Report' or *Biotechnology Research in an Age of Terrorism* (NRC 2004).

The BWG has developed a series of activities to stimulate discussion. In 2005 (20–22 March), IAP was one of the organising parties of an 'International Forum on Biosecurity' in Como, Italy. Together with the International Council for Science (ICSU), the InterAcademy Medical Panel (IAMP) and The National Academies of the United States, IAP hosted the Forum. One of its purposes was to serve as a major convening and coordinating mechanism to share information about activities that were underway or planned to address the biosecurity issue. These deliberations contributed to the Meetings of Experts and States Parties to the Biological Weapons Convention (BWC) in the summer and fall of 2005.

In December 2005, IAP issued a *Statement on Biosecurity* (see Appendix 4.1). This statement responded to the call from States Parties to the BWC during their fifth review conference in 2002 to 'promote common understanding and effective action (…) on the content, promulgation, and adoption of codes of conduct for scientists' (see the chapter by Revill and Dando for further background).[3] As an organisation consisting of member organisations, it was initially seen as useful for IAP to develop a code of conduct for its members. Eventually though IAP took the decision to produce a statement that contained five guiding principles that could then be 'translated' in codes of conduct by its member organisations. This *Statement on Biosecurity*, endorsed by 69 IAP member academies in 2005, was presented at the 2005 BWC meetings and has continued to be referred to (Kellman 2007; Guthrie 2007).

Since this declaration, biosecurity has stayed on the agenda of the Panel. The BWG enabled the IAP and its member academies to become internationally recognised voices for the inter-section of security and biological sciences. The member academies of the Working Group, as well as others, have been important sources of advice to their own governments on national policy. Moreover, IAP is increasingly recognised as an important representative on biosecurity issues for the international scientific community. As a sign of this, it was invited to the BWC Meeting of Experts in Geneva during August 2008. In the spring of 2008, IAP again was one of the coorganising parties for the 2nd International Forum on Biosecurity in Budapest referred to in Chapter 1. The working groups at the 2nd Forum produced a number of ideas for future activities, both for the BWG as well as for collaborative activities with other scientific organisations. For example, one working group recommended that IAP establish a task force to develop a clearinghouse for educational materials on biosecurity. Another recommended developing an IAP statement on appropriate models for oversight of dual-use research.[4]

Another strand of activity conducted or prepared by the BWG has been international workshops on biosecurity. A workshop in China, organised by the Chinese Academy of Sciences, took place in December 2008. An African workshop planned for 2008 had to be postponed for organisational reasons. Moreover, IAP has conducted two surveys of its member academies. These surveys asked members to provide details of activities undertaken in the field of biosecurity. While most responding academies had undertaken some initiatives, this was most commonly limited to publishing the *Statement on Biosecurity* to their website. The development of a (national) code of conduct on biosecurity was in fact only taken up by the Netherlands. For a summary of the answers on the second questionnaire see Appendix 4.3.

A workshop was planned for mid-2009 to be organised by IAP in cooperation with other international scientific groups. Its purpose was to develop recommendations for the most effective approaches to educating life scientists internationally on dual-use issues. The intention was for the workshop to:

- survey strategies and resources available internationally for education on dual-use issues and identify gaps;
- consider ideas for filling the gaps, including development of new educational materials and implementation of effective teaching methods; and
- discuss approaches for including education on dual-use issues in the training of life scientists.

Biosecurity policy in the Netherlands: The role of the Royal Netherlands Academy of Arts and Sciences

Biological weapons – and more specifically bioterrorism – attracted considerable attention after the attacks of September 11, 2001. Less well known is that before 2001, the Dutch authorities had already paid attention to the possible threats of the dual-use of biological agents. The Netherlands does not have a history of developing or using biological weapons. Indeed, as far as can be ascertained, there have been no attempts to develop such weapons by any Dutch government. The Netherlands has been a State Party to the Geneva Protocol (1925) as well as in the BWC (1972) since their inceptions.

Pre-2001, most of the attention to biological weapons in the Netherlands was linked to the broader issues of Chemical, Biological, Radiological and Nuclear (CBRN) weapons. In a common letter of 17 October 1997, the Ministers of Defence and of Science already stated:

> In the past twenty years the threat of warfare with biological weapons has grown worldwide. The Biological Weapons Convention of 1972, that prohibits the development, production and possession of biological and toxin weapons, has not been signed by a great number of countries. A growing number of countries have the disposition of biological weapons for offensive use. Moreover, these weapons can be produced more easily because of modern technology, while place and time of production hardly can be discovered.

The ministers concluded that the Netherlands had a lag in the development of means that could provide effective protection against biological weapons. Because of this a research programme was started for developing such means of protection (Tweede Kamer 1997).

With hindsight it is remarkable that all the attention in the late 1990s was devoted to the possible threats of states that were not then party to the BWC. A terrorist threat is not spoken of. A few years later, the concern with a terrorist threat was explicit in the June 2001 report *Verdediging tegen bioterrorisme* (*Defense against bioterrorism*), published by the Dutch Health Council (Health Council 2001). The Health Council issued the work at a request of the Ministry of Health in 1999. The report gave a list of recommendations intended to better coordinate existing preventive and precaution measures as well as to make researchers and medical doctors more aware of the possibility of the intentional spread of pathogenic organisms. The idea was to edit a handbook that would provide tools and rules for acting in the case of bioterrorism.

After the 9-11 attacks and the anthrax letters, a complementary report was produced in 2002 wherein the June 2001 recommendations were elaborated further (Health Council 2002). Given the remit of the Health Council, both reports concentrate on the medical aspects; specifically the prevention, development of vaccines and insight into disease symptoms.

Legal and political aspects of biothreats in the Netherlands are handled by the intelligence services and the office of the National Coordinator on Terrorism. They undertake analyses of a wide spectrum of threats. The overall conclusion from these assessments is that the likelihood of an attack with biological weapons is very limited, either in the Netherlands or more generally.[5] One of the reasons for this is that the production of pathogenic agents requires sophisticated biological and medical knowledge. As such, horror stories that suggest that every high school student could download recipes for biological weapons from the Internet that cause mass casualties are highly exaggerated (KNAW 2007, p. 21).

But even if the risks are very small, it should still be acknowledged that the possible consequences of a bioterrorist attack could be immense. Small pox or anthrax epidemics could take tens of thousands of victims. In addition, the affect of deliberate disease on agriculture or animal husbandry could be huge; has been illustrated by recent outbreaks of animal diseases. Even if the effects are limited in terms of the number of victims, political and economic damage cannot be discounted. The panic after the anthrax letters affair was enormous, and not only in the United States.[6]

The Netherlands may have a clean record as far as biological weapons development and use is concerned, but the story is different regarding nuclear weapons. The notorious Pakistani nuclear scientist, Dr. AQ Khan worked for Dutch universities and Dutch companies early in his career during the 1970s. He was involved in a project to enrich uranium. In 1975 Khan returned home to Pakistan. A few years later it became clear that with technology taken from the Dutch company URENCO, Pakistan was developing its own nuclear weapon. Because of this painful history, the Dutch government and Dutch scientific world has become alert to the possible destructive application of scientific knowledge. A recent example is the prohibition on students and researchers from Iran entering some laboratories for nuclear research or following certain 'high risk' courses. This decision was based on Resolution 1737 of the Security Council of the United Nations (2006). In practice, it should be noted that the effect of the measure is negligible. Until the end of 2008 no Iranian student was affected. Nevertheless the scientific community expressed unhappiness about the measure. In a letter dated January 2009, president of the KNAW, Robbert Dijkgraaf, asked the government to withdraw the restriction.[7]

In the field of biosecurity, comparable measures were not taken until the last few years. Two kinds of policies were developed: In cooperation with the office of the National Coordinator for Counterterrorism, new physical security measures were introduced. The potential weak spots in Dutch laboratories and research institutes were assessed and, where necessary, supplementary security measures were implemented to minimise the risk that the laboratories could unwittingly provide materials that could be used in a bioterrorist attack. These measures varied from improved physical security, to control over the import and export of biological agents, to screening activities. The second policy measure was directed at raising awareness in the scientific community of biosecurity issues. As a follow-up of the IAP Declaration on Biosecurity and the discussions during the 2005 meetings of the BWC, the Dutch government asked KNAW to develop a 'Code of Conduct on Biosecurity'. The KNAW established a working group to perform this task. The presumption underlying the initiation of this activity was that if a Code of Conduct was to have its intended effect, the content had to link-up with relevant scientific, social and political developments and with the daily practice of scientists and their organisations. For that reason relevant actors from science, industry and government were involved in the development of the code from the outset. A focus group of advisors was established to make practical comments and suggestions based on their experience as researchers and policymakers.

For most members of the focus group the issue of intentional misuse of life sciences was new, although they were familiar with questions of biosafety. The reactions and responses of the members of the focus group were comparable with reactions elsewhere in the world:[8] they were not familiar with the risks related to the intentional misuse of biological agents; they were worried that new measures would hamper the progress of research; and were concerned that new measures could affect the freedom to publish results of scientific research. There was also concern about the further bureaucratisation of science and the possibility that the import or export of biological agents from or to colleagues in other countries would be hampered.

The KNAW working group aimed to convince the members of its focus group that a code of conduct was not intended to prescribe new rules, let alone to hamper scientific progress. The main purpose of a code was to raise awareness. The debates that led to the Code of Conduct did begin to foster awareness, albeit still in a rather small circle of scientists. Some of the focus group members organised meetings in their institutes or discussed the issue with colleagues. With the help of the insights that were developed by the stakeholders' suggestions, ideas were identified and then translated into issues for inclusion in the Code of Conduct.

In line with the design of other codes of conduct in the area of biosecurity, it was decided that the KNAW code should be a concise document, which should concentrate on the main issues related to the possible dual use of life sciences research. Thus the Code begins with the statement that:

> The aim of this code of conduct is to prevent life sciences research or its application from directly or indirectly contributing to the development, production or stockpiling of biological weapons, as described in the Biological and Toxin Weapons Convention (BWC), or to any other misuse of biological agents and toxins.

The code of conduct offers rules of conduct and responsibilities of scientists, and gives suggestions for regulation and sanctions on the following issues: awareness raising, research and publication policy, accountability and oversight, internal and external communication, accessibility, shipment and transport. It was considered important that these issues should be elaborated on and applied in laboratories, universities and other relevant institutions. (See Appendix 4.2 for further details).

The KNAW stressed that the code of conduct is not a goal in itself and should not be text that disappears into desk drawers or filing cabinets. After publication of the Code of Conduct, a series of awareness raising activities were organised by the KNAW in collaboration with the Ministry of Science. A number of debates and workshops brought together scientists and other involved parties, such as funding organisations and industry, who were involved in such discussions for the first time. Presentations and publications were delivered to participants on request and audiovisual materials were prepared. These activities were intended to ensure that biosecurity issues became a part of the individual and collective awareness of life scientists, in the same way as biosafety is in the Netherlands. It was also hoped that the cooperation that was sought with the national coordination group of biosafety officials would help to translate and apply the code of conduct in the daily practice of laboratories, research institutes and so on.

Biosecurity and dealing with security risks

It would be naïve to believe that a code of conduct would make abuse of the life sciences impossible. As was said during a 2007 conference of the National Science Advisory Board on Biosecurity (NSABB): 'A code of conduct can make good people better, but probably has negligible impact on intentionally malicious behaviour.'[9] The attention to mitigating the risks of a terrorist attack with biological weapons is understandable in the light of the terrorist assaults in the United States, Spain, Great Britain, and – more recently – India. However, it is important to see the problems in perspective. The chance of an attack with biological weapons is very limited. Recent research in the Netherlands led to the qualification of biological weapons use as a '*low likelihood, high impact risk*' (Bakker 2008, pp. 143–4). In that context a code of conduct may be more effective than more rigorous measures that may hamper the continuation and freedom of scientific research.

In general, the more imminent or probable a threat is perceived to be, the more willing the public will be to accept far reaching security measures to counter it. Any consideration of whether such measures are necessary should start by asking the questions: What are the threats? What is the chance that the threats will be realised? Are the same measures necessary for all kinds of threats? What are possible side-effects of security measures? Since these questions do not always get the attention they deserve, I consider below possible pitfalls in dealing with the issues of biosecurity. These are intended as a more or less provocative mix of empirical and normative considerations with the intention to stimulate further debate.

Tunnel vision

Over the past few years the Netherlands have experienced examples of criminal cases in which prosecutors and police made serious mistakes as a result of what can be termed 'tunnel vision'. In these cases the information gathered by police was interpreted in such a way that it strengthened the belief in the guilt of the suspected offender. Information that contradicted this conviction was neglected. The result was that in several cases innocent people were imprisoned for years (Wagenaar 2002).

What is the risk that such tunnel vision occurs in security policy?

It is conceivable that a focus on security issues can lead to policy issues being subordinated to security issues, or judged only in their relation to them.[10] To give a fictitious, but not unrealistic example from the life sciences, it may be questioned why a student from a Middle Eastern country may wish to come to a European laboratory for his PhD research. The idea that this person may just wish to become a good scientist in order to help his/her country to fighting serious diseases may be set aside by the tunnel vision driven view that he or she could be a potential terrorist or wishes to steal materials. It is possible that the measures taken by Dutch government with regard to preventing Iranian students from studying freely in the Netherlands may be an example of such a tunnel vision.

While awareness of the potential for the misuse of the materials or results of life science research is important, this awareness should not lead to distrust being the default attitude in a laboratory.

Anticipated decision regret

'Anticipated decision regret' is an attitude which leads individuals to take actions that are directed at preventing possible future incidents. It is expressed as 'if I take this preventive measure now, it will mean that I do not have to blame myself (or get blamed by others) for not having done everything to prevent that incident from happening'. This attitude can be seen in healthcare. Increasing numbers of preventive screening tests are offered that provide information about the chance of developing some kind of disease, even though the chance of contracting the disease may in reality be very small. It is also possible that the measures taken to prevent the disease negatively influence the lifestyle of the individual involved. Dutch medical sociologist Tjeerd Tijmstra (2001) provides some – often hilarious – examples of anticipated decision regret: if a pregnant women is offered a screening test for a disease for which the risk is 1 at 90,000, she is likely to agree to the test – even if her doctor explained to her that her chance of having a car accident while driving to the clinic was equivalent to the child having the disease. Her motivation would be that she could not forgive herself if the child did have the disease and she had not done everything in her power to address it.

There are signals that 'anticipated decision regret' has become a prevalent attitude in security issues. After 9/11 security measures to counter potential terrorist attacks were given high priority. It appeared as though some governments were willing to invest a lot of energy in minimising the risk of terrorist attacks because they did not want to take the risk that they had not done everything they could to prevent an assault. This attitude could be the result of past experience. For example, officials of the Dutch government were reproached for not doing enough to prevent the murder of film director Theo van Gogh in 2004. These reproaches led to decisions directed at minimising the chance of new attacks. The creation of a National Coordination Center for anti-terrorism is an example. A good deal of money and a lot of energy are devoted to this issue. Most Dutch citizens found this acceptable, if not desirable. It is not farfetched to suppose that this is one of the effects of 'anticipated decision regret'. Yet it is easy to forget that the chance of becoming a victim of a terrorist attack is still many times smaller than the chance of being killed in a car accident. The chance that a terrorist would use biological agents in the attack is even less likely.

Stigmatisation

The concept of stigmatisation refers to the psychological phenomenon in which the (potential) enemy is often depicted in a way that does not, or only partially, coincides with reality: stronger, more evil, unreliable, more numerous. Often characteristics are attributed to a greater group or to a total country: *the* Russians, *the* Muslims, *the* communists. The evil attributions serve as legitimation for (counter)measures against the enemy. If your adversary indeed is so bad, perverted and wicked, the use of violence against an individual or group presenting the threat is both easily understandable and justifiable. If the enemy is made up of ordinary citizens who wish for a decent and secure life, this only becomes visible after the conflict has ended. In Europe, and elsewhere, this was a lesson learned after the Cold War when it was discovered that Russians were not very different from us.

After 9/11 this stigma appeared to have been transferred to the Muslim community. In such a context crimes and acts of terror by a small group become examples of a generalising stereotype. The decision of the Dutch government to ban all Iranians from nuclear research can be seen as an example of this way of thinking.

Life sciences, politics and security

What relation do these concepts from the world of security and politics have with the life sciences community? Until a few years ago these were two almost completely separated worlds. Historically, in general biologists and other life scientists have not been involved in security politics. The exception has been a relatively limited group of biologists and other life scientists who work in biodefence or who took part in biological weapons programmes. Most of these life scientists did not take part in public debates on biological weapons or weapons of mass destruction more generally. This is unlike physicists who played a part in the debate about nuclear weapons from the beginning.

Although life scientists have a long history of involvement in state biological weapons programmes – both running and starting them

– there has been relatively little debate within the life sciences community about the role of scientists in preventing biological weapons development. It is clear that in relation to the international discussions about biosecurity, it was the political and security communities who took the initiative to involve life scientists, as was the case with the initiative of the Dutch government to ask for a code of conduct on biosecurity.

This absence from the field of biological weapons prevention and related security politics does not mean that life scientists do not have any regard for the social and political aspects of their activities. On the contrary, since the beginning of the era of genetic modification, life scientists have been central to social and ethical discussions about the implications of their work. Well known in this regard is the Asilomar Conference of 1975, where the life scientists decided to maintain a moratorium of some aspects of recombinant DNA research because they could not yet guarantee that this research would not be dangerous.

In spite of the temporary limitations on research, biology and biotechnology developed rapidly after the 1970s. This brought life sciences to the centre of societal and political debates, although not always willingly. Initially biologists were inclined to concentrate their contributions to the public debate on what they saw as the advantages of the new developments: new medicines, more effective ways of producing food and so on. In doing so they neglected the fears of many people about the results of genetic engineering. The consequence was that they were very often surprised by the negative reactions of the public to genetically modified foods.

Life scientists learned fast from this experience. Some became well known in the media, and eloquently presented the case of the life sciences in sometimes complicated and difficult debates about genetics, cloning and stem cell research.

Few in the life science community were familiar with the risks of bioterrorism prior to the anthrax attacks of 2001. Most shocking was that the danger could come from within. This was highlighted by the alleged involvement of Bruce Ivins – a well respected scientist of the United States Army Medical Research Institute of Infectious Diseases (USAMRID) who was suspected by the FBI of being behind the anthrax letters of October 2001. In the United States the Ivins case led to (renewed) attention on what has been referred to as 'biosurety': awareness of the threats that can come from within.[11]

In closing it is worth reflecting on why life scientists and their organisations have become involved in security issues in recent years. Why has biosecurity gained such significance?

Quite clearly the events of 11 September 2001 and the anthrax letters in the same period had a great deal to do with the elevation of the perception of threat. These events raised the possibility that those in the life sciences could be a perpetuator of terrorist attacks.

A second reason, (already referred to above) is the initiative of the BWC State Parties in 2005 to stimulate the development of codes of conduct. The choice of this as a topic for the interim process arose from the efforts of BWC State Parties to propose a range of activities in order to prevent a total crisis for BWC after the failure to negotiate verification measures in 2001. (See Revill and Dando in this volume).

Another important factor is the occurrence of new infectious diseases that threaten humans and animals: HIV/AIDS, SARS and Avian influenza are some of the most well known examples. As noted in the Introduction, some authors – such as Fidler and Gostin (2008: 2) – have referred to naturally occurring infectious diseases as a biosecurity issue. They see this broadening of the concept of security as a way to release it from the 'traditional state centred military-biased perspective' (Fidler and Gostin 2008: 6). They draw on the recently developed concept of 'human security' to defend this view (Human Security Centre 2005).

Increasing awareness among scientists that their work is influenced by globalisation, is an additional factor. Growing international personal and commercial contacts are one of the reasons that viruses can spread rapidly across the world. Globalisation has another consequence: that terrorist activities are no longer limited to regional and local conflicts.

Notes

1 http://www.interacademies.net/CMS/About.aspx
2 http://www.interacademies.net/Object.File/Master/7/952/IAP%20Panel2008.pdf
3 As in the Final document of the Fifth Review Conference of the State Parties to the Convention on BWC (UN 2002).
4 This recommendation is taken seriously by the IAP Biosecurity Working Group, but given its limited possibilities it was not (yet) possible to take action.
5 http://english.nctb.nl/Diverse_vragen_en_antwoorden/CBRN_terrorisme/FAQ_3.aspx
6 To give an example of an irrational reaction: in The Netherlands the story goes that fences were put before the entrance of the Dutch Foreign Ministry. Because as is well known, viruses are stopped by fences!
7 http://www.knaw.nl/pdf/KNAW_letter_Iranian_students.pdf (January 2009)
8 As in the seminars held by Malcolm Dando and Brian Rappert in several countries. See Rappert (2007).
9 International Roundtable conference NSABB (25–27 February 2007). See http://oba.od.nih.gov/biosecurity/biosecurity.html
10 To give an example from Great Britain, where Gordon Brown qualified good education "the best weapon against terrorism" *The Guardian*, 1 January 2007.

Of course this is not necessarily the proof of a tunnel vision, but it can lead to it, if no longer education, but fighting terrorism is the central issue.

11 The concept of biosurety was introduced in debates during an international NSABB Roundtable on biosecurity issues: November 2008 (Bethesda. ML).

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Appendix 4.1

IAP Statement on Biosecurity (December 2005)

Knowledge without conscience is simply the ruin of the soul.

F. Rabelais, 153219

In recent decades scientific research has created new and unexpected knowledge and technologies that give unprecedented opportunities to improve human and animal health and the conditions of the environment. But some science and technology research can be used for destructive purposes as well as for constructive purposes. Scientists have a special responsibility when it comes to problems of 'dual-use' and the misuse of science and technology.

The 1972 Biological and Toxin Weapons Convention reinforced the international norm prohibiting biological weapons, stating in its provisions that '*each state party to this Convention undertakes never in any circumstances to develop produce, stockpile or otherwise acquire or retain: microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic or other peaceful purposes.*'

Nevertheless, the threat from biological weapons is again a live issue. This document presents principles to guide individual scientists and local scientific communities who may wish to define a code of conduct for their own use. These principles represent fundamental issues that should be taken into account when formulating codes of conduct. They are not intended to be a comprehensive list of considerations. These principles have been endorsed by the national Academies of science, working through the InterAcademy Panel, whose names appear below.

1. Awareness. Scientists have the obligation *to do no harm*. They should always take into consideration the reasonably foreseeable consequences of their own activities. They should therefore:

– always bear in mind the potential consequences – possibly harmful – of their research and recognize that individual good conscience does not justify ignoring the possible misuse of their scientific endeavor;

– refuse to undertake research that has only harmful consequences for humankind.

2. Safety and Security. Scientists working with agents such as pathogenic organisms or dangerous toxins have a responsibility to use good, safe and secure laboratory procedures, whether codified by law or by common practice.

3. Education and Information. Scientists should be aware of, disseminate and teach the national and international law and regulations, as well as policies and principles aimed at preventing the misuse of biological research.

4. Accountability. Scientists who become aware of activities that violate the Biological and Toxin Weapons Convention or international customary law should raise their concerns with appropriate people, authorities and agencies.

5. Oversight. Scientists with responsibility for oversight of research or for evaluation of projects or publications should promote adherence to these principles by those under their control, supervision or evaluation.

Appendix 4.2

Code of conduct on biosecurity in The Netherlands

BASIC PRINCIPLES

The aim of this code of conduct is to prevent life sciences research or its application from directly or indirectly contributing to the development, production or stockpiling of biological weapons, as described in the Biological and Toxin Weapons Convention (BWC), or to any other misuse of biological agents and toxins.

TARGET GROUP

The Biosecurity Code of Conduct is intended for:

1. professionals engaged in the performance of biological, biomedical, biotechnological and other life sciences research;
2. organisations, institutions and companies that conduct life sciences research;
3. organisations, institutions and companies that provide education and training in life sciences;
4. organisations and institutions that issue permits for life sciences research or which subsidize facilitate and monitor or evaluate that research;
5. scientific organisations, professional associations and organisations of employers and employees in the field of life sciences;
6. organisations, institutions and companies where relevant biological materials or toxins are managed, stored, stockpiled or shipped;
7. authors, editors and publishers of life sciences publications and administrators of websites dedicated to life sciences.

Rules of conduct

RAISING AWARENESS

- Devote specific attention in the education and further training of professionals in the life sciences to the risks of misuse of biological, biomedical, biotechnological and other life sciences research and the constraints imposed by the BWC and other regulations in that context.
- Devote regular attention to the theme of biosecurity in professional journals and on websites.

RESEARCH AND PUBLICATION POLICY

- Screen for possible dual-use aspects during the application and assessment procedure and during the execution of research projects.

- Weigh the anticipated results against the risks of the research if possible dual-use aspects are identified.
- Reduce the risk that the publication of the results of potential dual-use life sciences research in scientific publications will unintentionally contribute to misuse of that knowledge.

ACCOUNTABILITY AND OVERSIGHT

- Report any finding or suspicion of misuse of dual-use technology directly to the competent persons or commissions.
- Take whistleblowers seriously and ensure that they do not suffer any adverse effects from their actions.

INTERNAL AND EXTERNAL COMMUNICATION
Provide (additional) security for internal and external e-mails, post, telephone calls and data storage concerning information about potential dual-use research or potential dual-use materials.

ACCESSIBILITY
Carry out (additional) screening with attention to biosecurity aspects of staff and visitors to institutions and companies where potential dual-use life sciences research is performed or potential dual-use biological materials are stored.

SHIPMENT AND TRANSPORT
Carry out (additional) screening with attention to biosecurity aspects of transporters and recipients of potential dual-use biological materials, in consultation with the competent authorities and other parties.

Appendix 4.3

Summary of Replies to the Follow-Up Biosecurity Questionnaire

30 January 2008

In order to gain insight about further activities done by academies on the issue of Biosecurity, the 2006 Biosecurity Initiative Questionnaire has been repeated after a year. Again, the list of questions was sent to all member academies of IAP, this time divided into two groups: those who responded to the first questionnaire and those who did not. Of the 94 members of IAP we received 21 replies to the questionnaire, 11 of which were new respondents.

There were 69 signatories to the Biosecurity Statement. Part of the reason for repeating the questionnaire was to urge academies that had not yet signed the Statement, to reconsider doing so. As a result of this reminder, 2 member academies have decided to sign the statement.

Following is a list of some activities academies have undertaken in the field of Biosecurity this past year or are planning for the coming months:

Academy of Sciences of Albania:
– National Scientific Conference of GMO's

Academy of Sciences of Cuba:
– Cuban standard on Biosecurity in development

Israel Academy of Sciences and Humanities
– in preparation: legislation concerning control of dangerous biological agents
– in preparation: report on the issue of Biotechnological Research in the Age of Terrorism

Polish Academy of Sciences
– organized conference on dual use

Académie Nationale des Sciences et Techniques du Sénégal
– national code in preparation
– seminar Biosecurity and National Capacity Building in the Ummah, Dakkar March 2008

Zimbabwe Academy of Sciences
– code of conduct developed

The following are some observations made by respondents that might be interesting to discuss further:

– most African countries do not give high ranking to a possible threat, as they are not involved in making biological and toxin weapons
– international coordination of activities in this area will be extremely valuable
– collaboration and technology transfer between scientists in developing and developed countries might help developing countries to get more involved and raise the awareness
– more seminars, both national and international, should be encouraged and initiated
– restrictions on sharing information can potentially affect some positive developments for alleviating biosecurity issues

5
Biosecurity at the OECD

David B. Sawaya[1]

On the surface, the Organisation for Economic Cooperation and Development (OECD) seems an unlikely place to take up the issue of biosecurity. It is an institution well known for providing statistics, norms, and 'soft law',[2] not undertaking hands-on security or arms control work. Indeed some employees describe the extent of the organisation's work to outsiders as, 'covering the dossiers of just about every government ministry, except defence and culture'.

Yet, there are challenging problems in addressing concerns about biosecurity requiring the inclusion of a broad range of organisations. Securing dangerous pathogens and other biological materials poses unique challenges that require non-conventional security mechanisms. Unlike nuclear and chemical materials, many biological materials are very difficult to detect accurately using current remote sensing technologies. In general, the amount of a pathogen required to undertake an attack is much less than that of chemicals and access is much easier than for a nuclear device or weapon. Biotechnology techniques are becoming more pervasive and user-friendly, while equipment that was once advanced and only accessible to well-funded research laboratories is now relatively cheap and easily obtained (NRC 2006). Furthermore, much legitimate biotechnology research, which could provide large socioeconomic benefits, can be applied to both legitimate and malicious uses. This is often termed as the 'dual-use' potential of knowledge and technology.[3]

These factors do not necessarily make it possible to employ biological materials to create 'weapons of mass destruction' (WMD) due to the significant scientific and engineering hurdles associated with large-scale production, storage, delivery and dispersion. They do however indicate an increasing risk of small groups undertaking targeted attacks or even of well-intentioned scientists unwittingly publishing research that is later used for harm. The latter was brought to the public eye in a vivid manner in 2005 when the full genome of the extremely virulent 1918 flu virus (which killed somewhere between 20 and 100 million people) was published by an American-led research team (Taubenberger *et al*. 2005).

WMD threats are dealt with using traditional defence and intelligence activities including satellite surveillance, espionage, etc. However these techniques are much less effective in detecting biological weapons held by small groups. For instance, as Furukawa details in another chapter, the Japanese doomsday cult Aum Shinrikyo conducted seven attacks between April 1990 and August 1993. These attacks were not only unsuccessful, no one outside of the cult realised that they had occurred until the Japanese Government's investigation into the 1995 Sarin attacks in the Tokyo Metro revealed documents referring to the attempted bioattacks of several years before (see also Stratfor 2007).

However, small-scale attacks causing relatively few deaths can be very effective in causing panic as was demonstrated by the anthrax attacks of 2001 in the United States. This present day threat of the misuse of biology calls for a new approach to biosecurity; one aimed at involving all stakeholders internationally to proactively manage risks associated with legitimate research, put in place appropriate cooperation measures, and secure dangerous biological materials at their source.

This is where the OECD comes in. Since its origins in 1961, the OECD has worked with its Member Governments,[4] much as the name suggests: to promote economic cooperation and development. This often manifests itself through the creation of consensus around challenging economic issues. This consensus can lead to 'soft law' which, though not a truly binding international legal agreement, has the advantage of being easier to achieve than hard law and is flexible enough to adapt to changing conditions. It also has the potential to morph into hard law at a later date if necessary.

The OECD's history of developing soft law tools for biotechnology in the 1980s with regard to safety led to its involvement in 'biosecurity'. Member Governments have come to recognise the economic, social, and technological risks associated with not putting in place proper biosecurity measures, the need for internationalised action, and the attractiveness of the OECD as an alternative to the slow consensus nature of traditional international forum – such as the Biological Weapons Convention (BWC) – in dealing with unconventional risks posed by non-state actors. As OECD countries account for approximately 75 per cent of global research and development (R&D)[5] and gaining consensus within the OECD is quicker to achieve than in other larger international organisations, it is a useful forum to address pressing biosecurity concerns.

The following sections present, chronologically, the history of the OECD's involvement, first in biotechnology broadly and later in biosecurity (see also Table 5.1). This begins with work in the early 1980s on biosafety related to transgenic organisms, followed by work on maintaining and securing biological resources, and finally a two pronged approach providing both a top-down and bottom-up approach to biosecurity. In addition, within each section the OECD's efforts to create safe and secure scientific environment without hindering research is underlined. While reflecting on work conducted and underway, conclusions are drawn as to where gaps and challenges remain, and what role the OECD might continue to play in the future.

Early involvement in safety and biotechnology

The OECD has long been involved in issues of safety related to science-based products. This began in the late 1950s with the foundation of what would become the Nuclear Energy Agency (NEA) aimed at ensuring the safe use of nuclear power. This emphasis on safety continued in the 1960s with work on ensuring the safety of chemical products. The impetus for involvement in biotechnology came in the 1970s when biotechnology came to the attention of policymakers following the voluntary moratorium on recombinant-DNA research, and the subsequent conference in Asilomar.

This led to some of the first intergovernmental discussions concerning the use of transgenic organisms at the OECD in the early 1980s. Safety was identified early on as the most urgent policy issue involving biotechnology. A serious health or environmental incident involving biotechnology was seen as the hypothetical nail in the coffin of a technology with the potential for providing major socioeconomic benefits. Although significant differences amongst the views of Member Governments concerning the risks associated with modern biotechnologies existed, there was willingness to compromise as a result of the general consensus that the opportunities for biotechnology outweighed the risks and that research needed to continue.

The debates led the OECD to publish *Recombinant DNA Safety Considerations* (commonly known as the 'Blue Book') in 1986. The publication proposes that the risks associated with biotechnologies can be managed through good governance. By introducing the concept of 'Good

Table 5.1 Timeline of some major events shaping the OECD's involvement in biosecurity

1958	The European Nuclear Energy Agency, later to become the Nuclear Energy Agency (NEA) was formed within the OECD's predecessor organisation to ensure the safe use of nuclear power
1960s	Work on ensuring the safety of chemical products
1974	Voluntary moratorium on rDNA research
1975	Asilomar conference brings biotechnology to the attention of the policy community
1980	Biotechnology is included in the OECD's work programme for the following year
1986	Publication of *Recombinant DNA Safety Considerations* (commonly known as the Blue Book)
1992	Revised version of the Blue Book, entitled *Safety Considerations for Biotechnology* published
1993	*Safety Evaluation of Foods Derived from Modern Biotechnology – Concepts and Principles*. This publication raises the issue of 'substantial equivalence'
1994	Creation of the Working Party on Biotechnology (WPB)
1998	Japan proposes that the OECD's Working Party on Biotechnology examine Biological Resource Centres
2001	*Biological Resource Centres: Underpinning the Future of Life Sciences and Biotechnology*
2001	The September 11 and anthrax attacks occur in the United States
2002	Creation of the OECD Group of Experts on Biosecurity to the Task Force on Biological Resource Centres (need to verify when this occurred)
2004	IFP Conference on Responsible stewardship
2005	Creation of www.biosecuritycodes.org
2006	OECD/Russian Federation workshop on biosecurity and innovation in Moscow
2007	Best practices for biosecurity in Biological Resource Centres and renewed mandate in February 2007 to conduct implementation work
2008	OECD, Chinese Academy of Sciences, Inter Academy Panel workshop on biosecurity and dual-use research of concern in Beijing

Industrial Large-Scale Practice' the Blue Book, 'set out the first international safety guidelines for biotechnology applications to industry, to agriculture and to the environment,' (OECD 1992) and has become the *de facto* international standard for assessing the environmental release of transgenic organisms (biosafety). The success of the Blue Book and the increasing prevalence of biotechnology products led the OECD to continue to focus on biosafety with ongoing work on novel foods and feeds as well as the harmonisation of biotechnology regulatory oversight. This work laid out a framework for evaluating the safety of food developed from modern biotechnology based on whether or not the biotech food is, 'substantially equivalent to analogous conventional food product(s), if such exist' (OECD 1993).

A move towards science and security concerns (pre-2001)

With a *de facto* safety framework provided by the Blue Book in place allowing states to manage the risks associated with biotechnology products, the OECD continued to concentrate on encouraging scientific advance while recognising the dual-use nature of some biological material. In 1998 Japan proposed that the OECD examine Biological Resource Centres (BRCs) as, 'a key component of the scientific and technological infrastructure of the life sciences and biotechnology' (OECD 2001). BRCs are collections which house culturable organisms, or parts thereof, for preservation and use in R&D activities. The main concern was that the financial sustainability of many BRCs, in the face of increased demand, was at risk. This coupled with complicated and varied access procedures could, over time, negatively impact on biological research activities.

In addition to research sustainability, some Member Governments were becoming concerned about with the risk of misusing dangerous pathogens stored in BRCs. A number of historical conditions drove biosecurity to the attention of the international community. First, the use of chemical weapons in the Iraq-Iran War led to the creation of the Australia Group which attempts to reduce the risks of chemical and biological weapons through export controls (Matthews 2007). Second, the end of the Cold War in the early 1990s brought a host of non-traditional security issues to the fore. The defection of some Soviet scientists brought the extent of bioweapons research conducted within the USSR to light (Alibek and Handelman 1999) driving an international interest in addressing sensitive research in biology.

However, these concerns were only beginning to emerge during this timeframe, and the specific terminology 'biosecurity' is notably absent in the first BRC publication *Biological Resource Centres: Underpinning the Future of Life Sciences and Biotechnology* which was released in early 2001. The publication does note the need for protection of health and the obligation to transfer biological materials (particularly those that are toxic or pathogenic) in accordance with relevant laws and regulations, but this is referred to under the guise of '[P]rotection of human, animal, plant, and environmental, health and safety'. While these issues are clearly considered important, the issue is not necessarily raised as a call for BRCs to be used as a tool for reducing the risk of misusing biological materials, but rather as an area in which BRCs could harmonise regulations so as to facilitate international scientific exchange and cooperation.

A focus on biosecurity and a two-pronged approach (post-2001)

This perspective changed dramatically in late 2001 following the September 11th terrorist attacks and the subsequent anthrax mailings in the United States. The heightened security environment caused many governments to reconsider the priority placed on government programmes, particularly in the areas of transport security and biodefense. These events also led to a re-examination by OECD Member Governments as to how existing international fora could be adapted to best stem the threat posed by terrorism, especially non-conventional threats such as biological, chemical, and nuclear weapons.

The OECD's existing expertise in biotechnology coupled with its proven track record of bringing countries together under the banner of soft law led to its increased involvement in attempting to achieve international consensus on how to reduce the risk of misuse of biological materials and research. The OECD in cooperation with its Member Governments, led by the United States, designed a two-pronged approach to biosecurity in response to the attacks. The first, a top-down approach, builds on the existing BRC project by emphasising biosecurity and the BRC network as a means of securing dangerous biological materials. The second, a bottom-up approach, attempts to work with interested communities of scientists, policymakers, security experts, and private enterprises to foster a culture of responsibility that minimises the risks associated with dangerous materials and dual-use research. The combination of these two approaches provides a safety net that not only secures dangerous materials and involves all relevant stakeholders in ensuring security; it maintains an environment conducive to scientific advance and the use of biotechnology to advance wider socioeconomic goals.

Shortly after the anthrax attacks, an expert group on biosecurity was formed to advise the OECD's project on BRCs. Concerns were growing about the possibility of further biological attacks and securing the dangerous pathogens housed in culture collections around the world become a priority. This logic was reinforced by the revelation at the time that the anthrax strain used during the 2001 attacks was identical to a strain housed in a US military laboratory (MacKenzie 2002). As the BRC network model existed, adding security measures as a requirement for inclusion in the network would allow sensitive materials to be maintained for scientific use while minimising the risk of unauthorised and dangerous people obtaining them. However, these measures only addressed physical security measures.

Recognising that biology research is increasingly global; to be effective, the BRC network also needed to include actors that lay outside the OECD. To this end dialogue was stepped up with non-member countries and BRC meetings and discussions were opened up to 12 non-OECD countries and the United Nations. The OECD and the Russian Federation also held a joint meeting on biosecurity and innovation in September 2006. This was followed by the publication of *Best Practices for Biosecurity in Biological Resource Centres* in 2007.

Work is ongoing, and in February 2007 the BRC mandate was renewed to develop a risk assessment methodology for culture collections. France and Germany are financing demonstration projects to evaluate the benefits of implementing recommendations from the BRC project. Outreach work, particularly to non-OECD countries, also continues to be a priority, and in December 2008 the OECD, the Chinese Academy of Sciences (CAS), and the InterAcademy Panel (IAP) hosted a joint workshop on biosecurity and dual-use research concerns in Beijing.

While the BRC work is an essential step towards providing biosecurity, it is not intended to provide protection against well-intentioned scientists unwittingly conducting research or publishing results that could be used for harm. Therefore, as a complement to the BRC project, the OECD began working to support the creation of bottom-up self-regulatory mechanisms. This was very much in line with the mixed, top-down and bottom-up approaches, laid out in the Fink Report. The challenge is to craft a system that is inclusive of interested stakeholders and encourages their active participation in enhancing security and oversight without unduly hindering research.

Urged on by the United States, in 2004 the OECD International Futures Programme (IFP), which has been working on risk management issues since 2000, conducted a workshop on 'Promoting Responsible Stewardship in the Biosciences: Avoiding Potential Abuse of Research and Resources' in Frascati, Italy. Participants came from a wide range of backgrounds including government, academia, industry, public research organisations, scientific societies, and the science publishing field.

Several interesting conclusions were drawn from this gathering (Oborne 2004). First, biotechnology itself does not *per se* pose a risk, but there is a risk of misuse. Protecting against that risk needs to be reconciled with maintaining an open research environment. Second, a complex, and at times uncoordinated, regulatory network is now in place that includes international, national, and self-regulatory elements. This complex web of regulation and law is confusing and poorly understood within the scientific community. Finally, while it could be difficult to address dual-use biological research without hindering research, self-regulatory mechanisms, and codes of conduct in particular, could be potentially useful tools. This last conclusion was mirrored by the identification of codes of conduct as a potential biosecurity tool by the Biological Weapons Convention Review Conference in 2002 and the subsequent annual meeting focusing on codes of conduct in late 2005.

In an attempt to address these challenges, in 2005 the IFP created the website www.biosecuritycodes.org which aims to provide some clarity to the complex network of actors and legal instruments active in biosecurity and to support the creation of effective self-regulatory mechanisms. The site contains information on legislation, definitions, and relevant actors from private and public sectors, as well as a database of codes of conduct in use or development. The site is informally supported by an open network of individuals that contribute information and materials for posting. At the time of writing it contained 28 relevant codes from various international organisations, governments, national academies and academia, and research institutes and non-profit bodies.[6]

Remaining challenges and the future of biosecurity within the OECD

Despite the progress that has been made, considerable work remains at an international level to reduce the risks associated with misuse of biological materials and research, and progress is slow. Firstly, definitions need to be aligned among nations, and terminology standardised. Secondly, the double nature of biosecurity measures must be recognised: physical security of potentially dangerous biological materials versus tools to address broader dual-use concerns for information and research. Thirdly, it is important to move forward with established processes to create international agreements. The OECD assists in all these categories of action with its 'soft law' approach to consensus building and maintaining conditions conducive to scientific advance.

Definitions

The first major challenge will be to frame the biosecurity debate with robust definitions. The urgency of this challenge was echoed by Georgi Avramchev, Chairman of the 2008 Meeting of States Parties to the BWC, in a statement to the UN General Assembly in October 2008 (UN 2008). Resolving the question of how biosecurity is defined, and how it differs from biosafety, is essential to future progress. This may appear to be a mere problem of semantics, but common understanding of terminology could have a major positive impact on strengthening biosecurity internationally.

This is so because robust definitions are the corner stone of any strong international agreement. In order for countries to agree to take collective action on a specific issue, it is imperative that they all agree on what actions are needed and the extent of those actions that the agreement entails. Without such common understanding, some countries may not take all the necessary measures creating gaps in the system while others could overact wasting scarce resources. Furthermore, the way in which an issue is defined identifies for government what departments, ministries, or agencies need to be involved in a solution and facilitates a realistic assessment of what resources are required to address the challenge.

A lack of well understood definitions for biosecurity could also lead policymakers to erroneously develop ineffective strategies to ensure it. Ostfield (2008) notes that the use of terms such as WMD and chemical-biological-radiological-nuclear (CBRN) may lead to an ill-advised fusion of strategies to address these threats, 'rather than recognising the unique nature of biological materials and biological threats'. Since they overlap to some extent, the measures required to ensure bio-safety and biosecurity are different; a similar case could be made for the improper use of these two terms. If poorly understood and used interchangeably, policymakers and lab directors may mistakenly believe that they have addressed both biosecurity and biosafety through implementing measures for only one.

The OECD has defined biosafety and biosecurity as follows:

- **Biosafety** – The safe handling practices, procedures and proper use of containment facilities to prevent accidental harm caused by living organisms either directly or indirectly to individuals within laboratories or to the environment.

- **Biosecurity** – Measures to protect against the malicious use of pathogens, parts of them, or their toxins in direct or indirect acts against humans, livestock or crops.[7]

An informal survey by the author of six languages, including three that use Latin script (English, French, and Italian) and three that do not (Chinese, Japanese, and Russian), was conducted on the use of biosafety and biosecurity. The results, shown in Table 5.2, indicate that much work remains to harmonise terminology. Indeed many of those interviewed, including professional interpreters, noted that it was difficult to describe the precise usages of the terms because they were often used in a vague and sometimes seemingly interchangeable ways. This poses challenges for translation and interpretation in international fora, and ultimately for crafting international agreements.

A review of English language literature and discussions with interested parties makes it abundantly clear that there is no consensus around the OECD definitions presented above. Almost all would agree that there is a difference between the two terms. This comes from the difference between the root words, safety and security, that though often used interchangeably are commonly understood in English. People also generally agree that biosafety had something to do with laboratory containment and the protection of individuals and the environment. This however is where the similarities end.

As documented in other chapters in this volume, the term biosecurity is used by many different actors in many different ways. The multitude uses of biosecurity in English may explain why, although biosafety is included, biosecurity is absent from the *FAO Glossary of Biotechnology for Food and Agriculture*.[8] The confusion has led some in the arms control and security communities to propose scrapping the term altogether, or surrendering it to another group's usage, in favour of a potentially less ambiguous expression such as pathogen security.

French and Italian pose similar challenges to the use of the terms biosecurity and biosafety. Neither language makes a distinction between safety and security in common language use. As agreements, laws, and regulations must be put in place, this is tantamount to having a confusion between 'safety' and 'security' in areas of government responsibility. It is however possible to distinguish between biosafety and biosecurity, but these are seen as technical words and their use is mostly reserved to scientific documents. In French, the translation issue is further complicated by the fact that the translation of biosafety, *biosécurité*, is very similar to, and could easily be confused with the word biosecurity in English.

Analysing the use of terms in languages that do not use the Latin alphabet is more challenging due to the difficulty of translating alphabets and characters. In all three languages examined (Chinese, Japanese, and Russian), there is no commonly understood difference between the terms safety and security. In Chinese, biosafety is used to encompass roughly the activities of both biosafety and biosecurity as defined by the OECD. In Japanese, both terms can be used directly through their conversion into Japanese through the transcription system known as 'katakana'. There does not appear however to be an agreed upon definition for the Japanese terms. Biosafety is used to refer both to good laboratory practice and environmental protection, while (similarly to English) biosecurity is used for everything from the use of biometrics, to the protection of animal health, to protection against bioterrorism. Russian is the language where the usage of the two terms most closely mirrors that of the OECD definitions. However, this is only a well understood distinction within the Russian scientific and arms control community, and may not encompass non-state or non-malicious actors, such as terrorists or unwitting scientists. China, Japan and Russia all have important biological research capacities and their inclusion in any international agreement on biosecurity will be essential. Without a common understanding of these terms, compliance and national implementation of any agreement could be ineffective.

The resolution of a definitional issue such as this will not come easily and is bound to take time to resolve. The key will be bringing the right people together to create international consensus on definitions for use in all international fora. This includes representatives of central governments, senior scientists and academics, members of the relevant business communities, healthcare officials, and the relevant international organisations (e.g. BWC, Food and Agriculture Organisation, Interpol, OECD, World Health Organisation). As the debate moves forward, the use, maintenance, and improvement of online tools such as the biosecurity website created by the IFP could be a potentially powerful tool for facilitating the debate and disseminating results.

Addressing dual-use research

The next major challenge that confronts the development of an effective international biosecurity regime is how it would address dual-use research here, as defined by the Fink Report.[9] As noted above, much biological research is inherently dual-use. For instance, a team of Chinese researchers recently published work showing that the H5N1 avian influenza virus could be rendered significantly more virulent by removing a

Table 5.2 Usage of 'biosecurity' and 'biosafety' in select languages

Language	Use of biosecurity and biosafety
Chinese	In Chinese the words biosafety and biosecurity correspond to a single term, '*sheng wu an quan*' (represented by the characters '生物安全'). This encompasses both safety measures (*e.g.* those used during research or in the approval of biotechnology products) as well as security procedures to protect against malicious use. The root, '*an quan*', is used in common language for both safety and security and understood according to the context in which it is used.
English	Biosafety and biosecurity are two distinct terms stemming from the distinction between safety and security in everyday language. Despite this distinction however, the two words are often used interchangeably. In addition, the word biosecurity is used in various ways by different communities. In some areas it is used to refer to the protection of biodiversity from invasive species and in others it is in reference to the protection of livestock from disease.
French	It is possible to make a distinction between biosafety (*biosécurité*) and biosecurity (*biosûreté*). These terms would not be used in common language however and the difference between the root terms (*sécurité* and *sûreté*) is not equivalent to that of safety and security in English.
Italian	Italian does not commonly make a distinction between security and safety. However, in the context of the Italian *Comitato Nazionale per la Biosicurezza e le Biotecnologie*, the term biosecurity (*biosicurezza*) is used to define oversight of risks derived from the use of 'biological agents'. The term biosafety has been found in some official documents, but this is drawn directly from English and is used within the context of the potential risks associated with GMOs.
Japanese	The terms biosafety (バイオセーフティ) and biosecurity (バイオセキュリティ) are available as 'katakana', or the transliteration of foreign words into Japanese. Both terms are used differently according to context. Biosafety, for instance, within the scientific community is used to refer to good laboratory practice, while at the legislative level it refers to protection against invasive species. Biosecurity is not used in any government texts, but it has been used by the poultry industry to refer to measures to protect against infectious pathogens or viruses, by an insurance company in regards to countermeasures to a bioterrorism attack, and a by the banking industry in reference to a biometric ID system.
Russian	There appears to be a distinction between biosecurity and biosafety, but this differentiation may only be understood within the Russian scientific/arms control community as there is no clear distinction between safety and security in everyday Russian. While the Russian terms would generally correspond to those proposed by OECD, it is not clear that biosecurity could be used to refer to non-state actors or regulations on scientific research.

sequence of 15 genes. The research was undertaken to examine the significance of a naturally occurring modification that had been noticed in some influenza populations (Long *et al*. 2008). These results could provide important information essential for the development of protections against emerging viruses. However, with the information provided in the paper, a reasonably competent technician with the proper equipment could use the results to either select or create a more virulent strand of the H5N1 virus. While mass production and dissemination of such a virus would be a challenge today, it would not be impossible for a determined group to use this to cause illness and death while also creating a panic.

A wide range of possibilities are available to deal with the potential threat posed by dual-use biological research. These could range from a very strict top-down oversight that could require approval prior to the publication of research results and/or the registration of scientists, biological materials, and research tools to maintaining current regulatory frameworks without any modifications specifically aimed at enhancing biosecurity.

Scientific openness is a key to the efficient advance of science,[10] and overly stringent security controls would hinder research. Likewise, a *laissez faire* approach could result in the malicious use of knowledge and materials that would be detrimental both for society and science. Therefore, the optimal result is likely to fall somewhere in between a totally open and a very restrictive approach. This would combine some elements of a top-down biosecurity structure, which do not unduly hinder science, and a bottom-up approach that encourages stakeholder education and participation.

The design of such a system will require significant planning and a properly crafted approach must take into account the effectiveness of the individual pieces and the combined effect of the system. At the same time, it has been noted that any new regulations need to be implemented with due consideration to the already large amount of safety and security procedures already in place (Lentzos 2008).

For example, there are many unanswered questions related to the implementation of codes of conduct for life scientists. Are codes sufficient tools to protect against the risks posed by dual-use research? If a code were to be implemented, how would it be developed? Could it be intertwined with existing procedures and regulations, and if so would this be best done at the national level, through the university system, or otherwise (Rappert 2007)?

The decision of what oversight mechanisms to choose and how to implement them should be based on a thorough analysis of the costs and benefits of the proposed options. Although it is often necessary to ensure public safety, regulation can be very costly. For example, following the 2001 Anthrax Attacks in the United States, the *Public Health Safety and Bioterrorism Preparedness Act of 2002* was adopted. This law put in place three regulations[11] that established a list of 'select agents and toxins' and required registration as well as verification of minimum-security levels of facilities containing these agents. A regulatory impact assessment found that first year compliance costs ranged from USD 1 million to USD 4 million, with annual maintenance costs thereafter from nearly USD 100,000 to up to USD 700,000 per major research establishment. Regulatory cost information is also available concerning the United Kingdom's *Anti-terrorism Crime and Security Act* (2001) which put in place similar regulations. In this case, there were costs to laboratories, but they were limited because the new regulations piggy-backed on previous legislation (House of Commons 2003).

While costs of this magnitude may only represent a small share of operating expenditures for large research facilities, these could be unbearable for smaller facilities with more modest resources. This could, on the one hand, ensure that only facilities that are sufficiently resourced to provide adequate biosecurity remain operational. On the other hand, if regulations are too stringent, the closure of some facilities could result in a reduction of scientific productivity and ultimately innovation. This problem could be compounded at an international level if the countries involved contain strong R&D capabilities. The United States' 2002 bioterrorism law also included regulations that increased security on the transfer of pathogens and toxins among research facilities. There is evidence that this has had a negative impact on research in some English laboratories that exchange biological materials with American labs (McLeish and Nightingale 2005). This emphasises the point that uncoordinated regulatory development could create a complex web of regulation that increases costs and impedes cooperation on research and the exchange of materials.

So how should one choose between the various regulatory proposals that are on the table? One potentially useful tool would be a cost-benefit review of proposals side-by-side and in a variety of combinations to determine their various strengths and weaknesses. On the cost side, this could be done through a review of the costs of the proposal to both oversight authorities and research institutes. Quantifying the benefit from more effective protection measures, which mostly comes in the form of a reduced risk of a biosecurity breach, is more complicated, but nonetheless feasible. One way of quantifying benefits would be to calculate the costs associated with a biological attack, and multiplying it by the difference in the probability that it might occur before and after the protection measures were implemented. This would need to be coupled with an effective risk assessment approach as costs and benefits will depend on the types of materials involved (e.g. smallpox versus salmonella). Although theoretical, a consistent cost-benefit approach could provide a useful tool in helping decisionmakers craft intelligent and minimally burdensome regulatory systems.

Developing cost-benefit analyses to identify optimal or best biosecurity practices is an area where the OECD could make a significant contribution. The OECD contains significant expertise on quantifying complex problems of risk and identifying best practice. Some steps have been taken in this direction to analyse the potential of codes of conduct as a biosecurity measure. A working document produced by the OECD suggests a framework for measuring the costs and benefits associated with codes for life scientists. Measurement is broken down into various categories including those associated with holding negotiations prior to development, adoption and implementation, the consequences of codes on research, risks of dual-use research, closer cooperation between actors, and changes to research priorities (Mirsaeedi 2007).

Much more work is required however as the report only suggests a framework for measurement. It does not undertake any of the quantitative analysis that would be required to translate this work into actionable policy recommendations. It is also not clear that such a framework would be useful to evaluate other biosecurity approaches. While it may be applicable to other bottom-up regulatory schemes, top-down approaches are likely to have a much different set of costs and benefits that would require an altogether different analysis. This would be an additional challenge for an analysis of policy options whose ultimate goal would be to come up with a strategy that combines the biosecurity options which minimise risks to a suitable degree without hindering science to the greatest extent possible.

It would be imprudent to use primarily cost-benefit techniques to assess biosecurity challenges, as these tools are not well adapted to such a complex lot of socioeconomic and behavioural patterns of human action. Cost-benefit approaches, in this case, are primarily a heuristic device to frame the cost issues, while integrating risk assessment techniques.

Although a useful tool to aid in policy development, cost-benefit analyses have limitations. First and foremost among these is that not all of the impacts resulting from a specific policy action will be foreseeable. This element of uncertainty implies that policies will always have to be crafted using the best available knowledge and designed in such a way that they can adapt as new information becomes available. Cost-benefit analyses should also be recognised as only one tool among many and need to be used judiciously.

Another beneficial tool which could be used and where the OECD's expertise in biosecurity could be beneficially leveraged is in risk assessment and governance. Many biosecurity risk assessment methodologies exist,[12] and stock needs to be taken of the various proposals to analyse their effectiveness. This would need to take into account what role economic and geographical differences play in biosecurity risks associated with certain pathogens, the overlap between biosafety and biosecurity frameworks, and options for risk communication and sharing risk assessment expertise. Conclusions could then be drawn about best practices for assessing the risk of microorganisms for the purpose of securing them in laboratories.

Ultimately, the goal of any risk governance framework should be to provide a suitable level of protection against dual-use concerns without hindering scientific advance or innovation. To that end, frameworks should endeavour to be forward-looking so as to identify and mitigate emerging risks.

Conclusion

The biological sciences promise to improve quality of life through the development of a variety of new applications and products ranging from new innovative health therapies to cleaner industrial production methods. Society must balance this promise against a risk that biological knowledge and resources could be misused either maliciously or unwittingly. Given the unique nature of biological materials, the threat of misuse is a global problem and any solution must in turn be global.

A robust international biosecurity framework will be a key component of any global solution to mitigating risks associated with misuse of the biological sciences. Developing this framework will require ensuring that the scope and intent of biosecurity measures are apparent to all involved through robust definitions and crafting intelligent, effective and efficient biosecurity policies, which do not impinge on innovation, based on quantifying the costs and benefits of various biosecurity measures. These are areas where the OECD's unique experience and expertise could be put to good use, but a coordinated approach will require much broader participation.

In addition to a robust biosecurity framework a coordinated global solution is needed to mitigate risk. This should include enhanced international collaboration on biosurveillance, outbreak detection, development and distribution of medical countermeasures, and response to an incident (Ostfield 2008). This will require uniting the expertise of individual scientists, businesses, national governments, and international institutions. Nothing short of a political consensus is needed to nudge forward this global dialogue among communities.

Notes

1 David B. Sawaya is a Policy Analyst within the OECD's International Futures Programme. The views expressed in this chapter are his own and do not necessarily reflect the views of the OECD or its Member Governments.

2 Soft law is 'used to describe an agreement/provisions that are so flexible in terms and nature and leave much room for discretion that they have a less binding nature. It may be used to encourage broader adhesion to a proposal' (UNEP. n.d.).

3 The US National Science Advisory Board for Biosecurity (NSABB) defines dual-use research as, 'research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel' (NSABB 2007).

4 At the time of writing there were 30 Member Countries (see www.oecd.org/pages/0,3417,en_36734052_36761800_1_1_1_1_1,00.html). In mid-2007, OECD Member Countries agreed to invite five countries (Chile, Estonia, Israel, Russia and Slovenia) to open membership discussions and offered enhanced engagement, with a view to possible membership, to five others (Brazil, China, India, Indonesia and South Africa).

5 Expressed in 2005 USD purchasing power parity (PPP) (OECD 2007).

6 See www.biosecuritycodes.org/codes_archive.htm

7 See www.biosecuritycodes.org/gloss.htm

8 The FAO defines biosafety as, 'the avoidance of risk to human health and safety, and to the conservation of the environment, as a result of the use for research and commerce of infectious or genetically modified organisms' (FAO n.d.).

9 The Fink Report notes, 'Biotechnology represents a "dual-use" dilemma in which the same technologies can be used legitimately for human betterment and misused for bioterrorism.'

10 In 2004 OECD Ministers reaffirmed their belief in the importance of scientific openness stating, 'Ministers recognised that fostering broader, open access to and wide use of research data will enhance the quality and productivity of science systems worldwide' (OECD 2004).

11 See US CDC Final Rule 42 CFR 73 and US APHIS Final Rules 7 CFR 331 and 9 CFR 121.

12 See for example www.biosecurity.sandia.gov/subpages/riskassess.html and www.cdc.gov/OD/ohs/biosfty/bmbl5/sections/SectionVI-Principlesof-LaboratoryBiosafety.pdf

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6
Clarifying Biosecurity Terminology: Recent Activities at the US National Academy of Sciences

Benjamin Rusek[1]

Introduction

The United States National Academy of Sciences (NAS), 'advisor to the nation on science, engineering and medicine', brings together committees of experts to work *pro bono* on national and international science policy issues.[2] For several years, groups within the Academy have sought to raise awareness that some life science research can be used for nefarious purposes. Addressing the so called 'dual-use dilemma' (see the Introduction chapter) became particularly significant in the US after the anthrax mailings of October 2001.

As part of the effort to address the potential misuse of life science research, the NAS Committee on International Security and Arms Control (CISAC) thought to examine the ambiguities in the meaning of the word 'biosecurity' and other associated terms. This chapter describes several activities by CISAC to address the definitions of biosecurity and related security terms. These were exercises designed to help define an expansive set of topics and issues in a critical space as well as a way to engage partners across cultures, countries, international organisations, and political ideologies.

Background

The NAS understands that scientists and technical experts have an important role to play in applying their experience to international affairs. Other organisations also value this perspective (Keynan 2008). For example, members of the Pugwash Conferences on Science and World Affairs believe that international contact between scientists, policy experts and former high level military or government employees can have an important impact on often highly complex international security problems.[3]

CISAC is a standing committee of the NAS established to apply scientific knowledge and technical expertise to international security problems.[4] Since 1980, CISAC has counted as members a mixture of esteemed scientific, technical, political, military, engineering and medical experts to function as a bridge between the US and other governments at critical times when government-to-government communications are difficult or not feasible. The majority of CISAC's work falls under what is called 'Track II' diplomacy[5] ('Track I' being official or diplomatic interactions between governments). These Track II dialogues with international partner organisations are the key part of the NAS's link to the international community on security issues. Today, the Committee regularly meets with formal counterpart groups in Russia, China, and India as well as informally with groups in other countries. A small professional staff serves as fundraisers, dialogue coordinators and in-house experts to support the activities of the Committee.

Biological focus

CISAC leadership formed the Biological Threats Panel (BTP) in 2004 to address the scientific and technical dimensions of biological weapons, bioterrorism, issues related to successful implementation of the Biological and Toxin Weapons Convention (BWC), and other contemporary challenges related to the rapid growth in biotechnology and life science research. The BTP continues work started in 1986 by CISAC's Biological Weapons Working Group (BWWG), whose initial focus was on concerns about Soviet compliance with the BWC during the final stages of the Cold War. In 2002, the BWWG began a new activity to explore how the scientific community can contribute to preventing destructive applications of research in biotechnology and undertook a series of international consultations to examine the range of existing national and international schemes to address biological threats.

This work and that by other groups at NAS led to the report, *Biotechnology Research in an Age of Terrorism* (NRC 2004), often referred to as the 'Fink Committee' Report after its chair Dr. Gerald Fink. That report and the follow-on study *Globalization, Biosecurity and the Future of the Life Sciences* (NRC 2006) recognised that effective steps to curb the potential misuse of biological research would need to be undertaken internationally. Biological research is a global enterprise and thus any meaningful approaches to address the threat must ultimately be global as well.

These reports were useful for framing the dual-use biotechnology discussion in the US and abroad. The reports recognised that an essential first step to addressing the problem is raising awareness through engagement with the international scientific community. Most life scientists have had little experience with biological weapons or bioterrorism issues and therefore little reason to consider the potential misuse of their discoveries. Education is also needed, both about the nature of the problem and about the responsibilities of scientists to address and manage the risks.

Biosecurity terminology

Starting in 2005, several small Carnegie Corporation of New York[6] 'Biosecurity Challenge' grants allowed CISAC's Biological Threat Panel to build on the NAS reports and activities and organise meetings to explore other aspects of biological risk. One aspect of the problem identified by the Panel was the ambiguous definition of 'biosecurity' and related terms across languages, cultures and disciplines.

The lack of common terms to describe the problem is one of the immediate difficulties that arise in a discussion of the potential misuse of life sciences. The term 'biosecurity' presents many difficulties in this regard. No such term exists in some languages and in many languages when 'biosecurity' is translated, the result is often the same word or expression that is used for 'biosafety' – a different concept. French, German, Russian, and Chinese are all examples of languages where this is an immediate practical problem. In Mandarin Chinese, for example, *shengwu anquan* means biosafety and a specially created word, *shengwu anbao* means biosecurity (Wang 2007). But recently, when researcher Michael Barr interviewed Chinese scientists, he found that many use *shengwu anbao* to refer to biosafety (Barr 2008 and his chapter in this volume).

Even more serious, as noted in the Introduction for this book, the term biosecurity also provokes another major concern. It conveys a different meaning to audiences at different times and in different places. For example, to many, biosecurity refers to the obligations undertaken by states adhering to the Convention on Biodiversity and particularly the *Cartagena Protocol on Biosafety*, which is intended to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology.[7] Biosecurity can also relate to gene flow between manufactured and wild relatives and is also used in the context of ownership of the means of food production.

The term may also have specific national meanings. In New Zealand, for example, it is used to describe efforts to protect the island nation from potentially harmful invasive species, regardless of whether the introduction of the organism was intentional or unintentional (see the Dunworth chapter for further details). To the US agricultural community biosecurity may describe the protection of livestock from animal disease, or the control of the movement of bioagents in and out of a country, and measures that would involve restricting access to farms including inspections and quarantine of produce, food safety inspections, and the prevention of food product tampering.

The label biosecurity has been applied to efforts to protect dangerous pathogens in research laboratories or dedicated collections from theft or misappropriation by those who would use them to do harm. Both the World Health Organisation (WHO 2004) and the Organisation for Economic Cooperation and Development (OECD 2007) have produced guidelines related to practices that treat the term in this way (see the chapter by Sawaya in this volume).

The security (i.e., military, intelligence, national defence, and homeland security) and law enforcement communities often define biosecurity as the control of 'select agents' that can pose severe threats to human and/or animal health.[8] It is used where it is important to establish safeguard and security measures to keep pathogens in labs, unauthorised people out, and prevent criminal activities. A recent NAS report notes how the term is used in the US security community in its review of the US Department of Defense Biological Nonproliferation Program. Biosecurity 'encompasses all direct or indirect measures that contribute significantly to (1) preventing inappropriate persons from gaining access to materials, equipment, or technology that could be used in producing biological weapons; or (2) detecting, characterizing, or responding to outbreaks of diseases that involve biological pathogens or toxins. It is an overarching concept that includes measures taken at the international, national, and local levels that reduce the likelihood that pathogens could be deliberately misused. It encompasses, but is much broader than, biosafety' (NRC 2009).

As stated in the definition above, biosecurity is closely linked to biosafety. Biosafety includes measures to prevent accidental theft, loss, or release of an agent using physical barriers, record keeping and monitoring, training, and incident response plans. But biosecurity also describes societal and ethical issues that are not always included in discussions of laboratory practices to ensure biosafety. 'Simply stated', said two Sandia National Laboratory scientists, 'biosafety aims to protect people from dangerous pathogens, while biosecurity aims to protect pathogens from dangerous people' (Salerno and Estes 2003). The problems with the terms biosecurity and biosafety are numerous, yet no one has coined or popularised a better way to describe the broad range of activities that they cover.[9]

Advancing the International Biosecurity Dialogue: Clarifying Definitions

As previously stated, education is needed, both about the nature of the problem in the life sciences and about the responsibilities of scientists to address and manage the risks. Based on preliminary informal discussions with international partners the BTP established how broadly the issue of biosecurity terms affected the life sciences community and decided that an exploration of the definitions of key terms across the community could be an important component of awareness raising and educational efforts. The BTP organised a one-day planning meeting on January 27, 2006, titled 'Advancing the International Biosecurity Dialogue: Clarifying Definitions', sponsored by the Carnegie Corporation's 'Biosecurity Challenges' programme to address the issue.

It was not the intent of the meeting organisers to arrive at a consensus on a definition nor did they feel that it would be useful to construct universal definitions. They understood that dialogue involving the term biosecurity and biosafety is hindered to a degree across languages, cultures and disciplines (and even within languages, cultures and disciplines) because they do not have a universally understood meaning. Instead, the purpose of the meeting was to attempt to establish overlaps and areas of agreement between definitions used by different communities and determine whether further examination of this topic could contribute to reducing definitional confusion.

Biological Threats Panel member Gerald Epstein of the Center for Strategic and International Studies (CSIS) chaired the meeting. Dr. Epstein and CISAC staff[10] developed an agenda and a participant list that included more than 40 experts from different communities that use the term biosecurity or are involved in activities that fall under the heading 'biosecurity'. Representatives from academe; public health, medicine and epidemiology; intelligence; law enforcement; homeland security and civilian biodefence; national defence; the pharmaceutical industry; international development and humanitarian assistance; agriculture; environment; legislative; regulatory; and continuity of business operations communities attended the meeting in person or by tele/video conference.

The workshop began with several introductory presentations on how 'biosecurity' is used in different contexts. The participants addressed usage by the agriculture and environmental (invasive species) communities; the variety of meanings associated with US legislation and US 'select agent' regulations; language used in debates over genetically modified organisms and living modified organisms; usage or avoidance of the term in international humanitarian activities; and usage to describe business continuity in the face of pandemics. Representatives of organisations that include 'biosecurity' in their titles were asked to explain why the term was selected and their interpretation of its meaning. One participant explained that this term was useful for branding and was selected particularly to appeal to the security community. To illustrate the problem of creating a biosecurity taxonomy, participants discussed the meaning of 'bioethics' and also learned about a compendium of definitions developed within the invasive species community.

At the meeting, the OECD discussed their efforts to resolve the problem of definitional translation and use of 'biosecurity' in different languages. The OECD representative explained that all OECD countries received a survey with questions on the terms biosecurity and biosafety – what each includes, and how the terms are translated into their native languages. The sample languages included: French, Swedish, Finnish, Norwegian, Danish, Icelandic, Flemish, Dutch, German (Austrian, German and Swiss), Italian, Greek, Spanish (Iberian, Mexican, Chilean, Argentinean), Portuguese (Luso and Brazilian), Japanese, and Korean. The OECD also surveyed non-member governments including China, Taiwan, Singapore, Russia, India, and Pakistan (Hindi and Urdu), Thailand and Vietnam as well as English language usage in the US, Canada, South Africa, Australia and New Zealand (see chapter by Sawaya on the OECD).

In the workshop, participants did not attempt to develop universal definitions, but instead the discussion offered some guidance for people using the word biosecurity and some useful conclusions on what additional efforts might and might not be useful. Several themes arose from the broad spectrum of viewpoints offered during the meeting and were summarised by the Chair:[11]

- Some participants emphasised that those using the term biosecurity should be as specific as possible regarding what that word means and consider the context in which it is intended to be used. For example, one participant said he never used 'biosecurity' without an adjective (e.g., 'laboratory biosecurity' or 'pathogen security') and several said that they try to avoid the term entirely. Participants generally shared the view that if other, more specific or more precise language can be used, it should be. Anyone using the term biosecurity must be sensitive as to whether his or her audience understands the context of that communication and therefore understands what is intended by it. When the term is used to communicate between different communities that may not share an understanding of the definition, the context should be made clear and definitions explicitly provided. This is particularly important in broader communication with the public, when one cannot assume the audience will share any common understanding.

- A number of participants noted that in many cases, debates over semantics were really debates over policy, resources, and legislative authorities. Although clarifying a definition might permit a more focused discussion of the underlying issue, definitional clarity does not substitute for policy choices. The inclusive nature of the terms should not be used as an excuse to avoid clarification although it often is. One participant noted that the definitions of biosecurity are often not reconciled and different definitions of biosecurity even exist in separate parts of the same US law.
- Many meeting participants reiterated that it would not be worthwhile to try to come up with a single agreed definition of biosecurity that encompasses all perspectives, particularly since these perspectives differ with respect to questions of 'security of whom?' and 'security of what?' in ways that are not necessarily reconcilable. Moreover, since the word is already in the vernacular, it would be difficult to replace it with a new term (although, as noted, to the extent that if a more precise language can be used, it should be).
- There was a sense from many participants (although some disagreed and others did not express an opinion) that there might be value in further developing a taxonomy of the issues, perspectives, and meanings that fall under the heading of biosecurity in all fields. This might permit a better look at which aspects of the term were being handled by which communities, or were not being addressed at all.[12]
- The international ambiguity in the definition of biosecurity was a large part of the original motivation for the meeting. How biosecurity translates – or fails to translate – into other languages is a very important issue, but one that is distinct from ambiguities or overlaps in English. To the extent that one can be more precise in using the term, though, the translation issues become much more manageable.

To conclude the meeting, Dr. Epstein made several suggestions for future work. To address the more general communication problem he thought it would be useful to consider the functions of the terms biosecurity and biosafety in common discourse (as distinct from, but related to, their meanings). This would entail identifying and categorising the commonalities and differences of biosecurity and biosafety definitions from representative and/or important documentary contexts, and tabulating these commonalities or differences. He suggested that it might be a useful exercise to look for specific examples, discussions, or debates in which ambiguity or uncertainty about the meaning of biosecurity makes a difference, and then complete the exercise of providing additional clarification or understanding needed to resolve the ambiguity or advance the discussion on a case-by-case basis.

Clarifying definitions as security engagement

Biosecurity work by CISAC builds on established relationships with other national academies and science organisations abroad. CISAC had success using the discussion of ambiguous terminology to address an expansive set of key topics and issues and engage partners during several meetings after the 'Advancing the International Biosecurity Dialogue'. A project to develop a bilingual glossary opened lines of communication with new foreign experts and constructed an authoritative multi-language glossary of terms creating a lasting product that will serve as a foundation for subsequent efforts. These activities are described in detail below.

Work with Russia

After the 'Advancing the International Biosecurity Dialogue' meeting, CISAC staff learned that similar discussions on biosecurity were taking place in Russia. CISAC has frequent meetings with a counterpart group in the Russian Academy of Sciences (RAS). In 1981, CISAC began discussions with scientists at the then Soviet Academy of Sciences on technical issues related to Cold War arms control. The groups maintained the relationship through the break up of the Soviet Union and have had more than 30 bilateral meetings in total.

The Russian Government began to formally address the issue of biosecurity and biosafety domestically in October 2004. A federal government-wide commission headed by the Minister of Health and Social Development that included representatives from key ministries and agencies was set up to deal with the issue. Its mandate was to address 'such aspects as coordination of scientific research, creation of a system for early identification of dangerous pathogens, refurbishing scientific centres with new equipment, enhancing biosecurity and biosafety of facilities containing large quantities of dangerous pathogens, creation in collaboration with the customs service of a more effective system of control on the borders and on the entire Russian territory, and providing new equipment to medical centres and epidemiology control centres' (Kobyakov and Orlov 2005).[13]

At a joint NAS-RAS meeting in June 2006, CISAC staff learned about a project by the Moscow Medical Academy (MMA) to develop a Russian glossary of biosecurity terms. At the meeting, a RAS group representing the Russian medical, agriculture, research and production communities expressed interest in pursuing a project to connect the Russian language effort with American partners. Some efforts have been made to establish English to Russian and Russian to English translations of various categories of biological terms, but there has been no systematic effort undertaken to compile a glossary of these terms, and no comprehensive English/Russian glossary is currently available.[14]

Later in the year BTP members, CISAC staff and the Russian TEMPO[15] organisation held a meeting to learn about the MMA glossary and explore the scope of a joint project. The meeting detailed the development of an educational glossary for the lecturers and students at the MMA.[16] The glossary was constructed because the MMA found it challenging to communicate across communities during their work with the Russian Agricultural Academy of Sciences (RAAS) and the RAS. The glossary contains descriptions of English terms in the Russian language related to biosafety, infectious diseases, epidemiology, microbiology, genetics and social diseases. Much of the work was drawn from the Russian official agent list that is similar to the US select agent list.[17] The MMA glossary contains several definitions for biosecurity based on an index that draws from regulatory documents, treaties, and health/agriculture texts. To put terms in context it also includes multiple references for single terms that are coded according to whether the definition was derived from international law, Russian laws and regulations, or other sources.

At the meeting, CISAC staff discussed how the MMA education glossary could form the basis for a joint English and Russian glossary detailing biosafety and biosecurity terminology. The joint glossary would define 'biological weapon' in both English and Russian as a way to improve understanding within and across cultures and even within Russia. Representatives from TEMPO noted that the Russian media have defined a first stage biological weapon to include genetic weapons that could increase indigenous diseases and target ethnic groups. They said that some had mistakenly speculated that the multi-drug resistant tuberculosis epidemic in Russia had been introduced intentionally.

Another important function of an English-Russian glossary would be to clarify specific linguistic ambiguities. In Russian, viruses in the orthopox family, like ‘fowl pox’ (*ospadisterit ptits)* and ‘chicken pox’ (*ospa vetrianaia)* all use the same root: *ospa*. In addition, Russian doctors and scientists may use the word *ospa* as a synonym for ‘smallpox’ or in a colloquial or generic way for just ‘pox’. It is easy to see how a reference to an orthopox virus can become a reference to smallpox out of context. The news media can confuse the issue; a Russian outbreak from the orthopox family of viruses has been reported in the foreign press as a smallpox outbreak, which would be a truly extraordinary event. An authoritative bilingual glossary could help to clarify this ambiguity.

Representatives from the MMA, Gamalaya Institute, and the Russian Academy of Medical Sciences (RAMS) agreed to work with CISAC on the project in English and Russian and then if possible, extend the glossary beyond English and Russian to include other languages. TEMPO would bring in experts from RAS, RAMS, the Ministry of Foreign Affairs, RAAS, the Ministry of Defence and Ministry of Public Health. Though the English/Russian glossary of biosecurity terms has not yet come to fruition, working with Russia on issues related to biological security has opened up lines of communication with Russian experts on biological issues and has proven to be beneficial to progress on other Track II conversations between American and Russian groups.

Work with China

Since 1988, CISAC has conducted a Track II dialogue with nuclear scientists and policy experts in the Chinese Scientists Group for Arms Control (CSGAC), a subgroup of the Chinese People’s Association for Peace and Disarmament, a foreign policy think-tank associated with the Chinese government. Many CSGAC members work at the Institute for Applied Physics and Computation Mathematics of the Chinese Academy of Engineering Physics.

In 2006, CISAC and CSGAC agreed to pursue a joint project to produce an authoritative glossary of nuclear security terms in English and Chinese to clarify key concepts and promote greater understanding between the groups. English and Chinese working groups with members that were familiar with technical nuclear concepts carried out the project under the supervision of CISAC and CSGAC. The groups held several joint meetings in Beijing and exchanged dozens of draft lists of definitions during the 18-month project. In 2008, the working groups jointly published a final text that includes English to Chinese and Chinese to English translations and definitions. The process proved to be a useful mechanism to encourage candid discussions between the organisations. The project did not address biosecurity, but the lessons learned could be applied to future joint biosecurity projects with Chinese or other foreign partners.

The glossary of approximately 1000 terms is organised into three general categories – non-contentious terms, terms that have a meaning in one language that is different from the other language, and terms that have multiple definitions in each or both languages. The working groups carefully translated the non-contentious terms into both languages. In the glossary, these appear as paired terms with no definition. The more contentious terms required a detailed discussion of the definition and were defined. Although there was a single meaning in one language for a particular term, it was sometimes the case that in the other language, there were several possible meanings, each distinct from the other. For these terms, the working groups engaged in discussions to come to agreement on a common definition in both languages. The third category contains terms for which there are different contextual meanings within a single language and no universal definition across languages. For these terms, the working groups agreed on universal translations for each definition that might be encountered in contentious military or diplomatic discussions.

The detailed discussions about specific terms proved to be enlightening for both groups. One such exchange centred on why the famous Chinese phrase 'assassin's mace' (*shashoujian)* was not included in the original list of definitions provided to CISAC. CISAC cited the 2004 US Department of Defense (DOD) Annual Report on the Military Power of the People's Republic of China where assassin's mace is defined as: 'a range of weapon systems and technologies related to information warfare, ballistic and anti-ship cruise missiles, advanced fighters and submarines, counter-space systems, and air defense, designed as asymmetric solutions to blunt US intervention or deny access to the theater of operations' (Department of Defense 2004). The CSGAC working group responded by agreeing to define the term because of its frequent use by the US Government and Congress but did not agree with the definition as presented by the DOD. In the final text, both groups agreed to the definition: 'A type of metal weapon. Chinese classical novels describe the means of throwing the mace at the adversary unexpectedly in order to win during fighting. It is a metaphor for an adept ability or unique skill used at a critical moment' (NRC 2008). This is a significant departure from the unique war fighting method articulated in the DOD definition.

Conclusion and future work

It is not possible to completely divorce politics from discussions about sensitive issues; however, creating multi-lingual glossaries of mutually agreed upon terms is a useful tool and a relatively non-contentious way to approach and define the boundary of a sensitive issue. Discussing terms is a good way to enhance trust, identify a range of possible meanings, increase understanding across disparate groups and even open a gateway for future candid discussions and agreements between official representatives at a later date.

For CISAC, talking about terminology helped to create an enduring professional working relationship at the Track II level. Projects designed around clarifying the definitions of biosecurity terms with Russia and nuclear security terms with China made it possible to discuss controversial topics that would otherwise be difficult to discuss directly. Though interpretation will always be contextual, definitions are difficult to create on short notice. Not only have these discussions proved fruitful by resulting in tangible products including reports detailing the discussions that can be conveyed to government representatives and a Chinese-English glossary of nuclear terms, the work has opened up new lines of communication with both Russia and China. In the future, CISAC and CSGAC hope to develop a project that explores incorporating the glossary discussions into a trilateral interaction with key Russian, Chinese and American experts.

Appendix 6.1: Biosecurity taxonomy

Prior to the meeting on 'Advancing the International Biosecurity Dialogue: Clarifying Definitions', CISAC staff[18] prepared a draft taxonomy that lists many definitions and meanings of 'biosecurity' and related terms. This taxonomy is classified into categories and included below.

Comprehensive

A biosecurity guarantee attempts to ensure that ecologies sustaining either people or animals are maintained. This may include natural habitats as well as shelter and productive enterprise (especially agriculture) and deals with threats such as biological warfare or epidemics.[19]

(A) In general – The term 'biosecurity' means protection from the risk posed by a biological, chemical, or radiological agent to: the agricultural economy; the environment; human health; or plant or animal health. (B) Inclusions – The term 'biosecurity' includes the exclusion, eradication, and control of a biological agent that causes an agricultural disease.[20]

'Biosafety' is a term whose meaning shifts with diplomatic and scientific context, its two major usages relating to laboratory containment and to biotechnology hazards. 'Biosecurity' is a closely related term increasingly heard in arms control and in health and agriculture; but which also lacks a consistent usage. In animal health, it sometimes refers to preventative disease management. In Australia and New Zealand, it often refers to invasive alien species, while in the US it is increasingly used in reference to anti-terrorism measures related to agriculture ('farm security'). Still others use biosecurity to refer to access to a safe and appropriate food supply.[21]

The broad meaning of biosecurity literally means the safety of living things or the freedom of concern for sickness or disease. Another definition of biosecurity is 'security from transmission of infectious diseases, parasites and pests'.[22]

Until recently, the term biosecurity was used in the United States primarily to describe an approach designed to prevent or decrease the transmission of infectious diseases in crops and livestock…Increasingly, however, the term *biosecurity* has been applied more broadly to encompass efforts to prevent harm from both intentional and unintentional introductions of organisms to human health and infrastructure and the environment, as well as to the agricultural crop and livestock industries.[23]

The management of risks posed by organisms to the economy, environment and people's health through exclusion, mitigation, adaptation, control, and eradication.[24]

Pathogens/Counterterrorism

Biosecurity is the state which 'biodefense' protects: the active detection of threats too small to detect physically, including artificial molecules, genetic or viral agents, beyond chemical and biological agents that occur in nature or with normal bulk-manufactured techniques.[25]

Although the terms 'biosecurity' and 'biosafety' are sometimes used interchangeably, they refer to different issues. Whereas biosecurity measures aim to prevent the *deliberate* diversion of deadly pathogens for malicious purposes, biosafety measures are intended to prevent *accidental* infections of researchers or releases of pathogens from a research facility that could endanger public health or the environment.[26]

Biosecurity: Precautions taken to minimize the risk of introducing an infectious agent into a population.[27]

…Yet the FAO's [Food and Agriculture Organisation] definition of biosecurity does not include steps to protect high-consequence microbial agents and toxins against theft of diversion from biomedical laboratories and transportation systems. Moreover, the US and international systems for biosafety do not address biological laboratory and transportation security. In fact, the objectives and strategies of biosafety and biosecurity are fundamentally different.

Separating the concept of biosecurity from that of biosafety will help establish a well-understood concept that can address biological weapons nonproliferation issues. This step also would significantly strengthen the US position within the BWC. In contrast to biosafety, the objective of biosecurity is to protect facilities against the theft or diversion of high-consequence microbial agents, which could be used by someone who maliciously intends to conduct bioterrorism or pursue biological weapons proliferation.[28]

The US policy to mitigate the biological weapons threat encompasses a number of initiatives, among them the national implementation of biosecurity – that is, security systems and practices to protect dangerous biological materials in legitimate research facilities from theft and sabotage. By mitigating the biological weapons threat at the source, biosecurity aims to stop bioterrorism before it starts.[29]

Agriculture

Biosecurity is a relatively new concept and a term that is evolving as usage varies among countries with different specialist groups using it in different ways. For FAO, Biosecurity broadly describes the process and objective of managing biological risks associated with food and agriculture in a holistic manner.[30]

Biosecurity is a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) that analyze and manage 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 (GMOs) and their products, and the introduction and management of invasive alien species and genotypes. Biosecurity is a holistic concept of direct relevance to the sustainability of agriculture, food safety, and the protection of the environment, including biodiversity.[31]

The most common definition of biosecurity is 'the practical steps taken to reduce the risk of spreading infectious and contagious disease'.[32]

Definition: Embodies all the cumulative measures that can or should be taken to keep disease (viruses, bacteria, fungi, protozoa, parasites) from a farm and to prevent the transmission of disease (by humans, insects, rodents, and wild birds/animals) within an infected farm to neighboring farms.[33]

Biosecurity – Security process of preventing biological contamination on the farm.[34]

Environment

Biosecurity refers to measures that protect New Zealand's economy, environment and people from exotic pests and diseases. It includes preventing new pests and diseases arriving, and eradicating or controlling those already here.[35]

This paper has argued that biosecurity should be viewed as a key component of national security. There are some working definitions of biosecurity. The [New Zealand] Biosecurity Act does not define 'Biosecurity' but a definition has been proposed as part of the Government Estimates (1997): 'the cost effective protection of any natural resource from organisms capable of causing unwanted harm'. This is both a broad and narrow definition. It is broader than 'quarantine' that has a focus on border protection while natural resources are defined in the Act to encompass organisms, landforms and ecosystems. It is narrow in that it neglects the critical human dimensions and focuses on the economic benefits which may not reflect the critical areas of national identity and public health.[36]

Biosecurity encompasses protecting against any risk through 'biological harm', not least being the economic impact from the spread of pest insects.[37]

In the forestry sector, biosecurity encompasses three main fields of activity: forest protection and phytosanitary issues; naturalization of introduced forestry trees and their impact on ecosystems or individual species; and the release of new genotypes, including genetically modified organisms.[38]

Biosecurity: Protection of all natural resources from biological invasion and threats.[39]

Biosecurity definitions in context

Biosecurity should be recognized as a new interdisciplinary field of study which is intended to prevent or reduce the threat, use and impacts of new and emerging disease to humans, animals and plants through natural, accidental and intentional means.[40]

The Center for Biosecurity is an independent, nonprofit organization of the University of Pittsburgh Medical Center (UPMC). The Center works to affect policy and practice in ways that lessen the illness, death, and civil disruption that would follow large-scale epidemics, whether they occur naturally or result from the use of a biological weapon.[41]

This [biosecurity regime] will entail mutually reinforcing strands, which need to include: enactment of legally binding control of access to dangerous pathogens, transparency for sanctioned biodefense programs, technology transfer and assistance to developing countries to jointly advance biosafety and biosecurity, global awareness of the dual-use dilemma and the potential mis-use of science by terrorists, and development of a global ethic of compliance.[42]

The problem of biosecurity in an age of bioterrorism is how to constrain malignant applications of powerful bioscience responsibly without damaging the generation of essential knowledge.[43]

It [biosecurity] must address both the challenge of biological weapons and that of infectious disease. The right approach should benefit public health even if major acts of biological terrorism never occur. Our thinking about biological security must transcend old misplaced analogies to nuclear and chemical security.[44]

The anthrax attacks on the United States in the autumn of 2001, and the fear and confusion that followed, made clear that the country lacks a comprehensive strategy for biological security – the protection of people and agriculture against disease threats, whether from biological weapons or natural outbreaks.[45]

Scientists and the US government must work together to implement a comprehensive approach to biosecurity that addresses not only bioterrorism, but also the more common incursions of invasive alien species. This approach should also address the potential for the deliberate use of invasive alien species as agents of bioterrorism.[46]

Notes

1 Benjamin Rusek is a staff officer for the Committee on International Security and Arms Control (CISAC). He would like to thank National Academies staff members Anne Harrington and Jo Husbands, and Gerald Epstein from the Center for Strategic and International Studies, for their helpful comments on this chapter. The opinions expressed in this article are solely those of the author and do not necessarily represent the views of the Committee on International Security and Arms Control or the US National Academies.

2 More information about the institutions operating under the National Academy of Sciences, including the National Academy of Engineering, Institute of

Medicine, and the National Research Council is available at: http://nationalacademies.org/.
3 More information about the Pugwash Conferences is available at: http://www.pugwash.org/.
4 Additional information about CISAC is available at: http://www7.nationalacademies.org/cisac/.
5 The CISAC defines Track II diplomacy as interaction in which skilled and informed private citizens engage in a dialogue with the aim of promoting mutual security, conflict resolution and confidence-building.
6 More information about the activities of the Carnegie Corporation is available at: http://www.carnegie.org/.
7 Further information on the Convention may be found at: http://www.cbd.int/convention/ and on the Protocol at: http://www.cbd.int/biosafety/.
8 Select Agents are "agents that [the US Department of Health and Human Services] considers to have the potential to pose a severe threat to human health." See: http://www.selectagents.gov/NSARFaq.htm#sec1q3. The current list of select agents is available here: http://www.selectagents.gov/resources/List%20of%20Select%20Agents%20and%20Toxins_111708.pdf
9 A taxonomy of biosecurity definitions is included in Appendix 6.1.
10 Saharah Moon Chapotin a Christine Mirzayan Science and Technology Policy Graduate Fellow at the National Academies (now at the United States Agency for International Development) worked with the author and other CISAC staff to help organise the meeting.
11 Points taken from a Chair's Summary prepared by Gerald L. Epstein immediately after the meeting and incorporated into an internal meeting summary prepared by CISAC BTP staff.
12 The taxonomy of biosecurity definitions included in Appendix 6.1 was prepared by Saharah Moon Chapotin and CISAC staff and distributed to participants in advance of the meeting.
13 Subsequently some Russian experts have criticised the effort stating that the programme suffered from a lack of funding and that 'there are no "real, constructive programs" among Russia, the United States and Europe for cooperating to counter the threat of biological terrorism' (Global Security Newswire 2005).
14 Other groups in Russia have called for a glossary. In 2005 Russian PIR Centre (Center for Policy Studies) scholars state a 'common glossary of terms of biosecurity by Russia and Western experts could pave the way to further more substantial cooperation and ensure that both sides at least have a common understanding. Based on that further steps could be taken, including scientific exchanges, transparency and confidence-building measures, and creating commercially viable and mutually beneficial joint ventures…such a measure in theory would greatly streamline cooperation and increase its effectiveness.' See Kobyakov and Orlov 2005, p 16.
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16 Glossary of Biosafety Terms published by the Anti-Plague Institute in Saratov.
17 See endnote 8.
18 Saharah Moon Chapotin worked with CISAC BTP staff to prepare this list of definitions.

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Part II

In Comparison

7
The Importance of China as a Biosecurity Actor

Michael Barr

Introduction

Any discussion of China and biosecurity cannot omit the well-known fact that the Chinese were victims of one of the worst biowarfare campaigns of the twentieth century. During the Second Sino-Japanese War (1937–1945), Unit 731 of the Japanese military dropped plague-infected fleas, aerosolised anthrax, and cholera and typhoid cultures across the country (Guillemin 2005). It is estimated that hundreds of thousands of civilians and military personnel were killed as a result. Although these attacks occurred more than a half century ago, Chinese collective memory of them remain strong and are kept alive through both political and cultural representations. Since becoming a signatory to the Biological and Toxins Weapons Convention (BWC) in 1984, Chinese statements to the Convention have repeatedly referred to its victimisation. On a more public level, the 1987 film *Men Behind the Sun*, served as a graphic depiction of the bioatrocities committed by Unit 731. The movie's explicit portrayal of Chinese suffering at the hands of the Japanese Imperial Army caused public outrage in Japan and led to death threats against the film's director. More recently, memories of biowarfare surfaced in 2003, when 29 people were hospitalised after a construction crew in north-east China inadvertently dug up Japanese-produced chemical shells that had been buried during the war.

In addition to these historical considerations, China is a crucial player in contemporary biosecurity negotiations for at least four reasons. Firstly, China has been the source of numerous emerging and re-emerging infectious diseases, SARS and H5N1 (avian influenza) being the best known. Farming practices and the live handling of fowl in southern China provide an ideal environment for viruses to jump species. Added to this, rapid urbanisation and heavy migration from the countryside to cities means that outbreaks could potentially spark epidemics as migrants introduce diseases into new populations. Beyond these risks, the fact that China is a source of disease outbreak also means that the number of laboratories in the country working with high risk disease pathogens will remain large, thus increasing the chances for accident or deliberate misuse.

Secondly, of equal importance to China's role as an international biosecurity actor is the burgeoning growth of its civilian and military life science and biotechnology industries – a growth perhaps best symbolised by the success of Chinese scientists in 2002 in decoding the rice genome. Massive government investment and incentive schemes have helped to lure back overseas trained scientists, resulting in a proliferation of labs. By 2000, Beijing-based genomic centres were estimated to have had more sequencing capacity than France and Germany combined (Schneider 2003). More recently, the OECD puts Chinese levels of investment in scientific research and development at US$115 billion, behind only the US and Japan, with a sustained annual growth rate of 18 per cent from 2000 to 2005 (OECD 2007). These trends will continue since Chinese leaders have sought to promote the life sciences as a key factor in the sustained growth of the national economy – and, crucially for biosecurity purposes, in its national defence. A parallel development to the trends cited above is military-related life science research. Data is hard to obtain as Beijing maintains strict control over information deemed to have security related implications. But as Cheung (2008) has shown, the civilian and defence economies are increasingly integrated to form a dual-use technological and industrial base. At the same time, the Chinese military have sought to reduce the role of the state and remove bureaucratic obstacles to help foster a more competitive and entrepreneurial culture. Their goal has been to facilitate the rapid diffusion and application of technology and knowledge for defence purposes.

A third critical element in Chinese biosecurity discussions are international concerns over the effectiveness of its regulatory environment. High profile arrests and anti-misconduct campaigns have not discouraged some from cutting safety measures in order to benefit financially. The most recent case of contaminated powdered milk is only one issue in a list of health scares from poor food production. There are similar worries in regards to the life sciences since government regulations are often open to local interpretation and uneven enforcement (Medeiros 2005). In the context of medical ethics, China has been characterised by some as the 'Wild East' – a place where procedures for recruiting volunteers and ensuring informed consent come second to potential scientific gain and personal profit (Wilsdon and Keeley 2007). For biosecurity purposes, the obvious concern here is that despite official regulations, gaps in successful implementation and loose systems of accountability could possibly result in security blunders. One challenge in overcoming this problem is that, in many cases, politics and party seem to rank higher than the law. This could be seen in the initial response to the SARS crisis when many local officials misrepresented the number of cases in their area out of fear of the political consequences and of causing damage to the Communist Party's reputation.

The fourth element worth citing is Beijing's growing use of soft power – its increasing ability to mobilise its economic, cultural and diplomatic influence to shape the international agenda. In Latin American and in Africa, Beijing has successfully usurped American influence by offering unconditional aid and development packages, as well as providing a political model to other leaders about how they can promote economic expansion without relinquishing political control. This slow but certain change in the international balance of power means that the solution to many international issues, such as North Korea's nuclear ambitions and the conflict in Darfur, have required the involvement of the Chinese. In relation to biosecurity, China has begun to play an active role in promoting non-proliferation but it remains to be seen if or how it will use its new found status to more assertively influence the actual agenda of the BWC.

These factors provide some context to biosecurity in China. In what follows, I draw on observations from interviews and discussions in Beijing, Shanghai, and Guangzhou with life scientists and policymakers in infectious disease hospitals, district level Centers for Disease Control (CDC), university research labs, the Chinese Academy of Sciences (CAS), and the Ministry of Health. The chapter aims to identify the views of Chinese scientists and government officials on biosecurity matters and attempts to highlight some of the key issues which need to be considered by those involved in promoting biosecurity awareness.[1]

Terms and definitions

One way of illustrating the difference between Chinese and general Western perceptions of biosecurity is to examine the language used to describe the phenomena. The term *shengwu anquan* is used to refer to biosafety – meaning laboratory procedures and policies aimed at reducing accidental exposures. Biosafety includes instructions on how to work with, store, and export pathogens and toxins properly in order to avoid accidents that could be harmful to people, animals, and plants. The term *shengwu anbao* signifies biosecurity – referring to the wider societal issue of the protection and control of pathogens and toxins to prevent their deliberate theft, misuse, or diversion for the purposes of biological warfare or terrorism. Biosecurity includes efforts to prevent and contain infectious disease outbreaks. It includes researchers' personal knowledge, choices and behaviour, as well as society's collective responsibility to safeguard a population from the dangers of pathogenic microbes.

As Wang Qian (2007) notes however, proper use of the terms tends to create some confusion amongst scientists and policymakers, in part since *shengwu anbao* is a newly created word. In practice, I found that many respondents were not familiar with the new term and offered widely varying opinions about what they thought it referred to. Often when *shengwu anbao* is used, it is meant to refer to issues of safety, not issues regarding dual-use or biosecurity *per se*. In addition, there seems to be a divergence in awareness depending on where one works. I found that scientists at large academic facilities tended to be slightly more aware of the new phrase and of the issues associated with it, than were scientists at smaller hospitals and district level CDCs. As we will see below, usage of these terms reflects the fact that whilst laboratory safety is on the increase in China, there remains little knowledge about the issues of dual-use or about the general security implications of biological research.[2]

Infectious disease as security concern

The difference in terminology points to another fundamental issue – that is, how Chinese microbiologists define a biorisk or a biosecurity concern. Whilst there is much fear (especially in the West) of a bioterrorist attack, the biosecurity worries in China are somewhat different. The present discourse in China is less about potential attacks than about dealing with the current and present danger of naturally occurring infectious disease outbreaks. One scientist, only half jokingly, told me that while America has many enemies, China did not – the implication being that concerns over bioterrorism were far down their list of priorities. This view was echoed by a senior director in the Ministry of Health, who had responsibility for emergency planning. His view was that infectious disease represents an 'every day' concern and that the primary challenge for his office was not the risk of attack but rather raising public awareness about disease risk and finding the resources to develop effective systems of disease prevention and outbreak response, especially in lesser developed regions.

That disease constitutes the main biological risk in China is not a surprising finding given the history of outbreaks in the country. Much has been written about the 2002/03 SARS epidemic, which infected over 8000 people worldwide and killed approximately 800. Since then, Chinese authorities have established a sophisticated disease surveillance system and a public health network that links national authorities to rural areas, where many of the vulnerabilities lie. This system allows authorities at the Centre for Disease Control and Prevention in Beijing to monitor sickness and disease patterns across the country so little intervention time is lost should an outbreak occur. As mentioned in the introduction of this chapter, the countryside is an important front in China's war on disease since the rural healthcare system has been weakened by 20 years of privatisation and fiscal decentralisation. This means that over a hundred million migrant labourers lack basic health coverage, and may be reluctant to seek treatment if unwell. This, in turn, increases the risk that a disease could be transmitted from rural to urban areas since outbreaks of many conditions tend to start in rural areas due to live animal markets and consumption patterns. SARS, for instance, is widely believed to have begun in civet cats, a delicacy in some parts of China. These twin facts – inequitable service delivery and a floating population – pose significant biosecurity-related risks, which the government has only recently begun to address through a greater investment in health insurance and rural development schemes (Kaufman 2008).

Site visits are a dramatic way to appreciate these new schemes to improve disease prevention and preparedness. In visiting the Beijing CDC, I learned that nearly one half of the 18 district labs (including both city and outlying areas) were in the process of constructing new facilities. Many of these upgrades include the installation of higher level biosafety labs, which will allow for more dangerous pathogens to be handled and stored. These higher level labs require more stringent training and safeguards for researchers and also carry the chance of greater consequences should something go awry. Such labs are not limited to Beijing. In Shanghai, the national government devoted one billion RMB to establish the new Shanghai Public Health Clinical Center of Fudan University. Formerly known as the Shanghai Infectious Disease Hospital, the Centre was expanded, re-named and re-located to 33 hectares of land, one hour outside the city (its move was, in part, because of urban residents' concerns about living next to such a facility). The Centre boasts a staff of more than 700 and houses Shanghai's first BSL-3 lab as well as a 500 capacity infectious disease hospital, with an extra 100 beds available in case of emergencies.

China's recent growth in advanced, well-regulated laboratories signifies the depth of the impact SARS has had on Chinese perceptions of biosecurity concerns. One microbiologist and biosecurity expert at the Chinese Academy of Medical Sciences explained to me that SARS was as important to China as the September 11th terrorist attacks were to the United States. He felt that the events were comparable in terms of their political, economic and psychological fall out. Although the Chinese economy continued its pattern of overall growth for 2002/03, the outbreak hit service industries such as retail and tourism particularly hard and temporarily damaged levels of investor confidence in the country (Rawski 2006). It is important to bear these points in mind when considering which issues the Chinese attach priority to, what they decide to invest in and, crucially how they assess and handle emerging national security risks. It is worth noting here that compared to their counterparts in the US and EU, Asian-based life scientists (including those in lesser developed areas of China) report that a lack of funds and equipment, as well as delayed shipments of key viral samples, due to export controls are serious problems (Sandia National Laboratories 2006). This fact stands in stark contrast to the US, which in the words of one observer, spends 'billions of dollars on the development of speculative technologies for hypothetical threats, when that money might otherwise go towards purchasing and distributing already-extant therapeutic or prophylactic technologies that would significantly impact the global burden of disease' (King 2005).

Of course none of this is to say that Western analysts and policymakers do not take infectious disease seriously as a national security issue. The linkages between disease and security have attracted much attention recently (Kelle 2007; Davies 2008; Selgelid and Enemark 2008; Cecchine and Moore 2007). Most notably, in 2004, the BWC itself highlighted the nexus between disease and security and called for infectious disease outbreaks to be contained through early detection, strengthened networks of surveillance, and immediate response systems at the national and international level. As the UN aptly framed the issue, 'the security of the most affluent state can be held hostage to the ability of the poorest State to contain an emerging disease' (UN 2004: 14).

The point worth making here is that in China, these concerns are not merely hypothetical. The issue is twofold. First, there are the bare facts regarding the sheer number of mortalities. The death toll from infectious disease in China alone far exceeds the number of global deaths from all acts of terrorism. In 2007 alone, the Chinese Ministry of Health estimated that nearly four out of every 1000 people were diagnosed with an infectious disease – 13,000 of which died. Arguably, as Western governments consider themselves on the 'front-line' of a war on terror, China considers itself on the 'front-line' of a war on disease. Second, there is also a security risk associated with the spread of disease in politically sensitive areas, which are already prone to public demonstrations and protests. Rates of HIV and Hepatitis B, for example, are particularly high in areas such as Xinjiang in north-west China (Gu and Renwick 2008). Some Chinese officials contend that Muslim insurgent groups in Xinjiang pose one of the biggest security threats to the country. Whatever one thinks about the authoritarian tendencies of the Chinese leadership, the point here is that from Beijing's perspective, there is a definite link between disease and security, as anything which promotes social unrest and instability is a threat to the legitimacy of the Communist Party rule.

Although, as I have indicated, China considers disease to be its main biological risk and has thus invested heavily in its capabilities to study and contain pandemics, the sudden growth in this sector has also opened potentially serious gaps in biosecurity. In the remainder of the chapter, I shall examine China's role in the BWC and the merits and challenges associated with national legislative efforts to promote biosecurity.

Building biosecurity awareness

After initially criticising the BWC as a 'fraud' and an example of 'sham disarmament' for not prohibiting the actual use of biological or chemical weapons, China eventually joined the BWC in 1984 with the stipulation that it would cease to be binding in regard to any enemy states whose armed forces or allies do not observe the Convention's provisions. Unfortunately, since that time there have been some doubts as to the veracity of Chinese claims regarding its own research facilities. Although Beijing has consistently claimed that it never researched, produced, or possessed biological weapons, US intelligence believes that China maintained an offensive biological weapons programme based on technology developed prior to its accession to the BWC. These reports have never been confirmed, though they were echoed by Ken Alibek, the former director of a Soviet germ-warfare programme. He claims that China suffered a serious accident at a biological weapons plant in the late 1980s, resulting in two epidemics of hemorrhagic fever. According to Alibek, whose claim remains unsubstantiated, Soviet analysts had concluded that Chinese scientists had been attempting to weaponise viral diseases when their experiments went awry (Broad and Miller 1999).

Dispute also arose in 2002 when the US imposed sanctions on three Chinese firms accused of supplying Iran with materials used in the manufacture of chemical and biological weapons. In the same year, China's main legislative body, the State Council, passed two sets of regulations on dual-use (State Council of China 2002a, 2002b). Moves to formulate these regulations preceded US sanctions but in passing them, Chinese leaders recognised their significance in fulfilling 'China's international non-proliferation obligations' and in promoting 'normal trade and economic co-operation' (People's Daily 2002). The regulations contained measures to strengthen export controls to prevent the diversion of dual-use biological agents, related equipment, and technologies which could be used in weapons production. It also included an export licensing system and provisions for the criminal prosecution of domestically-based violators. Significantly, the export control list covered within the regulations provided an extensive list of pathogens and toxins, thus putting China in accord with control lists of the Australia Group (to which it still does not formally belong). The dual-use legislation is a good example of how China has adapted to international norms, which is befitting of its increased stature and of its emergent role in international organisations. In political science terms, it is evidence perhaps that China seeks to be a *status quo* actor. However, despite these new laws, there are of course many obstacles and challenges for the promotion of biosecurity and biosafety in China.

A good example is that in 2004, a batch of the SARS virus at the National Institute of Virology in Beijing, mistakenly thought to have been inactivated, was moved from a BSL-3 storage container to a non-regulated lab where medical students were working on diarrhoeal diseases. The breach of security subsequently resulted in eight infections and one death, as well as the temporary closure of the Institute and quarantine of over 700 individuals suspected of coming into contact with the virus. The problem was not a failure of equipment, technology, or insufficient regulations – instead, it was the result of human negligence.

One microbiologist at Fudan with an interest in security issues, refers to this problem as a laboratory without 'software'. Her meaning is that much attention has been paid to the so-called 'hardware' – the building of hi-tech labs, autoclaves, cabinets, locks, doors, and so on – while the human element has been neglected. That is, the behaviour, management skills, expert knowledge, and duties of care needed to safely operate high level laboratories have not kept pace with the introduction of new facilities.

A key point, however, is that the element of human 'software' includes much more than laboratory safety. Yet statements by the Chinese Delegation to the BWC Meeting of Experts (2008b) show that their focus is almost entirely on safety, not the wider issue of dual-use. According to their declaration, biosecurity 'education and awareness raising' refer solely to 'laboratory safety management and technical training, biosafety licensing, preparedness for health emergency and response and veterinary biosafety'. These efforts are obviously important and are to be supported. However, like other countries with growing biotechnology sectors, China has yet to fully embrace educational measures and codes of conduct aimed at addressing a broader agenda of oversight of the life sciences and how biological research might be exploited for illegitimate purposes.

A small number of top universities and scientific associations, including CAS have sought to establish an internal code of ethics which aims to promote scientific ethics, as well as the integrity and moral character of staff. CAS has also set up a special commission for scientific integrity to promote transparency, autonomy and accountability of scientific research. These types of codes are to be encouraged and broadened to specifically promote dual-use awareness. Yet it must be noted that CAS is essentially the scientific arm of the government, supported by the State Council itself, and considered to be the most prestigious scientific institution in the country. Whilst bodies like CAS may set a useful example, the real challenge lies in reaching provincial and district level laboratories, especially outside of the main urban settings, where it is harder to monitor activities. It is useful to note, for example, that a 141-page biosafety and biosecurity booklet distributed to Beijing area hospital laboratories shortly before the Olympics is dedicated entirely to *shengwu anquan* (biosafety) and disease control (Beijing CDC 2007). No mention is made of biosecurity (*shengwu anbao*) or the possibility of dual-use of facilities or research findings. Based on this evidence at least, raising biosecurity/bioterrorism awareness at the level of hospital laboratories has, unsurprisingly, some distance to go yet.

This point can be re-emphasised by again examining statements made by the Chinese Delegation at the BWC meeting (2008a). Their declarations defined 'training in biosecurity' as 'knowledge of relevant laws and regulations, licensing systems, and protective skills'. This is important of course, but knowledge of relevant laws is not enough. A further 'software' problem is the challenge of legal enforcement. This is not a new problem, nor is it unique to China. But there are no less than 53 government sponsored regulations and laws pertaining to biosecurity and biosafety in China, the vast majority of which were passed after the SARS outbreak.

With seven different government ministries publishing regulations and laws related to infectious disease, there is clearly a need for officials in Beijing to decide how best to streamline the system. As Julie Fisher aptly argues, the implementation of the new biosafety and biosecurity regulatory framework at the local level in China may well pose problems of successful implementation, 'particularly if the framework is applied, as it should be, to the full range of laboratories that work with highly contagious infectious diseases. Without a well-designed plan and resources to ensure effective implementation of regulations and oversight of practices at all levels in China', advances in biosecurity and biosafety 'will, quite frankly, serve no purpose'. (Fisher 2007: 136)

Conclusion

The objective of codes of conduct and protective oversight systems are to provide reassurance that scientists pay attention not only to biosafety in their labs, but also to the broader public health and security implications of their research. In the course of presenting biosecurity lectures to staff and students in China, it was clear that they had given very little thought to their own responsibilities in the dissemination of their work or to the wider agenda beyond disease control. In this way, my findings support Dando and Rappert's (2005) study which found that academic life scientists in the UK and elsewhere are generally ill-informed about the potential destructive use of their research findings and techniques, and tend to believe that the advancement of science is inevitable. Moreover, many of the Chinese life scientists I interviewed were not particularly concerned about the dual-use implications of their work and did not regard 'bioterrorism' or biological weapons as substantial threats. The reasons for this varied but as in the West, many scientists in China tend to view scientific progress as inevitable and generally think that pressures to publish and present findings mean that research will, one way or another, be conducted and find its way into the public domain. These findings are also in line with a recent survey of over 300 Asian life scientists that found that there was better awareness of laboratory biosafety issues compared to biosecurity and that overall, awareness levels and perceived threats about biological terrorism remained very low (Sandia National Laboratories 2006).

This chapter has highlighted the importance of China as an international biosecurity actor and drawn attention to the fact that Chinese biosecurity concerns, whilst mindful of terrorism and deliberate misuse, are nonetheless focused more on current and present dangers of disease control and prevention. However, I have also argued that good biosecurity practice also entails a need to promote responsibility for the outcomes of research and the development and effective implementation of codes of conduct, which address issues far wider than mere lab procedures. It is not difficult to imagine research findings falling – or being sold – into the wrong hands or a lab accident causing a disease outbreak or published results giving unintended assistance to those who seek to use the life sciences as weapon. Thus, developing security awareness amongst the Chinese life science community is a crucial part of strengthening the biosecurity web of prevention and ensuring that regulations are enforced in all labs and areas of biological research.

Notes

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2 My own use of the terms biosafety and biosecurity in this chapter are thus: I use biosafety to refer to issues of lab procedures and accidental exposures. I use biosecurity a bit more loosely, to refer to the collective responsibility to safeguard populations against dangerous pathogens, whether they derive from naturally occurring disease or from intentional acts of bioviolence.

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8

Dealing with the Dual-Use Aspects of Life Science Activities in Japan

Katsuhisa Furukawa

Introduction: Threats and uncertainties

Today, in Japan, the subject of bioterrorism has received relatively little attention. This is because when it comes to national security affairs, Japan is primarily concerned with the potential threat of military confrontation in Northeast Asia. This threat is most clearly represented by North Korea's nuclear weapon programmes and ballistic missiles, and the increasing tempo of Chinese military modernisation with uncertain direction. The Northeast Asian regional security landscape contrasts sharply with that of Europe where the threat of traditional military confrontation among the major powers has become far less important than it was during the Cold War era.

In matters of naturally-occurring hazards, Japan has invested significant resources in preparing for major earthquakes. Furthermore, the country has to address the enormous challenges associated with a rapidly aging society. In matters of public health, Japan's healthcare budget is chiefly aimed at coping with chronic diseases among the elderly, rather than infectious diseases. Until the concern about the potential outbreak of Avian influenza began to attract public attention, there was a general perception that the risk of infectious diseases had decreased significantly over the past decades, especially after tuberculosis infection was contained. However, many Japanese infectious disease experts have been feeling that Japan simply underestimated the potential risk of infectious diseases outbreak and that the Japanese government has not invested sufficient resources to address the challenges of infectious diseases that may appear in the years to come.[1] Such concern has mounted after Japan experienced the spread of influenza A (H1N1) infection in 2009.

In fact, at the Japanese universities, the number of programmes on infectious diseases had steadily decreased until a few years ago when the threat of pandemic influenza came to the attention of the media. Nationally, a relatively small number of human resources are allocated for infectious diseases research. Japan's National Institute of Infectious Diseases employs only about 200 experts while it performs various functions equivalent to that of the US National Institute of Health, the US Center for Disease Control and Prevention (CDC), and the US Food and Drug Administration. Public health infrastructure for infectious diseases research has been also viewed as weak. A Biosecurity Level 4 laboratory was established at the National Institute of Infectious Diseases in the 1980s, but its operation was suspended due to the opposition of the surrounding residents, and it has been run as a BSL-3 laboratory. There has been little political will to enable operation of this BSL-4 laboratory. Previously, the Japanese National Institute of Infectious Diseases sent samples of dangerous pathogens for diagnosis to the BSL-4 laboratory of the US Center for Disease Control and Prevention. After the US instituted the Select Agent List rule, however, the transfer of such samples to the US CDC has become difficult, and Japan has sought new partnerships with the BSL-4 laboratories in Europe. With increasing concern about the influenza pandemic as well as bioterrorism after 2001, the Japanese infectious disease experts and crisis management authorities are worried that the lack of a functional BSL-4 laboratory in Japan may make it very difficult for them to respond to a pandemic or bioterrorism events swiftly and effectively, which might result in a large number of casualties.

Given this context, an increasing number of experts and officials have begun to be concerned with the risks of naturally occurring infectious diseases, but only a smaller number are concerned about the potential risks involved in the misuse of life science activities. As such, the issues of 'biosecuriy' (as referring to measures to prevent the misuse of science for harm) have received fairly limited attention so far in Japan. However, with the revolutionary speed of scientific advancement, this situation has gradually begun to change. This chapter explains the challenges that Japan has faced and the efforts that Japan has made to cope with the dual-use risk of scientific activities (conceived in a broad sense), as well as the tasks to be addressed in the years to come.

Japan and biological weapons

Japan is no stranger to biological weapons (BW) issues. The BW programmes of the Unit 731 of the Japanese military from the late 1930s until the end of the Second World War in 1945 is notorious. More recently the cult organisation Aum Shinrikyo tried, but failed to develop biological weapons in the 1990s, and there have been other cases of biocrimes over the past century (Sugishima 2003).[2] Despite these experiences, Japan's attention to BW remained fairly limited until the country witnessed the US anthrax incidents in 2001. There are several reasons for this lack of engagement with BW issues.

First, after the end of the Second World War, the majority of Japan's scientific community pledged never to be involved in any research related to military programs. Indeed, the memory of the Unit 731's horrific BW experiments in China has haunted the Japanese scientific community since 1945, and any research associated with biological weapons had been regarded as a 'taboo' in Japan. This was until the anthrax incidents in the US in 2001, whereafter policymakers decided to invest in the development of counter-measures against bioterrorism.

The decision to reject any relationship with military activities by life scientists, or their so-called 'pacifist' ideological orientation, can be commonly observed in the scientific and academic community in Japan. While it is certainly a manifestation of the strong ethical pledge observed by the scientific community, it has also become a major contributing factor to blinding them to the potential risk of the dual-use aspects of their scientific activities. Since they believe strongly that their scientific experiments should be, and are directed towards the well-being of humanity, Japan's scientific community has given little attention to the dual-use aspects of their work and have a limited understanding of what this involves. The problem is exacerbated by the fact that the scientific community and the national security community rarely interact with each other, and the perception gap between these two communities over dual-use research is deeply rooted.

Additionally, many doctors and scholars involved in Japan's biological warfare programmes returned to the academic community after 1945. They took important positions at universities and in the medical community, and devoted themselves to the improvement of the public health, a reversal of their roles during war time. Most in the medical and biological science community hesitate to bring up this embarrassing memory for public discussion, and the ethical responsibility of these doctors and scholars was barely addressed publicly (Tsuneishi 1995). In many ways, the issues related to Japan's biological weapons programme have been regarded as a taboo.

Moreover, surprisingly, the BW programmes of the Aum Shinrikyo did not attract public attention. The Aum is notorious for its chemical weapon (CW) terrorism, but its BW programmes remained relatively unknown to the public. Since its biological terrorism efforts failed and did not cause any damage or casualties, there was no case for the police to prosecute. In addition, because the Japanese police's primary objective was prosecution, rather than prevention, no official police investigation was conducted to reconstruct the entire picture of the Aum's BW programmes. After the Aum Shinrikyo's sarin attacks in Tokyo subways in 1995, Japan strengthened its capabilities against chemical terrorism, but somehow, preparedness for biological terrorism fell behind until the 2001 anthrax incidents in the US.

Furthermore, there was an institutional reason behind the relative lack of attention to the dual-use risk of life science activities. In Japan, the issues related to biological research are under the jurisdiction of the Ministry of Health and Labour Affairs (MHLA) and the Ministry of Education, Culture, Sports, Science and Technology (MEXT). Both ministries have rarely handled national security affairs. They have limited human resources and little political will to address national security affairs. The MHLA is already overwhelmed by the task it has to reduce the significant national medical deficit, and has limited resources available for infectious diseases control and management. The MEXT is generally viewed as being coloured by 'pacifism' and not interested in national security affairs. At the time of writing, both ministries remain reluctant to be involved in biological weapons-related issues, with few exceptions. On the other hand, the national security apparatus, especially the Ministry of Foreign Affairs (MOFA) and the Japan Defence Agency (JDA: later renamed as the Ministry of Defence or MoD), have limited expertise in areas of bioscience. There is no biological scientist within the MOFA's arms control function. The JDA declined to be involved in BW-related research for fear of the Unit 731 memory. There was barely any institutional mechanism to bridge the national security apparatus and scientific apparatus.

Increased perceptions of the risk

Despite the attitudes discussed above, some changes have been observed over the past few years, especially since the late 1990s, in Japan's attitudes toward the dual-use risks associated with scientific activities. At least, some members of the scientific community have become attentive to such risk. This is in some ways the consequence of the fact that Japan has experienced a remarkable shift in its threat perception in general, triggered by North Korea's development of nuclear weapons and missiles and

Chinese military modernisation. Various news reports about the use of Japanese technologies by these countries' military programmes have alerted policymakers to the necessity to protect sensitive dual-use technologies.

The emerging threat of terrorism has also alerted the public to the potential capability of non-state actors to harm state and society, enabled by the proliferation of various dual-use technologies through globalisation. This is especially the case in relation to the anthrax letter incidents in the US, which followed the Al Qaeda's terrorist attacks on the United States on September 11, 2001. These events dramatically altered Japan's threat perception of non-state actors' acquisition of WMD-related materials and technologies. Later in 2008, the US Federal Bureau of Investigation concluded that it was former US Army researcher Bruce Ivins, not an Al-Qaeda terrorist, who appeared as the suspect in the anthrax incidents (although many of his former colleagues expressed dissenting views, arguing that the FBI's conclusion was wrong). In any case, these anthrax incidents are viewed as representing the possibility of how individuals can misuse biological agents to cause a panic in many countries around the world.

These developments over the past years have been gradually, but steadily, pushing the scientific community and relevant government ministries and agencies to address the complex challenges of how to manage the dual-use aspects of scientific activities, without undermining the competitiveness and vigor of the scientific community in Japan. This trend will most likely continue in the future, for several reasons.

First, there is an emerging view among the Japanese scientific community that they can no longer remain an observer on national security affairs.[3] This is partly because of the generational shift within the scientific community where the next generation, that is open to pragmatism and free from the wartime memory, has come to hold key positions.

Second, in order to address the challenges of non-traditional security threats – such as terrorism, crimes, natural disasters, or infectious diseases – the scientific community's capability needs to be harnessed. And as some scientists are involved in researching and developing new countermeasures for these threats, they have began to ponder how to manage the sensitive implications of their scientific research. In general, however, the majority view within the scientific community is that technologies will proliferate anyway and that there is not much they can do about it. There are also many who are not familiar with the concept of the dual-use risk and who do not consider it to be their problem.[4] Even so, there is an emerging segment within this community which is sensitive to the issues of dual-use risk (Global Security Institute of Keio University 2008).

Third, there has been growing pressure on the academic community from industry to be more responsible for the management of sensitive technologies for proprietary reasons. Traditionally, the Japanese academic community and universities have been driven strongly by the respect for academic freedom and international cooperation. In fact, today, most university research programs on natural science (engineering, biology, chemistry, material science, etc) cannot be sustained without the help of foreign students who often devote themselves to scientific research more sincerely than the Japanese students do. Open collaboration with international students and researchers is indispensable for the Japanese scientific community since the number of Japanese students has steadily declined as the general population declines in Japan. Thus, the academic community and universities have not been accustomed to the concept of stringent measures to protect their technologies.

This is problematic for the private industry, however, because there are an increasing number of joint R&D projects between industry and universities. In general, Japanese companies are concerned about protecting their intellectual property rights and complying with export control systems. The industry is now concerned with the relative lack of protection of sensitive technologies on the part of the academic community.

The Ministry of Economy, Trade and Industry (METI) has begun to address this problem. In early 2007, the METI circulated an administrative guidance to the Japanese universities and asked professors to be careful about granting foreign students access to R&D programs with sensitive dual-use potential. Pressed by the METI, the MEXT also agreed to this. On the other hand, however, the MEXT is concerned about how to make this guidance compatible with another MEXT policy which is to increase the number of foreign students at Japanese universities, a policy intended to strengthen Japan's international competitiveness and innovative capability. In fact, Japanese professors are at a loss as to how to make these two seemingly conflicting policies compatible with each other: accept more foreign students, but restrict their access to research programs with 'sensitive technologies' without defining what constitutes 'sensitive technologies'.

There does not seem to be any easy solution to this problem. In order to address this complex challenge, the METI established a study group on the management of information about sensitive technologies, which issued its final report in August 2008. One of its key recommendations was for universities to adopt responsible self-governance, to adopt and promulgate codes of conduct, and to institute education programmes to raise awareness about the importance of the protection of sensitive technologies.

In addition, in the spring of 2009, the METI submitted to the Japanese Diet session the draft legislation to amend the Foreign Exchange and Foreign Trade Act, which is Japan's export control-related law, and the Unfair Competition Prevention Act. One of the primary objectives of these amendments is to strengthen regulation of technology transfer which also covers universities and research institutions in addition to private companies. In June 2009, the Diet approved the bills, and the bills are slated to come into effect by the end of 2009. These amendments are not necessarily expected to introduce a strict legally-binding regulation on the dual-use research programmes at these institutions, but expected to oblige these institutions to institute responsible apparatus for relevant internal compliance programmes (METI 2009). The METI will establish ministerial ordinance to implement the amendments, which will specify the standard of institutional arrangement required for universities and research institutions.

Additionally, rapidly advancing science and technologies increasingly complicate the private sector's efforts to comply with the various existing rules and regulations governing the management of potentially dangerous materials and technologies. Perplexed by the safety implications of some of the emerging technologies, at least some private companies have begun asking for the government's instruction about the appropriate handling of new technological results in order to ensure their compliance with existing regulations and rules. However, there are an increasing number of cases where the Japanese government has not been able to provide concrete response to such inquiries.

The Japanese government's approach relies primarily on the assumption that those dangerous materials and technologies could be regulated by putting them on a regulation list. This approach may be effective in coping with the traditional weapons and technologies, but not with emerging technologies or new materials, whose dual-use implications are hard to evaluate swiftly. When such technologies or materials are put on the list, they may have become obsolete already. The technological advances clearly outpace the government's efforts for regulation. The government is feeling the pressure to cope with these new challenges.

The MHLA and the MEXT still remain relatively unaccustomed to addressing national security concerns, and have remained understandably reluctant to play a leading role in shaping an institutional framework to prevent the misuse of dual-use technologies for malicious purposes.

Despite this, since the anthrax letter incidents in the US, the national security apparatus within the Japanese government has strived to improve its preparedness steadily to deal with a terrorist attack using biological agents. The Japanese government enacted the Civil Protection Law and established the Civil Protection Plan. In addition, the Office of Crisis Management and National Security of the Cabinet Secretariat, together with local governments, have arranged various exercises to prepare for BW terrorism. The prevention efforts seem to lag behind those efforts for preparedness, on a relative scale. There is a discrepancy in Japan's efforts to construct an overall strategy to counter bioterrorism, between the prevention phase and the preparedness phase. The Japanese experts worry that unless the discrepancy is redressed, preparedness cannot be aligned with prevention effectively.

'Biosecurity' – not beyond the lab yet...

In Japan, the term 'biosecurity' often refers to 'laboratory biosecurity' (or is used to mean security measures employing biometric technologies). The Japanese government explains the concept of biosafety and biosecurity as below (Japan 2008):

> In Japan, there is no uniform definition of biosafety or biosecurity since their meanings vary according to the context in which they are used. Nonetheless, Japan views that the following concepts of biosafety and biosecurity are commonly used within the context of the BTWC:
> (i) ...Biosafety is understood as measures taken for the safety of personnel handling pathogens and toxins and of others in the laboratory, including accident prevention, as well as for preventing the contamination of people and the environment outside the laboratory through the leakage of pathogens and toxins. In ensuring biosafety, the approach of safety management is employed.
> (ii) ...Biosecurity is understood as measures taken for preventing the illicit development, acquisition and use of pathogens and toxins and relevant information and technology for purposes that run counter to the aims of the BTWC. In ensuring biosecurity, the approaches of non-proliferation and counter-terrorism are employed.

Japan's concept of biosafety and biosecurity is similar to the definition of laboratory biosafety and biosecurity used by the World Health Organisation (WHO). This concept is narrower in the scope than the definition of 'biosecurity' used by the US National Academies quoted below:

> The term 'biosecurity' is used to refer to security against the inadvertent, inappropriate, or intentional malicious or malevolent use of potentially dangerous biological agents or biotechnology, including the development, production, stockpiling, or use of biological weapons as well as natural outbreaks of newly emergent and epidemic diseases.

Japan's concept of biosecurity is not yet formulated in such a way to cover the broader issues associated with the management of the dual-use aspects of life science activities, such as code of conduct for scientists, criteria to identify dual-use research, or how to communicate sensitive research results.

In a way, this is a reflection of the current approach to manage biohazard risks in Japan: namely to regulate the management of dangerous pathogens and to ensure the safety of laboratory operation. It relies upon an agent-based approach, rather than a technology-based approach. It does not address the potential risk of emerging dual-use technologies, such as recombinant DNA experiments. When asked, many Japanese scientists and scholars express the deterministic view that it is simply impossible to regulate technologies because they will proliferate anyway. Over recent years, however, Japanese policymakers and the scientific community have been forced to tackle this challenge for several reasons as explained below.

The shift from voluntary management to legally-binding regulations to prevent biological terrorism

In December 2004, the Japanese government established an 'Action Plan to Prevent Terrorism', which called for 'Strengthening of Strict Control of Material Potentially Used for Terrorist Attacks' and 'Establishment of System to Control Pathogenic Microorganisms Potentially Used for Bioterrorism'.

Before this, dangerous pathogens were stored and managed by scientists voluntarily. However, an investigation report by the MHLA, released in October 2005, revealed a serious vulnerability in Japan's biosecurity and biosafety (MHLA 2005). According to this investigation, there were 144 facilities under the jurisdiction of the MHLA that stored pathogenic microbial organisms; this included 35 facilities that had bacillus anthrax and 87 facilities with multi-drug resistant tubercle bacillus. Surprisingly, among them, only 56 facilities had management manuals, and only

64 facilities had a central management system (Ministry of Health and Labour Affairs 2005). While the MHLA had asked these facility managers to comply with the biosecurity guideline established by the National Institute of Infectious Diseases, this expectation was not met.

Concerned with the relative lack of security at many laboratories, the Japanese government amended the 'Law Concerning the Prevention of Infections and Medical Care for Patients of Infections', for the third time in 2006 (Ministry of Health and Labour Affairs 2007). Under this revised law, legally-binding standards of laboratory facilities as well as possession, storage, use, and transportation of specific pathogens have been established. In terms of this law 49 genus, 79 strains and two toxins are placed under regulation. Contravention of the law, including facility, devices, registration of pathogens, and documentation, will be punished, either in the form of fine or imprisonment. In short, the Japanese government introduced a rule similar to the US Select Agent rule. This revised law went into effect on June 1, 2007. However, this law was initiated by national security apparatus and drafted by legal authority without consulting professional scientific experts sufficiently. As a result, this legislation invoked confusion among the public health and scientific communities, and a three-year moratorium was set for some part of this legislation.

More importantly, this law does not address the dual-use aspects of the recombinant DNA experiments. Since this law is primarily directed towards ensuring the health of the patients infected by diseases, the issues related to the management of biological agents by themselves are regarded as a 'byproduct' under this law. This may be another representation of the agent-based approach in Japan's conception of biosecurity.

Regulation lagging behind technological advance

Faced with the rapid advances in scientific research, however the Japanese government has been forced to redress the problem of this agent-based approach. According to Hiroshi Yoshikura (the chair of the MEXT Recombinant DNA Advisory Board until March 2009), there are an increasing number of research proposals involving recombinant DNA experiments, the risks of which are difficult to evaluate, even with help of the guidelines by the US National Institute of Health or WHO. Even when scientists who are concerned about the risk in their scientific experiments ask the MEXT for instruction, the MEXT officials find it difficult to respond with a clear answer. Yoshikura laments, '(the) regulation appears [to be] lagging behind the technological advance.' Yoshikura[5]

(2008) provides the following two cases of experiments to demonstrate the problem:

1. In the first case, the genome of virus belonging to a select agent virus, such as Ebola virus, was cut into component genes (including a backbone fragment that has packaging signals). They were cloned individually (sometimes in two or three) into different vector molecules. None of the clones contained more than a half of the genome. Then all of them were placed together in a cell. Infectious virions were produced but they never reproduced. They were pseudovirions. The biological risk of pseudovirions was minimal. However, all the genes were there. The recovery of infectious virus from them is not difficult with the routine technologies, particularly with the availability of negative strand RNA viruses.

   Some may claim that individual clones have no biological risk. Therefore, such clones should be made freely accessible to anybody who wants. An applicant may claim that the virions thus produced never replicate in the environment, and therefore, that the experiments should be conducted at biosafety level 1. These claims appear scientifically sound. But, in the current situation of openly accessible scientific environment, it is possible to collect different fragments from different sources to gather all the gene clones to get the full genome.

2. In the second case, vaccinia viruses carrying one or two genes of the target virus, for example HIV, had been produced and human trials had been conducted. (The vaccinia, canary pox, herpe and other large DNA viruses are good vectors on the account of their capacity to accept large foreign gene segments and of their environmental stability). Suppose there is a proposal to put more genes, even all coded genes of HIV, in vaccinia. An applicant may say 'as the HIV genome is fragmented into individual genes, the recombinant vaccinia never encodes the live HIV. Therefore, there is no biological risk so far as HIV is concerned'. However, it is possible to assume that the recombinant vaccinia may have acquired an increased risk by combining HIV pathogenicity and vaccinia's stability. But, the government reviewers are not sure of it. There may be other cases, such as recombination of Japanese encephalitis and yellow fever viruses. A certain combination of genes may produce a virus with different pathogenicity and antigenicity that is difficult to protect

by immunization. But no one can predict which type of combination will produce such a virus.

Given that the number of similar recombinant DNA experiments may continue to increase, Yoshikura argues that it is simply insufficient to try to restrict the dissemination of sensitive material and information by introducing legal regulation alone, and that it is necessary to update the existing guidance to be able to meet the scientific advances.[6]

Other laws and regulations relevant to biosafety and biosecurity

There are also other laws and regulations associated with biosafety and biosecurity in Japan. In terms of measures to prevent the proliferation of biological weapons, Japan has the Security Export Control Policy based on the Foreign Exchange and Foreign Trade Act (1949), its associated legislation, and the national BWC implementation law. In order to prevent animal and plant diseases, Japan has the Plant Protection Law (1950), the Domestic Animal Infectious Diseases Control Law (1953), and the Rabies Prevention Law (1953), all of which have been amended repeatedly. The MHLA also established a Biosafety Committee.

In areas relevant to laboratory biosafety and biosecurity, Japan has the following tools (Kurata 2007):

- the Risk Classification of Microbiological Pathogens (1976) currently administered by the MHLA
- the Rules for handling genetically modified living organisms (1979) currently administered by the MEXT
- the Regulation on the Safety Control of Laboratories handling Pathogenic Agents (1981) currently administered by the MHLA
- the Biosafety Guideline by the Japanese Society of Virology (1993)
- the Handling Rules of Microorganisms (1993) currently administered by the Institute of Animal Health of the Ministry of Agriculture
- the Biosafety Manual for Handling Microorganisms (1998) currently administered by the MEXT
- the Biosafety Guideline by the Japanese Society of Bacteriology (1999), and

- the Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulation on the Use of Living Modified Organisms (2004)

Additionally, in 1979, Japan established the recombinant DNA guideline, which is similar to the US National Institute of Health's guideline in structure and content.

When Japan became a state party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity in 2003, Japan enacted a domestic implementation legislation, or the so-called 'Cartagena Law', and the recombinant DNA guideline was replaced by this new law. This Cartagena Law legally obliges scientists to manage the dual-use risk associated with recombinant DNA experiments, at least to some extent. As Yoshikura (2008) explains:

> ...all proposals on recombinant DNA experiments, with certain exceptions, are reviewed by the internal review board (IRB) of each institution, under this law. The exceptions are those concerning recombinant DNA experiments using certain toxins and replicable viruses, which roughly correspond to the select agents in the US. They shall be reviewed by the advisory board of the MEXT.

In short, under this law, any research proposal associated with recombinant DNA experiments must be authorised both by the institution and by the government. This can be a very strong tool to oblige the scientific community to review the potential dual-use risk in their experiments. However, since the Cartagena Law's primary purpose is to protect biological diversity, its application for the purpose of counter-terrorism is limited. Concern for biological diversity alone cannot constitute a strong legal base to oblige the scientists to adopt stringent measures for counter-terrorism. In fact, many among the public health community and the national security community do not yet know this law's potential implication for biosecurity in broad terms. Also, in reality, the Internal Review Board (IRB) under this law has not been structured in such a way as to examine the risk of dual-use technologies. Many believe that there may be only a very limited number of technical experts who can examine the dual-use risk in Japan. Even so, there was an internal examination within the MEXT to examine the option of incorporating the requirement to 'prevent abuse/misuse of science and technology' into this internal review process.

Japan certainly needs a new law on biosecurity. However, there are many agencies or departments within the Japanese government that have some responsibility in relation to matters of biosecurity, and it is difficult to determine which should be the lead agency when implementing such a law. Because of this bureaucratic complexity, it is not easy to take a next step. Akio Nomoto, a member of the Recombinant DNA Advisory Board of the MEXT and professor of University of Tokyo, argues that the institution of the Cartagena Law has generated 'moral hazard' among the scientific community.[7] Previously, when the scientists and academic institutions voluntarily made the decision on whether or not, and how, to conduct those experiments that posed potential safety risks, they were far more concerned about managing such risk than they are today. After the Cartagena Law was instituted, many scientists and managers have come to take the position that any experiment could be granted as long as it is not illegal. Leaders of the scientific community have become concerned with the proliferation of such a legalistic mind-set and believe ever more strongly in the importance of the code of conduct to raise awareness among the scientists about their responsibility to manage dual-use risks.

Code of conduct: Not fully utilised for the dual-use risk

Scientific misconduct has been a serious concern in Japan. According to a survey by the Science Council of Japan (SCJ) of the Cabinet Office during the period from 1999 to 2004, misconduct by scientists included an unknown number of cases where data were fabricated, two cases where data were falsified, 26 cases of plagiarism, 14 cases of invasion of privacy, two cases where research funds were misused, and more than 80 cases where the same article was submitted to multiple journals, amongst others.

Concerned with the apparently rampant scientific misconduct, the Committee on the Code of Conduct for Scientists of the SCJ conducted another survey to investigate how the code of ethics had been operationalised at the Japanese institutions of higher education and scientific research as well as Japanese academic societies and associations. According to this survey, released in August 2006, only 13.3 per cent of respondents had already had a code of ethics in some form, while 41.3 per cent did not have any future plan to do so. The survey reported that 12.4 per cent of respondents had experienced problems related to academic misconduct, and 12.5 per cent had procedures for dealing with an allegation of misconduct, while 75.9 per cent stated that they did not (Science Council of Japan 2006).

Faced with this reality, the SCJ has decided to amend the Code of Conduct for Scientists which was eventually adopted on October 3, 2006. The Statement of the Code of Conduct for the Scientists states that, 'scientists' autonomy and integrity are now at stake.' The amended Code states, 'scientists must establish ethical norms to strictly control their own conduct, while fulfilling their obligation of accountability to society and consciously taking part in building and maintaining sound relationships between science and society.' As the 'Responsibilities of Scientists', the Code states,

> Scientists shall recognize that they are responsible for assuring the quality of the specialized knowledge and skills that they themselves create, and for using their expert knowledge, skills and experience to contribute to the health and welfare of humankind, the safety and security of society and the sustainability of the global environment (Science Council 2006).

While this Code is primarily intended to address the problems of fabrication, falsification and plagiarism, it is also clearly intended to emphasise the importance of scientists' responsibility for the use of science for 'the safety and security of society'. The Code also requests all scientific organisations 'to introduce their own research ethics programs to meet their purposes and needs, and to promote honest and autonomous activities of scientists' (Science Council 2006). The Code covers such issues as the responsibility of directors and managers of institutions, the need for ethics education programs, the mutual observation within a research group, the precautions in research process, the counter-measures against misconduct, and the establishment of a self-monitoring system. In short, the Code is drafted in such a way as to cover dual-use risks.

It is not clear how this amended Code has affected the management of scientific institutions. One SCJ member stated that the process of drafting the Code was more important than the finalised Code itself. The process provides an opportunity for relevant stakeholders to engage in intense discussion. Additionally, the Code's call for education on research ethics can become another important tool to engage scientists and students to discuss the dual-use aspects of their scientific activities. There are several examples where scientific institutions began to address the dual-use risks in their education programs, in accordance with this Code. For example, Japan's academic society associated with the International Union of Microbiological Societies (IUMS) will develop an institutional Code in accordance with the SCJ's Code as well as the IUMS Code of Ethics against Misuse of Scientific Knowledge, Research and Resources, in order to 'promote ethical conduct of research and training in the areas of biosecurity and biosafety so as to prevent use of microorganisms as biological weapons and therefore to protect public health and to promote world peace' (International Union of Microbiological Societies 2006).

Also, in 2008, under the leadership of Dr. Tomoaki Tsuchida, the Open Education Center of Waseda University started a new education program on research ethics which included the subject of the responsibility of scientists to prevent misuse of science. Moreover, the National Defence Medical College (NDMC) and the University of Bradford in the United Kingdom have been jointly developing a web-based education module resource which is scheduled to be completed by December 2009 (Dando and Yamada 2008). Upon completion, it can be used by other universities around the world to develop respective education courses for their students. The material will be posted on a website and will cover such issues as the threat of biological warfare and biological terrorism and the international regime that prohibits such weapons; the dual-use dilemma and the responsibilities of life scientists; national implementation of the BWC; and the building of an effective web of prevention. These examples are still small in number, but clearly indicate the gradually increasing awareness of the importance of biosecurity within the scientific community.

When it comes to the issues related to ethics of scientific experiments using embryonic stem (ES) cell, Japan already has a stringent legally-binding mechanism. All experiments using ES cell have been strictly regulated by law (Science Council of Japan 2000). All scientific institutions are legally obliged to establish an IRB. All proposals have to be approved by the institutional manager under consultation with the IRB. When a proposal is approved, then it will be sent to the Japanese government for authorisation. The government will ask an expert committee to examine the proposal. Any research proposal associated with ES cell research has to be authorised through this legally-binding process. One Japanese official points out that this review process may be more stringent than the ones adopted in the US or Europe. This existing institutional mechanism could potentially be used as a tool to examine the dual-use risk as well when the decision to do so would be made.

There is also an example of a university that has voluntarily adopted a stringent ethical rule. The Institute of Medical Science of the University of Tokyo has established a strict policy of internal review. When its IRB judges that some research proposal is inappropriate from an ethical perspective, the Institute prohibits the researcher from submitting the proposal to any external funding organisations, even if the proposal does not violate any existing law. This too could possibly be expanded to review the dual-use risk in the future.

Finally it is also important to engage scientists on issues of social norms. From Japan's experience of the Aum Shinrikyo, the cult organisation which attracted young elite scientists and conducted chemical and biological weapon terrorism in Japan, there were those scientists who could be detached from the reality on the ground relatively easily (Parachini and Furukawa 2007). Also, among the Aum leaders, there were those bright young scientists who had felt frustrated and disappointed with the authoritative culture of their research institutions which deprived them of the dream to become 'Albert Einstein' of Japan (Ito 2006). All in all, it is also important to improve the general management of research programmes at universities and research institutions, which constitutes a basic foundation of biosecurity.

The need for better engagement

As explained, key tools and institutional infrastructure already exist that may be useful for managing the dual-use risks of life science activities in Japan. In order to utilise their potential, however, several challenges have to be addressed.

First, the stakeholders need to know each other. There are many stakeholders relevant to biosecurity in government, industries, universities, and research institutions, but most of them do not know each other. This is exacerbated by the fact that most scientific stakeholders do not relate easily to the concept of 'security'. There is a persistent tendency among public health authorities and scientific authorities to avoid being involved in security-related affairs.

Second, the stakeholders need to learn how to communicate with each other. From the author's experience, it is not easy to engage scientists in discussions about the possibility of misuse of their scientific activities. They generally seem unhappy when somebody points out the possibility of a harmful application of their research activities. It is not a good starter for a conversation.

Third, a significant majority of the scientists are tired of administrative burdens and do not appreciate any additional regulation. In general, the Japanese scientists already feel overburdened by the existing regulations and rules.[8] Universities and academic institutions are experiencing resource constraints, and rarely have excess administrative capacity. Even those researchers who understand the importance of biosecurity argue that there has to be some mechanism to relieve their administrative burden in order to address the new challenge of dual-use risk. Government is expected to fund activities associated with biosecurity.

The author's program at the Research Institute of Science and Technology for Society (RISTEX) of Japan Science and Technology Agency has constructed a network among a few hundred stakeholders in biosecurity, including officials of all relevant ministries and agencies, and experts of universities and research institutions as well as journalists. The RISTEX programme offered seminars and conducted briefing to officials, experts and political authorities as well as members of the Science Council of Japan, in order to raise awareness among these stakeholders about the dual-use aspects of the scientific activities. This RISTEX program also invited foreign experts and officials, and arranged opportunities for these Japanese stakeholders to exchange views and information about biosecurity mutually. Such opportunities have proven significantly beneficial to advance awareness-raising since Japanese scientists and officials appreciate their interactions with foreign experts and officials. Japanese officials have been informed about, and some are even motivated by, other countries' endeavors.

From the experience of this program, scientists are not particularly interested in talking about biosecurity, but they do like to engage in discussion about advanced research experiments. As a starting point for engagement, it has proven effective to engage scientists in discussing specific advanced scientific experiments. Thereafter, dual-use issues can be naturally introduced into the discussion, as participants may more readily recognise the sensitive aspects of such advanced experiments.[9] Once motivated to engage in the discussion, these scientists and officials have come to ask practical questions about how to operationalise the concept of biosecurity in their daily management. For example, they ask what criteria should be used to find out which experiment has significant dual-use risk, or how they can possibly find an expert who can examine the dual-use risk of scientific experiments. So far, no one seems to have any good answers to these questions. Thus, there are requests for information about how these questions are addressed abroad. Japanese stakeholders want to know about concrete examples of how an internal review system has been operationalised within universities or research institutions abroad, if at all. Who does the review? How can we find staff members who understand both science and its national security implications? How do we establish a review mechanism at the universities? Should we expand the existing IRB for the recombinant DNA experiments in order to examine the dual-use risk as well? If so, how? What type of experts should be included in such a review board? Can they work together?

Norihiko Yamada, professor of the National Defence Medical College (NDMC), conducted preliminary trials to screen research proposals within the NDMC to identify the dual-use experiments with significant concern.[10] He used the 'Criteria for Review' developed by the Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology (known as the 'Fink Committee') of the US National Research Council. While these preliminary trials were not official, Yamada felt that the Fink Commission's criterion may be too broad for actual operation because all proposals simply passed this criterion. He felt that some other ones are necessary to make the Fink Commission's conclusions operationally effective. Yamada is not the only one. Yoshikura holds a similar view – that the Fink Committee's criteria alone are not sufficient from an operational perspective.[11] Additionally, Yamada felt that it was not meaningful to conduct such an internal review of research proposals at only one institution, and that collaboration among multiple institutions is required.

Even if an internal review mechanism is instituted, it would simply generate cynicism among the reviewers if such effort is isolated at one institution, and thus would be unlikely to produce any meaningful difference. As Yoshikura argues, in order to ensure those stakeholders that biosecurity measures are necessary, and not a waste of time or resources, it is essential for the stakeholders to have opportunities to exchange experience, best-practice and lessons learned, both domestically and internationally.[12] Those stakeholders can discuss and compare the relative merits and demerits of various tools, including codes of ethics, codes of conduct, statements, policy documents, and rules and regulations. Concerned stakeholders need to explore ways to develop the concept of biosecurity into operationally meaningful measures.

From the experience of the RISTEX programme, such opportunities can be best arranged through unofficial settings where officials and experts come together. Given the variety of the stakeholders and the complexity of their relationships, it is important to involve a number of governmental and non-governmental organisations. Non-governmental organisations can play a very important role as a bridge between various stakeholders on a global scale.

Finally, considering the reality of relatively limited resources available for biosafety and biosecurity in many countries, it may be wise to avoid simple proliferation of various international initiatives. In order to maximise the effectiveness of each initiative, international efforts are needed to strengthen coordination among, and streamline the duplication of, various existing mechanisms for biosafety and biosecurity both domestically and globally. Eventually, such an endeavour needs to be linked closely to existing institutional mechanisms for international cooperation, such as the international export control framework to address the issues of transfer of intangible assets or intellectual property rights.

Notes

1 For example, see remarks of Dr. Takeshi Kurata, Director-General of the Toyama Institute of Health and former President of Japan National Institute of Infectious Diseases, at the Regional Biosecurity Workshop, Singapore, 28–30 May 2007.

2 Before the Second World War, two biocrimes were recorded. For both cases, the perpetrators were medical doctors, and their motives were personal. In the first case, Teisaburo Takahashi, an otorhinolaryngologist, committed a series of biocrimes by giving confectioneries or appetiser contaminated by *Salmonella typhi* that he had cultivated to seven individuals, between 1935 and 1936, causing several deaths and injuries. In the second case, Dr. Kikuko Hirose gave confectionery contaminated by *S. typhi, S. paratyphi* A and B to her former husband in 1939, resulting in 12 people falling ill and one death. After the Second World War, a medical doctor named Mitsuru Suzuki was arrested by the police for suspected injuries utilising *S. typhi* and *Shigella sonnei*, in 1966. See Sugishima 2003.

3 For example, the Japanese Ministry of Education, Culture, Sports, Science and Technology has been funding research and development of science and technology for counter-terrorism, counter-crime and risk-crisis management since 2007, including detection technology of biological agents, explosives and dangerous articles, or simulation systems for prediction of hazardous materials distribution and damage mitigation. See, for example, Mizumoto 2008.

4 Author's meeting with the officials of the Science Council of Japan, in Tokyo, Japan, 22 September 2008.

5 Hiroshi Yoshikura was Chair of the Recombinant DNA Advisory Board, in the Ministry of Education, Culture, Sports, Science and Technology, Japan, until 31 March 2009, and Emeritus Member of Institute of Infectious Diseases, Japan.

6 Author's meeting with Hiroshi Yoshikura, Tokyo, Japan, 20 October 2008.

7 A comment by Akio Nomoto at a small group meeting to discuss biosecurity, at the Research Institute of Science and Technology for Society, Tokyo, Japan, 20 October 2008.

8 Author's discussion with Dr. Satoshi Saito of Keio University who leads the project on the Japanese biodefence and biosecurity commissioned by the MEXT, at the BWC expert group meeting in Geneva, 18–22 August 2008. Also author's discussion with Dr. Seiichi Saijo of the National Institute of

Infectious Diseases, at the occasion of the International Conference of the US National Science Advisory Board for Biosecurity in Bethesda, Maryland, USA, 4–6 November 2008.

9 For example, when the author arranged a meeting for Professor Malcom Dando of Bradford University and Dr. Brian Rappert at the Japanese National Institute of Infectious Diseases (NIID), with the specific title of 'The Life Sciences, Biosecurity, and Dual Use Research' on 14 March 2007, this meeting received fairly low interest on the part of the NIID. Despite the advertisement of this event with a relatively advanced notice, only several experts of the NIID participated in this meeting. Comparatively, when the author arranged another meeting for Professor Dando and Professor Nancy Connell of the University of Medicine and Dentistry of New Jersey, at the same NIID but with a different title of 'Select Agent Detection and Diagnosis' on 6 February 2008, about 40–50 NIID experts appeared in the meeting despite a very short advanced notice of only one day. Professor Dando and Professor Connell were able to discuss biosecurity issues in the broader context of explaining about the latest R&D of biological counter-measure against select agents.

10 Author's discussion with Professor Norihiko Yamada at the occasion of a study group meeting on BWC of the Ministry of Foreign Affairs, Tokyo, Japan, 3 June 2008.

11 Author's meeting with Hiroshi Yoshikura, Tokyo, Japan, 20 October 2008.

12 Author's meeting with Hiroshi Yoshikura, Tokyo, Japan, 20 October 2008.

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9
Biosecurity in New Zealand

Treasa Dunworth

Introduction

Surrounded by ocean and situated over 2000 kilometres from its nearest neighbour Australia, geographical isolation lies at the heart of how biosecurity has been understood and approached in New Zealand. Its physical remoteness has allowed a distinctive and unique biosphere to develop that was, and remains, relatively protected from disease. That, coupled with a moderate climate, has resulted in primary production especially agriculture, being the bedrock of New Zealand's economy. Thus, in New Zealand, biosecurity has been traditionally understood as measures aimed at keeping livestock and crops free from outside disease, although in recent decades, this vision had broadened to include general environmental protection. Reflecting this understanding, the first part of this chapter provides an overview of New Zealand's 'biosecurity strategy', showing how and why it developed in the way it did, identifying points of contention and, most significantly, demonstrating how biosecurity in this sense has become an integral part of the New Zealand psyche, both at governmental and popular levels.

The second part of the chapter shows that in New Zealand the terminology of biosecurity is avoided in security discourse, and explains this is partly due to the importance of biosecurity in the sense of protecting its agricultural sector, and partly due to a resistance to the rhetoric of terrorism. However, while the terminology is avoided, this section demonstrates New Zealand's strong tradition of opposing the deliberate misuse of the life sciences – whether that misuse is by states or non-state actors. That tradition is analysed in the context of New Zealand's broader foreign security policy, the hallmarks of which are the enduring importance of traditional alliances and unwavering support for multilateralism. However, as this section goes on to explain, New Zealand's approach to biosecurity, or indeed any security, cannot be fully understood without an appreciation of the anti-nuclear movement in New Zealand and its enduring and profound role in forging a national identity.

The chapter concludes that the dominant understanding of biosecurity has been, and will likely remain undisturbed, reflecting the fact that even as agriculture lessens in importance in terms of its overall contribution to the economy, the 'clean green' image of New Zealand has entered the national identity. The popular anti-nuclear movement has consolidated a security policy that is based on multilateral disarmament, and this too is now part of New Zealand's 'clean, green' identity.

Biosecurity in New Zealand: Keeping livestock and crops free from disease

Although the *term* biosecurity only entered the legal lexicon in 1993 with the enactment of the Biosecurity Act, the *idea* of biosecurity stretches back to pre-colonial New Zealand. Maori, the indigenous people of New Zealand, understood to have come to New Zealand as part of a great ocean migration across the Pacific in the thirteenth century AD, arrived in a land that had been entirely isolated for 80 million years (Salmond 1991). Maori settlement did have an impact on the physical environment. The Polynesian dog and Pacific rat (kiore) were introduced, as were a number of tropical plants (Jay and Morad 2006). It is estimated that by the early nineteenth century, there had been wide destruction of native forest through the use of fire and 34 species of birds had become extinct (Jay and Morad 2006).

However, that destruction proved to be negligible when compared to the toll European contact was to have. European settlement began in earnest in the early mid-1800s, although there had been sightings and contact since 1642. Initially, importation of plants and animals was completely uncontrolled (Jay and Morad 2006). As with the other colonies of the British Empire, the aim of the settlers was to build a neo-Europe. Thus, plants and animals familiar to the Europeans (mainly British) were imported, including farm livestock, domestic pets, agricultural, horticultural and ornamental plants (Morad and Jay 2003). The re-settlement of the European natural world reflected the ideology of the racial and evolutionary superiority of the new settlers – empire building in action.

The wholesale introduction of European plants and animals wrought profound and irrevocable changes on the New Zealand natural landscape.

However, it became quickly apparent that this would have unforeseen and sometimes undesirable effects. First, the introduced species threatened to overwhelm indigenous plants and animals. For example, the introduction of rabbits, sheep and possum wreaked havoc on the fragile indigenous ecosystems (Jay and Morad 2006). Further, exotic diseases entered the biosphere, causing severe damage to indigenous systems.

As a consequence, what would be termed as biosecurity measures today were put in place. There were two, complementary, approaches. First, procedures were put in place to control the introduction of exotic plant and animal species and as well as inadvertent introduction of disease. For example, livestock was subject to quarantine on arrival in New Zealand. The second approach was to manage those species and diseases which had already gained entry. This proved less than successful. The attempts to control rabbits epitomised the difficulties. Introduced by settlers early on, rabbits quickly multiplied in the South Island. In response, what seems to be the first example of biosecurity (as defined above) legislation – the Rabbit Nuisance Act 1876 – was enacted. The Act created Rabbit Boards, which employed special rabbit hunters, the costs of which were partly subsidised by the government. This turned out to be a costly, but ultimately ineffective, strategy. There were also attempts to eradicate rabbits by introducing their natural predators (in the northern hemisphere at least) – stoats, weasels and ferrets, none of which were native to New Zealand. This was a complete failure – not only did the introduced species fail to reduce the rabbit population, but they wreaked their own devastation on native birds.

The Statute Book of the time reveals many other biosecurity concerns: the Small Birds Nuisance Act 1882, aimed at reducing the number of sparrows, the Orchard and Garden Pests Act 1896 and the Noxious Weeds Act 1900. These can all be seen as the start of New Zealand's 'biosecurity strategy'. Contemporary popular and political debate shows that the central concern was to protect the agricultural sector – the cornerstone of New Zealand's economy from the start of European settlement. Thus, while the term 'biosecurity' was not used in colonial New Zealand, the idea of some control on the introduction and spread of exotic plants and animals was clear from the start of European settlement.

As the twentieth century progressed, it became evident that existing systems were inadequate to protect New Zealand. The inexorable increase in global trade and of commercial air travel transformed New Zealand's geographical isolation and exposed it to ever-greater risks of inadvertent introduction of exotic pests and disease. At the same time, the idea of 'biosecurity' within New Zealand popular imagination was undergoing a transformation. The traditional understanding of 'biosecurity' as a means of protecting the agricultural sector – a decidedly anthrocentric approach – was giving way to a more holistic vision. In some respects, this broader concern with the environment for its inherent value had always been present among both Pakeha (European settler community) and Maori. For example, in 1894, the Tongariro National Park was created (New Zealand's first) when the area was gifted to the Crown by Te Heuheu Tukino, the chief of Ngati Tuwharetoa (Morad and Jay 2003). The Scenery Preservation Act 1903, although primarily concerned with protecting scenic areas so as to nurture the developing tourist industry, can also be seen as containing some ideas of pure conservation. These, and other initiatives, can be seen as the germination of today's 'Pure New Zealand' brand, marking the start of the shift from a purely anthropocentric concern with biosecurity to one that at least has elements of eco-centrism.

This shift continues. In 2007, New Zealand submitted a paper on biosecurity to the Meeting of Experts of the States Parties to the Biological Weapons Convention (BWC) in Geneva, explaining that:

> 2. Biosecurity has been a critical aspect of the New Zealand government administration for well over 100 years. Previously referred to as agricultural security, it was intended to safeguard the national agricultural system from mainly microbial diseases prevalent in the northern hemisphere but also found in the flora and fauna of all continents.
> 3. It is now seen in the widest possible sense, as an all embracing whole of New Zealand attempt to protect the land, its people, animals, agriculture, and the economic, social and environmental well-being of all its entities.

From a legislative perspective, the broadening vision of biosecurity is also evident. A number of Acts can be seen to form the overall legislative framework: the Conservation Act, the Fisheries Act, the Resource Management Act, the Wild Animal Control Act and the Wildlife Act. However, the centerpieces remain, the Biosecurity Act 1993 and the Hazardous Substances and New Organisms Act 1995 ('HASNO Act'). Indeed, the relationship between the two Acts shows the evolving tension between the old and the new conceptions of biosecurity in New Zealand.

The Biosecurity Act was passed in 1993 – the first of its kind in the world. The debate in Parliament at the time and the fact that it was referred to the Primary Production Select Committee reveal that the legislation was based on the traditional (agricultural) biosecurity concerns. New Zealand was facing a threat of a tuberculosis outbreak in cattle at the time and there was ongoing uncertainty about how exposed New Zealand might be if and when tariffs on agricultural trade were eliminated. These factors led to increased anxiety about biosecurity at the time.

In 1995, the Biosecurity Act was supplemented with the HASNO Act. The stated purpose of the 1995 Act was to:

> protect the environment, and the health and safety of people and communities by preventing or managing the adverse effects of hazardous substances and new organisms.

While this is clearly complementary to the aims of the 1993 Act, by now the tension between economic and environmental motives had become explicit and indeed unavoidable. A key part of the debate in the lead-up to HASNO was the way in which environmental imperatives should be balanced with economic and social development. It was clear that understanding biosecurity as purely protecting primary industries was completely inadequate for the self-image of New Zealand as it faced the twenty-first century.

The 1993 Act, although unprecedented at the time, quickly proved inadequate for a variety of reasons: inadequate resources, increased pressure at the border due to ever-increasing international trade and travel; and, importantly, heightened public expectation about the protection of the country's natural heritage (Biosecurity Council 2003). The government released a new 'Biosecurity Strategy' which aimed to make biosecurity more holistic and cohesive. By now, the new understanding of biosecurity has been adopted and is understood as:

> The exclusion, eradication or effective management of risks posed by pests and diseases to the economy, environment and human health.

The broadening vision is evident in today's institutional responsibilities for biosecurity. While primary responsibility lies with Biosecurity New Zealand, a division of the Ministry of Agriculture and Fisheries, it works in partnership with the Ministry of Health, Ministry of Fisheries, Department of Conservation and Te Puni Kokiri (formerly Maori Affairs). The broadening vision has brought about its own challenges in terms of reaching consensus about *how* biosecurity ought to be achieved – whether poisons which might affect human health should be used to eradicate introduced pests for example – and these debates remain alive and keenly debated today.

The foregoing discussion reveals that biosecurity is a concept that goes to the heart of the New Zealand psyche, born in large part from the isolation which both protected and made New Zealand unique. Interestingly, what was historically understood as a challenge, geographical isolation has come to be seen as an advantage. The government's Biosecurity Strategy 2008 refers to protecting New Zealand's 'natural advantage'. Alongside this broad continuity, there has been continual change. The strategies for biosecurity have to be constantly adapted to new and increased risks but, as we have seen, there has also been an evolution from the original anthropocentric understandings to a more holistic, eco-centric approach, which has brought about its own tensions, debates and adjustments. Regardless of the intensity of the debates, there remains absolute consensus that biosecurity is critical to New Zealand, and in turn it has fostered a 'clean, green' national image.

Biosecurity: Preventing the deliberate misuse of biological agents or the life sciences

As a term in New Zealand, biosecurity has never been used to refer to security against deliberate misuse of biological agents or the life sciences. Indeed, it would not be an overstatement to say that there is a palpable resistance to the expression in this sense. For example, in the introduction to the Biosecurity Strategy in 2003, 'bioterrorism' is not discussed at all. It mentions it in passing in the introduction and then, while noting that although the resulting damage would be on a catastrophic scale, points out that bioterrorism is simply another vector for transmission. In November 2008, the 6th New Zealand Biosecurity Summit was held with the theme 'New Technologies and Approaches to Biosecurity'. Across two days of discussions, there was a marked absence of everything other than the traditional (agricultural) concerns.

The resistance can be explained in part by the fundamental importance in New Zealand of biosecurity in the sense discussed in the first part of this chapter. Despite tensions around the philosophical underpinnings of New Zealand biosecurity strategy (anthropocentric or eco-centric) and related debates about how to manage biosecurity, there is fundamental, enduring and universal support for the idea that New Zealand needs to be protected from outside pests and diseases. New Zealand needs biosecurity. Because of that, it seems to be implicitly understood that the biosecurity regime should be insulated from the contentious and possibly divisive politics raised by 'bioweapons', whether in the hands of states or non-state actors.

The resistance to this second understanding is manifest in unwillingness to engage in the rhetoric of bioterrorism particularly where this might be seen to compromise or discredit the existing multilateral frameworks, which New Zealand believes are sufficiently flexible to deal with use or threatened use by non-state actors. As New Zealand stated in its 1540 report to the Security Council (New Zealand 2004: 2):

> New Zealand's strong and consistent policy is that all weapons of mass destruction (WMD) should be eliminated, and that this elimination should be verified and enforced through robust legally binding multilateral disarmament instruments. New Zealand provides no support whatsoever to any entity – whether State or non-State actor – attempting to develop, acquire, manufacture, possess, transport, transfer or use WMD and their means of delivery.

It went on:

> New Zealand will work with others to prevent illicit trafficking in nuclear, chemical, or biological weapons, their means of delivery, and related materials. The most effective way of doing this is through strong multilateral instruments with robust verification provisions (New Zealand 2004: 10).

In 2006, at the Sixth Review Conference of the Biological Weapons Convention (BWC), the New Zealand representative stated:

> Advances in life sciences and biotechnology, coupled with increased concerns over the threat of bio-terrorism, mean that this meeting is being held at an important juncture. It is vital that the Convention remains relevant and ready to meet these challenges. States must work together to agree to a pragmatic process which would enhance our collective security. New Zealand looks forward

> to working with all States Parties towards this goal. We must not squander this opportunity (New Zealand 2006: 3).

In its presentation to the Meeting of Experts in August 2007, on its biosecurity regime, there is an exclusive focus on agricultural aspects. In the final sentence of a three-page paper, it simply states:

> Bioterrorism can be dealt with under an effective biosecurity umbrella (New Zealand 2007: 3).

New Zealand has also taken the position that domestic legislation already covers non-state actors. In its 1540 Report to the Security Council, New Zealand stated that:

> The express prohibitions on aiding and abetting in the New Zealand Nuclear Free Zone, Disarmament, and Arms Control Act 1987 [...] as well as general prohibitions on aiding and abetting the commission of any offence under New Zealand law, taken together, mean that assisting or acting as an accomplice to the prohibitions contained in this legislation would be an offence under New Zealand law. This meets the terms of OP2, [of SCR1540] which calls on States to implement effective laws to prohibit the support and assistance for non-state actors engaging in any of the prohibited activities listed in OP2.
>
> The section in the Crimes Act prohibiting attempts would also make it an offence for non-State actors to attempt to carry out the prohibited activities under New Zealand legislation in relation to WMD. This is relevant to OP2, which calls on States to implement effective laws to prohibit non-state actors from attempting to engage in the prohibited activities outlined in OP2 (New Zealand 2004: 4).

Thus, New Zealand's position on any emerging non-state actor, or 'terrorist', threat is that the existing international architecture is adequate to deal with it due to the Article VI requirement in the Convention for States Parties to criminalise those activities. Further, that New Zealand's legislation is already sufficient to deal with any 'terrorist' act or threat. Reflecting this, the then Minister for Biosecurity in Parliament on 23 May 2005 confirmed that the Ministry of Agriculture and Forestry has no funding specifically devoted to surveillance, preparedness and emergency responses to acts of bioterrorism.

The resistance to the rhetoric of bioterrorism is not limited to government. An article in the *New Zealand Medical Journal* in 2002 on the impact of bioterrorism in Zealand argues that the New Zealand's bioterrorism threat in fact lies in an attack in the Northern Hemisphere, with subsequent spread of disease to New Zealand. However, having analysed those threats, the article concludes

> Terrorist use of smallpox, pneumonic plague and genetically engineered pathogens in the North Hemisphere could lead to imported cases reaching New Zealand and some risk of ongoing disease outbreaks. However, a range of disease control measures are available that could substantially limit the size of any resulting outbreaks. The risk of terrorist use of bioweapons needs to be considered in the context of the more important risk of pandemic influenza on New Zealand, the many thousands of preventable deaths in each year in this country (eg, from smoking and physical inactivity), and the current epidemic of meningococcal disease. (Wilson and Lush 2002: 250–1)

Similarly, the scientific community has not engaged in the rhetoric of biosecurity. For example, the Code of Professional Standards and Ethics 2003 issued by the Royal Society of New Zealand does not address the term in this sense. Rather it echoes the more general concerns of the public and the government of the need to protect agricultural and human health. The issue of 'biosecurity' simply has not entered the scientific debates.

However, while there is a marked resistance to the *term* biosecurity in security discourse, including not only in the context of terrorism, New Zealand has been and remains firmly committed to the concept of 'biosecurity' as referring to *security from the threat of biological weapons*. New Zealand had never possessed biological weapons or engaged in any kind of an offensive programme involving biological weapons. In 1930, New Zealand acceded to the 1925 Geneva Protocol. New Zealand signed and ratified the Biological Weapons Convention in 1972, becoming one of the original State Parties when it entered into force in 1975. A member of the Conference on Disarmament since 1996, New Zealand has been a steadfast supporter of the now-moribund negotiations on a binding Protocol to the treaty, which would have provided a verification system along the lines of the existing verification system in the Chemical Weapons Convention. New Zealand has also been committed to 'biosecurity' (as defined above) in less formal multilateral systems: it is a member of the Australia Group; the Proliferation Security Initiative and the Waasanaar Group, all of which in various ways are aimed at countering any illicit trafficking of strategic goods, including those which are precursors to biological weapons.

These multilateral commitments are reflected in New Zealand's domestic law. In 1987, domestic legislation banning the use of biological weapons was introduced to New Zealand with the Nuclear Free Zone, Disarmament and Arms Control Act 1987. The Act prohibits the manufacture, stationing, acquisition, or possession of or any control over, any biological weapon. The prohibition applies to biological weapons and includes means of delivery and equipment. Section 298B Crimes Act 1961 makes contaminating food, crops, water or any other products, a criminal act. Apart from these specific criminal provisions, there are general provisions within the Crimes Act 1961 which make any attempts to carry out those acts (s 72) or aiding or abetting anyone to carry out those acts (s 66) criminal offences. Finally, New Zealand controls the export of 'strategic goods' through a Strategic Goods List implemented by the Customs and Excise Act 1996.

All of the above commitments reflect New Zealand's general support for multilateralism, which has been an enduring feature of New Zealand's foreign policy. Even before it had cut its colonial umbilical cord, New Zealand participated in the post-World War I Versailles treaty negotiations. While its participation in the negotiations was not purely idealistic (New Zealand was especially concerned about its 'share' of German territories in the Pacific), it does show an early sense in which New Zealand was clearly connected with the wider world. This continued with its engagement in the United Nations. A founding member of the organisation, New Zealand was especially involved in the drafting of the Trusteeship Chapter of the Charter (McKinnon 1995). New Zealand has continued to advocate a multilateral approach in international relations – and its participation in all of the multilateral biosecurity frameworks is a manifestation of that approach.

The various biosecurity commitments reflect a second enduring aspect of New Zealand's foreign policy – the importance of its traditional alliances. Formerly a colony of 'Mother Britain', that relationship has always been important to New Zealand, which fought for the Empire in the Boer War (1899–1902) and fought alongside Britain in both World Wars. Unlike Canada and South Africa, New Zealand did not immediately seize independent nationhood as the Empire was dismantled. As renowned New Zealand historian JC Beaglehole put it so elegantly in 1939 (1939: 3):

> It is a 'Dominion' in spite of itself. It has not pursued, with passionate experimentation, the idea of equal nationhood; in the Imperial

> family it is the daughter-nation that preferred not to smoke and drink with its emancipated sisters, that shuddered a little and drew its garments somewhat closer when Canada and South Africa began to saunter on the boulevards of the world; that fervently hoped the day would never come when the financial journals of London should fail to rise up and call it blessed. For the economic bond, in subtle ways, appears transmogrified in terms of politics or mind.

While that connection to Empire has vanished, and New Zealand today increasingly sees itself as part of the Asia Pacific region, there remains a strong affinity with its traditional western partners, particularly the United Kingdom. Notwithstanding Britain's closer ties in Europe, New Zealand still maintains strong trade and diplomatic links with the United Kingdom. Like Australia, despite its geographical distance, it sees itself as a natural fit with its western allies in the BWC context and within the Conference on Disarmament.

Thus, commitment to multilateralism and the continuing value placed on her traditional alliances, are features of New Zealand's general foreign policy, and form the backdrop to New Zealand's commitment to biosecurity. However, as with any security issue in New Zealand, biosecurity cannot be understood properly in isolation from the anti-nuclear movement in New Zealand. That is because the anti-nuclear movement within New Zealand has forged a fiercely independent foreign policy which in turn has defined its position on 'biosecurity'.

The anti-nuclear movement in New Zealand dates back to the 1950s although nuclear testing in the wake of the Second World War in the Pacific did not initially face New Zealand opposition (Templeton 2006). However, as scientific understandings of the effects of nuclear radioactivity developed and became known, New Zealanders started to voice concern about the health effects of radioactive fall-out from the testing. Public opposition to the tests grew with suggestions that small amounts of Strontium-90, Caesium-137 and Iodine-131 were being deposited over New Zealand from the troposphere and stratosphere, possibly affecting supplies of milk, meat and vegetables. This reaction was entirely consistent with general biosecurity concerns.

In the early 1960s France shifted its nuclear test programme from Nigeria to French Polynesia. Thus began a long simmering dispute between the two countries. New Zealand protested the testing, including dispatching a frigate to monitor the environmental impact, but to no avail (Hay 1983: 5). In 1973 New Zealand resorted to legal measures, seeking a ruling from the World Court that the atmospheric testing in the Pacific was unlawful. However, because France announced she was ceasing the testing, the Court decided that it did not need to make a ruling, the question being moot.

Meanwhile, the growing mistrust of both nuclear energy and power within New Zealand led to a dispute with another traditional ally. New Zealand, Australia and the United States had entered into a mutual defence pact in 1951. The aim of the so-called ANZUS treaty was to discourage communist expansion and to increase US influence in the region. With the anti-nuclear movement gaining momentum, questions arose as to whether New Zealand could require confirmation that visiting US naval vessels were not nuclear powered or did not carry nuclear weapons in light of its obligations under the treaty. There were also questions about whether a proposed 'nuclear free zone' in the Pacific, including New Zealand, would be consistent with the treaty. A change in government in 1976, to the conservative National Party, more sympathetic to the United States position, deferred the dispute – at least for the time being.

The 1980s were a defining decade in terms of New Zealand's anti-nuclear position. In 1984, a Labour government was elected, with a strong anti-nuclear policy. What many termed a crisis in United States-New Zealand relations was quickly triggered by the government's refusal to accept a visit from the USS Buchanan – an American naval vessel, on the basis that the United States refused to confirm or deny the presence of nuclear weapons aboard. The dispute led to the United States suspending its treaty obligations with New Zealand. But the American reaction was counter-productive and served to deepen, rather than weaken popular support for the anti-nuclear policy. The long-standing dispute with France also reached a crisis the following year when French agents bombed the Rainbow Warrior, a Greenpeace vessel anchored in the port of Auckland, which was preparing to protest a nuclear test in Moruroa. The outrage in New Zealand at this unprovoked act of aggression transformed New Zealand's anti-nuclear movement from a partisan political policy into a defining feature of the national identity. That remains the case today. New Zealand has returned to the World Court to challenge the French undergound testing in the 1990s and was an active player in the 1996 requests for Advisory Opinions. Suggestions as recently as 2005 by the National Party (then in opposition) that it would reverse the ban on nuclear ships, so as to work towards a closer relationship with the United States had to be quickly abandoned in the face of overwhelming implacable public opposition. New Zealand remains proudly and defiantly nuclear-free.

New Zealand has always had an affinity with the ideal of disarmament. For example, in 1978, even when there was still considerable division of opinion about the importance of the ANZUS treaty to New Zealand, a poll showed that there was broad support for efforts to bring about disarmament (Levine 1980). The national identity forged as a result of the nuclear disputes with France and the United States, in foreign security policy terms, has consolidated New Zealand's abiding vision of disarmament. Even with the change in government, New Zealand's position regarding nuclear disarmament has remained absolutely bipartisan. New Zealand has actively supported all nuclear disarmament initiatives. This disarmament commitment is now also reflected in other security areas: the Chemical Weapons Convention and the Landmines Convention to mention just two. In terms of biosecurity, its commitment to multilateral disarmament is clear and consistent and thus squarely within its overall disarmament vision.

The nuclear disputes with France and the United States have had another important effect on foreign security policy. Despite its initial reluctance to cut its colonial ties, New Zealand has a strong tradition of independent foreign policy. This is demonstrated clearly in its engagement within the United Nations – it has consistently articulated a position that there is an important role for smaller nations within the multilateral system. However, the experiences with France and the United States have served to deepen that independence. While on one view, New Zealand 'lost' both disputes (US-New Zealand relations remain strained and success at the World Court has been limited), in fact, both at popular and political levels, the anti-nuclear policy is regarded with fierce pride as a reflection of New Zealand's independent spirit. In security terms generally, New Zealand's independent approach is reflected in its participation in the New Agenda Coalition, demonstrating that while New Zealand remains committed to its traditional relationships, it is willing to reach out to other 'like minded' states in the interests of disarmament. New Zealand's continued support for Nuclear Free Zones is also a manifestation of that independent security policy.

In the particular context of biosecurity, New Zealand's participation in JACKSNNZ (an informal grouping comprising Japan, Australia, Canada, Republic of Korea, Switzerland, Norway and New Zealand) demonstrates this independence. The group is working towards strengthening the BWC. While this naturally would include reviving work on the Protocol, that position is not pushed given the intractability of the USA position.

Meanwhile, however, the group continues to support stronger and more effective and more transparent national implementation of the treaty, with the ultimate aim of complete and verifiable disarmament.

Conclusion

Biosecurity is fundamental to New Zealand's well-being and for that reason any attempt to use this terminology in the context of bio-weapons is likely to continue to be resisted. At the same time, New Zealand has a long and strong tradition of opposing all weapons of mass destruction, including biological weapons and this is regardless of whether those weapons are in the hands of states or non-state actors. To a great extent, this opposition is part of New Zealand's anti-nuclear tradition, which, just like biosecurity in the agricultural sense, is now an embedded part of New Zealand's 'clean green' identity.

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10
Biological Weapons Prevention in South Africa

Chandré Gould

Introduction

The term 'biosecurity' – used to denote measures to reduce the threat of the misuse of science to cause harm – has very little currency in South Africa. It is not a term that has been used in policy-level discussions about biological warfare, 'weapons of mass destruction' or safety. Indeed, the term has been rejected by many in the scientific and policy community for its connotation with the terrorist acquisition and use of biological weapons, which is not viewed as a pressing threat to South Africa or the continent. Nevertheless, secure access to food, improved public health services, access to affordable medicine and to clean and consistent water have been identified by the government of South Africa, and the military, as vital to ensuring national security. In addition the control of pathogens, laboratory safety, and adherence to international norms against biological weapons development have been firmly on the state's agenda since just before the democratic election in 1994.

This is to say, that despite the rejection of the term 'biosecurity' by the state, and civilian scientific community, South Africa has placed a great deal of emphasis on matters that could be defined broadly as matters of 'biosecurity'. Indeed, the securitisation of developmental issues implies that 'biosecurity' means a great deal more than preventing the misuse of biological agents for harm.

In this chapter I consider the way in which national security is understood by the South African state and the resulting defence strategies; the relationship between the past experience of a chemical and biological weapons programme and current efforts to reduce the use or development of biological weapons; and the attitudes of the policy community, non-governmental organisations and the scientific community to concerns about the misuse of science; and reflect on initiatives to reduce the threat.

The place of biosecurity in the national threat perception

Since 1996 (two years after the election of a democratic government in South Africa) the concept of national security in South Africa shifted dramatically from that used by the apartheid government. No longer were notions of security focused exclusively on military threats to the state, as they had been. Rather, the concept of national security was broadened to encompass all issues of human security. The political commitment to addressing the underlying causes of insecurity was given impetus after 1994 because South Africa's transition to democracy and the end of the Cold War meant that South Africa no longer faced a conventional military threat. Within the human security framework the greatest threats to the security of the state and its citizens are understood to be of a socio-economic nature (Kruys 2005: 2): poverty, unemployment and inadequate access to quality healthcare.

According to Kruys (2005: 7–8) this is a common theme running through all strategic documents since 1996,

> The *South African White Paper on Defence, 1996* describes Southern Africa, the sub-continent, as under-developed, poverty stricken and plagued by illiteracy and unemployment. It is further stated that there is a debt crisis and environmental degradation and that masses of small arms are available in the area. These conditions are not confined to national borders and spill over into neighbouring states as 'non-military threats'. They include destruction of the environment, rampant disease and the cross border movement of refugees, drugs, stolen goods and small arms.

The 1998 Defence Review repeated that assessment reaffirming that there was no conventional military threat to South Africa, an assessment that remained relevant in 2009 (Department of Defence 2007). The Defence Review did provide a breakdown of what are termed 'Defence Contingencies' (a term used inter-changeably with 'threat') which included:

- invasion of the country with the intent of occupation,
- limited attacks on South Africa 'to neutralise the Republic of South Arfrica's (RSA) ability to project its military power in Southern Africa'

- internal military threats (in other words civil war)
- 'raids on South African territory using missiles, aircraft or mobile land forces. This could be done by foreign governments to persuade the South African government to change its policy or to punish South Africa for actions taken', and finally
- 'a blockade of South African shipping to coerce or punish the RSA for behaviour to the detriment of a major power'. (Department of Defence 2007: 6–7)

While the review acknowledged that the defence force had to be prepared to deal with these threats, it was regarded as unlikely that they would be realised. This being the case, the military strategic objectives articulated in the *Strategic Plan for FY 2002/3–2004/5,* and reaffirmed in the 2007 Strategic Plan prioritised the role of the military in promoting security, 'supporting the people', and 'defending against aggression' (Department of Defence 2007: 8). Under these broad objectives, in that order of priority, are listed activities. Defending against biological and chemical attack would, in this taxonomy, fall within the strategic objective of defending against aggression. What is relevant to this discussion is the relative importance given to each of these objectives. Based on the Department of Defence's *Strategic Business Plan FY 2003/4 to FY 2005/6* the objective 'Support to the people of South Africa' was the most important and 'Defence Against Aggression' the least important. These priorities may change over time as national security concerns are addressed and regional peace is achieved. But what is significant is that defence against chemical and biological attack were regarded as a low priority for the South African National Defence Force (SANDF).

An analysis of speeches and policy statements by government officials between the beginning of 2000 and mid-2005 reveals remarkable consistency in the interpretation of security needs in South and southern Africa. In none of the 'State of the Nation' addresses by President Thabo Mbeki in the three years, 2000–2002, is reference made to concerns about security – other than to address what are believed to be the root causes of insecurity – poverty, underdevelopment and inadequate public healthcare. In none of these speeches is terrorism mentioned, nor is the threat of attacks by non-state actors identified as an issue of particular concern for the country. Indeed, even in the State of the Nation Address of February 2002, a few months after the September 11 attacks in the US, terrorism and national security did not receive a mention. The president's address remained consistently focused on the need to address racism, underdevelopment and the AIDS pandemic (Mbeki 2000; Mbeki 2001a;

Mbeki 2002a) – issues that fall within the broad definition of human security – but do not fit the traditional mould of 'national security', understood primarily as military threats.

The government's position on security was again clearly articulated by the Director General of the Department of Foreign Affairs in June 2005 in stating that:

> It is common knowledge that there are more people dying from curable diseases and hunger in Africa than they are from war. The economic progress we are seeking will be meaningless unless it impacts positively on this challenge. Such diseases as malaria and TB are not only curable, but they can be prevented. The fact that they claim lives of large numbers of our people is a consequence of both the excessively priced medicines and the inadequate health infrastructure of most of our countries. To compound the problem is the HIV/AIDS pandemic, which poses a serious security threat, particularly in sub-Saharan Africa… This also suggests that we need to pay particular attention to enhancing food security…The same applies to water security. (Pityana 2000)

He argued that continental stability relied on the development and encouragement of democratic governments and good governance. Reference was made to the need to address conflict areas in the continent because conflict negatively impacts on development.

Under the Mbeki government, addressing the underlying causes of insecurity in the region and not just in South Africa was central to both South Africa's foreign policy and military strategy from the late 1990s. Intelligence priorities for 2000 were aimed at addressing *inter alia*:

- Corruption and crime
- Poor protective security within the state
- Regional security dynamics
- Continental stability issues
- International economic and technological threats and opportunities as they relate to South Africa
- Extremism and terrorism
- Addressing arms smuggling with a special focus on drug dealers; and
- Involvement of foreign and South African security companies in African conflicts (Nhlanthla 2000).

The urgent need to overcome the problems associated with a poor public healthcare system, particularly in light of the high number of

South Africans living with and dying from AIDS received a great deal of attention from the government. This is despite the irony that Mbeki's controversial views on HIV and AIDS (that HIV may not be the cause of AIDS, and that anti-retroviral drugs are toxic) may well have contributed to the slow delivery of anti-retroviral drugs and may have prolonged the effects of the pandemic in South Africa. The stark challenges faced by the public healthcare system were set out in 2001 by the Minister of Health, Dr. Manto Tshabalala Msimang:

> Most of the people who use our public health facilities are poor. In addition, many are unemployed and they live without adequate shelter, nutrition or clean water. Their health is undermined by their social circumstances and at the same time, social development is retarded by their ill health.

Key problems related to the quality of service delivery in public hospitals that was characterised by poor management, callous staff and inadequate resources. The extent of the crisis in healthcare was evident in the 2001 cholera outbreak which affected about 100,000 people over a nine month period and caused more than 200 deaths. For the government, this emphasised the link between poverty, development and health (Tshabalala Msimang 2001) and the need to focus on primary healthcare. Mbeki reiterated this view, and the continental nature of the problem in his address to the National Health Summit, stating that:

> In common with the rest of Africa, we are experiencing an upsurge in the communicable diseases strongly associated with poverty and underdevelopment – AIDS, TB and malaria…Our common concerns in the African health partnership have been the development of programmes to combat communicable diseases; the overall strengthening of our health systems; challenging trade practices that make essential medicines unaffordable for us; and mobilising increased domestic and external resources for health care on our continent. The New Partnership for Africa's Development, NEPAD, seeks to pursue all these objectives (Mbeki 2001b).

Even though this speech was made after the anthrax mailings in the US, no reference was made to the need to improve health services to deal with deliberate disease, an indication that this was not a concern for South Africa and a strong indication that Mbeki did not wish to be distracted from his developmental agenda by international security events.

An analysis of speeches and statements made by Mbeki in international forums reveals the South African government's reluctance to engage with the post-2001 security paradigm as articulated most forcefully by the United States and the United Kingdom. Scant reference is made in his speeches to the threat of terrorism. When reference is made to the issue it is placed within the context of the need to address the underlying causes of instability, such as in Mbeki's address to the United Nations General Assembly in 2002:

> We have a collective duty to reaffirm our united resolve to create a world free of the fear of terrorism. We have a common task to ensure that this organisation [the United Nations] truly lives up to its obligations to do all the things that make for peace…It may be that future generations will say that if we have learned anything at all from the horrendous events of September 11, it is to the accomplishment of these tasks that this General Assembly should dedicate its efforts. (Mbeki 2002b)

On a continental level South Africa positioned itself as a champion of good governance, a broker in the resolution of political conflict and as a strong supporter of the need for effective peacekeeping. In an address to the National War College in Nigeria in 2003 Mbeki said that '[P]eace, security and stability remains as one of the more serious challenges facing our continent'. He referred to the establishment of the African Union's Peace and Security Council which is primarily focused on peace keeping, peace-building and post-conflict reconstruction activities, the promotion of democratic practices, good governance and the rule of law as well as the protection of human rights and fundamental freedoms. He identified military coups, dictatorships and mercenary forces as threats to African security.

In one of his few references to terrorism he referred to the African Convention on Terrorism but placed equal emphasis on the problems of conventional weapons use and proliferation and the scourge of landmines. In this speech, reference was made at some length to the fact that the US response to the 9-11 event was to move towards unilateralism and he quoted the UN Secretary General, Kofi Anan, saying that 'Should states feel that they have the right to use force without seeking the UN's legitimisation of such action, it could result in a proliferation of the unilateral and lawless use of force.' He located the African response to the threat of the use of chemical, biological and nuclear weapons within multilateral agreements, the Nuclear Non-Proliferation Treaty (NPT), Chemical Weapons Convention (CWC) and Biological and Toxins Weapons Convention (BWC). In other words, the response of the South African government to the US response to September 11 was to condemn unilateralism and state that the solution to nuclear, biological and chemical proliferation lies in strengthening multilateral agreements. It is, therefore, reasonable and logical that the response has not been to forge ahead with national measures to defend against biological weapons use, particularly since the government's focus is on poverty reduction and health.

By 2005, the government's position had not changed, however, many statements by state officials began to refer to the interconnectedness of a globalised world in which the threats faced by individual states have relevance globally, as articulated by the Minister of Intelligence Services, Ronnie Kasrils (2005) in stating:

> security threats do not respect national boundaries – from invasion, war and conflict within states they extend to poverty, infectious diseases and environmental degradation. They encompass the spread and possible use of nuclear, chemical and biological weapons. They include terrorism and transnational crime. While the differences in power have historically determined the gravest threats to survival, the fact remains that the mutual vulnerability of rich and poor nations has never been starker. Today's threats where more than one in every six human beings live on less than a dollar a day, encapsulate the inextricable link between development and security. A more secure world is only possible if poor countries are given a real chance to develop as there can be no security without development and no development without security.

He also noted that South African national security is closely linked to African renewal – with the focus of the intelligence services having been on 'furthering peace, stability, democracy and sustainable development on the Continent.' With regard to terrorism his assessment of the threat of terrorism was clear, '[A]lthough there has been much media speculation over the possible effects of international terrorism on our country, we can say that we do not discern any imminent threat' (Kasrils 2005).

During 2004 and 2005 statements made by government officials began to reflect frustration that Africa's interpretation of the causes and requisite responses to security threats were not being heard at an international level. Indeed, the focus of powerful states on the threat posed by terrorism appeared to be drawing attention and activity away from development needs on the African continent. This came through most clearly in Mbeki's 2004 address to the United Nations General

Assembly, the tone and content of which had hardened considerably since 2002. While the issues of concern remained much the same, Mbeki spoke at some length of the problems resulting from global power imbalances. His frustration stemmed from the fact that the security concerns of powerful states were translated, with relative ease into issues which received global attention and obligatory injunctions, whereas the security concerns of less powerful states may be widely acknowledged, these states do not have the power to translate their conclusions into action. Other speeches by government representatives in 2005 drew from and echoed this analysis,[1] arguing that the achievement of the Millennium Development Goals must be placed 'centrally in international efforts to end violent conflicts, instability and terrorism and that investing in poverty alleviation and development is fundamental to conflict prevention and peace keeping' (Pahad 2005).

This analysis of policy statements about notions of national security, provides a very clear indication that the use of biological weapons in an attack on South or southern Africa was not regarded as a likelihood and discussions about the vulnerability of the region to infectious disease outbreaks would not include reference or consideration of the deliberate use of disease. There is no indication that the terrorist attacks in the United States on September 11 2001, the anthrax letters of October 2001, or the Madrid bombings had any influence on the way in which the state viewed the threat of biological weapons use by non-state actors. In considering the multiplicity of security threats faced by underdeveloped nations: poverty, inadequate health resources, the proliferation of small arms, illegal immigration, and so on, biological weapons were not going to be top of the state's agenda as far as responses to threats were concerned.

In 2008, Colonel Ben Steyn (South Africa's military expert on chemical and biological defence) noted in a presentation to a workshop held by the Institute for Security Studies and the Centre for International and Security Studies at Maryland on biosecurity in Africa that there are a number of factors that influence perceptions of the threat of biological weapons. This included 'issues such as poverty, availability of food, the reality of other threats, technological developments, political factors and the historical background.' He made the point that there is not a strong awareness about biological weapons or knowledge of biological weapons issues in Africa – and argued that this reduces the threat. He also said this state of affairs calls into question whether the best non-proliferation strategy is in fact to raise awareness about dual-use issues. Although it is arguably problematic to suggest that a lack of awareness is a good defence against the use or development of biological weapons, as South Africa's representative in international biological weapons forums, his views cannot be dismissed. His views also reflect a frustration at the ongoing focus of what may be regarded as 'unnecessary' attention on biological weapons threats.

Steyn compared conditions and perceptions in Africa with those in the US. He noted that the threat of terrorism in Africa is low while the threat of naturally occurring disease outbreaks is high. He also noted that the biological agents commonly regarded as posing a weapons threat are endemic to Africa. Finally he made the point that there are a very small number of biotechnology facilities (particularly research facilities) on the continent. This is very different from the situation in the US where the perceived threat of terrorism is high, so-called threat agents are found in laboratories rather than in nature, and where the capacity for relevant biotech development is high. The differences in the perceptions and realities calls, he argued, for a completely different approach. According to Steyn, 'comparing Africa with the US in terms of the scientific research environment is like comparing an under-fed infant with a strapping health teenager'.

Steyn's concern, it would appear echoes Mbeki's – that efforts to focus attention on biosecurity may suppress development. This is because international concern about the possible misuse of biological agents in Africa, or South Africa, could stop or reduce the already tiny trickle of funding to African research and development institutions.

Despite this analysis, Steyn is also a strong proponent of national measures to prevent the misuse of science. His views were not shared by many of the other participants in the meeting (all senior scientists) – many of whom saw the international biosecurity discourse as an opportunity to talk about the problems of capacity on the continent and to attract attention to the plight of science in Africa – even if it is because there is [unfounded] concern about misuse.

It would appear that this opportunistic approach to the international biosecurity discourse is not restricted to the scientific community. A senior researcher on terrorism at the Institute for Security Studies stated that in her experience, while most African countries share the view that the use of biological agents by terrorists is unlikely, recent discussions in regional (southern African) political and security forums have placed an emphasis on WMD threats in southern Africa. She ascribed the interest to the availability of international funding to improve control. So while the perception of threat may not have changed, these countries would wish to take advantage of the opportunity to upgrade border controls.[2]

The state response to biological weapons prevention

Although the South African state has a developmental approach to human security and does not regard military threats as pre-eminent, it has played an active role in international non-proliferation and disarmament forums. This part of the paper (i) reflects the involvement of South Africa in the Biological and Toxins Weapons Convention (BWC), (ii) considers South Africa's submissions to the Committee established to oversee the implementation of United Nations Security Council Resolution 1540, and (iii) reports on relevant national legislation.

Participation in the BWC

Since 1992 South Africa has played a significant role in BWC discussions and negotiations. As one of the promoters of a protocol to verify the commitment of States Parties to the BWC to not develop biological weapons, the country took an active role in the Ad Hoc group negotiations between 1992 and 2000 that were aimed at drafting such a Protocol to the Convention. These negotiations ended after the rejection of the Protocol by the United States in 2001. Despite this South Africa remained involved in annual BWC meetings and discussions and submitted papers on all the subjects under discussion since 2002. In February 2002 Regulation 7291 added the BWC as a schedule of the Non-Proliferation of Weapons of Mass Destruction Act, thereby making it a national law (Government Gazette 2002).

Since 1998 South Africa has made annual Confidence Building Measure (CBM) declarations in terms of the BWC (with the exception of 2001) and has made annual declarations of past and anticipated activities (in terms of Articles 6 and 10) to the Organisation for the Prevention of Chemical Weapons (OPCW) in terms of the requirements of the Chemical Weapons Convention.

UNSC 1540

Submissions to the United Nations Security Council (UNSC) Committee on Security Council Resolution 1540 provide a useful insight into what states have to say about national efforts to prevent the use and development of biological weapons by non-state actors. The South African submission to the UNSC 1540 Committee begins with a warning that the South African government held the view that in the implementation of the resolution, structures already in existence, particularly the International Atomic Energy Agency (IAEA) and the OPCW should take a lead role, and their activities should not be duplicated, a view shared by other developing states. It goes further to say that:

> The Government of South Africa, like other Governments, would also be concerned if the Security Council were to assume legislative and treaty-making powers on behalf of the international community that are binding on all States and that are not envisaged by the Charter of the United Nations. Like other Governments, the Government of South Africa will also not accept externally prescribed norms or standards, whatever their source, on matters within the jurisdiction of the South African parliament, including national legislation, regulations or arrangements, which are not consistent with South Africa's constitutional provisions and procedures, or are contrary to South Africa's national interests or infringe on its sovereignty. (Note Verbale 2005)

This reinforces the analysis offered in the previous section: as far as the state is concerned, the biosecurity threat posed by non-state actors is negligible.

National legislation

Biological pathogens are controlled (for non-proliferation reasons) under the Non-Proliferation Act, the Agricultural Pests Act, the Animal Health Act, the Genetically Modified Organisms Act and the Health Act. According to the South African submission to the 1540 Committee,

> All plants and plant sites that manufacture or produce chemicals, biological items, nuclear material or nuclear dual-use items and missile delivery items, have perimeter security and other security procedures in operation, including in some instances, the use of television monitoring systems in order to secure the facilities in the event of outbreak of fires, or against theft. Such systems are standard use in South Africa and are augmented by security personnel in motor vehicles. (Note Verbale 2005)

In addition, the South African Revenue Service (Customs and Excise) is responsible for activities relating to the legal import/export of goods from South Africa. The movement of people is controlled by the Department of Home Affairs, and the South African Police Service deals with illegal conduct relating to import/export and the movement of people into South Africa.

According to the UNSC 1540 submission '[C]omprehensive policing methods are used to curb activities of South African borders as well as at its ports of entry. South Africa, like most other countries, in responding to global security developments, is working on improving border controls to ensure maximum effectiveness' (Note Verbale 2006: 8). Indeed, the need to address the shortcomings of the border control system has been the subject of attention by the Minister of Safety and Security and the Minister of Intelligence since 2000.

With regard to the import and export of controlled items, the state requires permits for both the export and re-export of controlled goods. Export permits are issued by the Council for the Non-Proliferation of Weapons of Mass Destruction (NPC) under the Non-Proliferation Act (Note Verbale 2005: 8).

In June 2004, the Minister of Trade and Industry passed a regulation (administrative amendment) to the Non-Proliferation of Weapons of Mass Destruction Act, 1993. The regulation titled: 'Declaration of certain biological goods and technologies to be controlled and control measures applicable to such goods' provides a list of human pathogens, zoonoses and toxins which are to be considered controlled items. The list of controlled pathogens and equipments includes the Australia Group list of pathogens as well as the additional pathogens on the 'Warning List' and the 'Awareness raising guidelines' list of the Australia Group. This means that a permit has to be granted by the NPC before these items can be exported or re-exported. One of the drawbacks of the current system is that different government bodies or agencies have responsibility for export and import. Whereas for export a permit has to be sought from the NPC, import is controlled by the Department of Health.

In terms of Regulation 712 all laboratories that use, or have stocks of, controlled equipment or goods are required to be registered with the NPC. In addition, registered facilities must 'notify the Secretariat [of the NPC] not less than 21 calendar days after any listed biological agent, toxin or equipment has been transferred within the borders of South Africa or received from other facilities within the borders of South Africa, after any other change in the registration conditions.' Since there is no national list of laboratories that work with pathogens it is difficult to assess the percentage of laboratories that have not registered.

It is clear that the legislation is comprehensive; however, there are a number of shortcomings in implementation. The Secretariat of the NPC, located in the Department of Trade and Industry, is a small body that has responsibility for a multitude of tasks relating to the control of nuclear, chemical and biological agents, facilities and equipment. Its capacity, therefore, to ensure that all scientists and facilities are aware of their legislative responsibilities is limited. The Secretariat has appointed a staff member to contact laboratories and ensure that they do register and the registration of the 76 laboratories is evidence of this effort. However, it remains the case that few laboratory scientists are even aware of the NPC, let alone the relevant national legislation.[3] The following section considers the views of the scientific community on the international discourse on biosecurity, and attempts to explain the ambivalence of the scientific community to this discourse.

The national discourse in context

Dealing with the past

The current approach to the biological weapons prevention by the scientific community in South Africa is informed by two significant factors – the past experience of a state chemical and biological weapons programme during the 1980s and early 1990s; and the post-Apartheid emphasis on science, and the life sciences, in particular as a significant contributor to reducing the human security threats posed by food shortages and disease.

After the revelations at the Truth and Reconciliation Commission (TRC) in 1998 about the Apartheid military's bizarre foray into chemical and biological weapons research and development (TRC report 1998) – the scientific community was silent. This silence continued throughout the trial of Dr Wouter Basson, medical doctor and head of the programme. Although the state failed to prove that Basson was personally involved in the development and use of chemical and biological assassination weapons it was found conclusively by the trial judge that he had been head of a programme that had sought to develop chemical and biological weapons as well as their counter measures. Several scientists who had been highly regarded in their fields, even prominent members of professional associations, testified about their own involvement in the programme, including how they personally developed and gave members of the police and their colleagues in the military biological and chemical assassination weapons. Rather than rallying to condemn the actions of their colleagues, the professional associations and most individual scientists remained silent. Perhaps in the hope that by remaining silent they would avoid being contaminated by the aberrations (such as the development of chemical and biological assassination weapons) that characterised the chemical and biological warfare (CBW) programme.

While that may be true for many in the scientific community, there were others who actively supported Basson and who were opposed to action being taken by the professional associations to sanction Basson. Indeed scientists who had participated in the programme and spoke out about their involvement at the Truth Commission's public hearings in 1998 were in some cases subject to threats and abuse from colleagues. It was widely rumoured that members of a small group of medical professionals who approached the Health Professionals Council of South Africa (HPCSA) to urge them to sanction him for his involvement in the programme, received death threats thereafter.[4]

In many ways the post-Apartheid states' response to the TRC's revelations about the chemical and biological weapons programme, and indeed the revelations from the criminal trial of Basson, created the conditions within which it was possible for the scientific community to marginalise concerns about implications of the programme for the conduct of scientists more generally. The state made it clear that their official view was that the Apartheid chemical and biological warfare programme was predominately defensive in nature and that any offensive weapons development (which was restricted to biological and chemical assassination weapons, irritants and incapacitants) was undertaken by 'bad apples', individuals who had acted on their own and without a state mandate (South Africa 1995).

For the state, taking this position was seen as necessary to protect its international reputation, particularly in the context of the BWC. At the time of the revelations about the CBW programme South African diplomats were actively involved in negotiations to strengthen the BWC through the introduction of verification measures. South Africa took a very strong position on the need for a verification protocol.[5] The integrity of its negotiators, who had served the Apartheid government, would have been undermined if the state had acknowledged that there had been a state-sanctioned offensive biological weapons programme. In addition, such an admission would have required the state to change its Confidence Building Measures submission in terms of which it was clearly stated that South Africa had not had a past-offensive biological weapons programme (South Africa 1995). Thus, in the interests of the 'greater good' of getting better international control, it was clearly decided not to admit to the offensive nature of the past programme. This was easy to justify in that the programme was, in international terms, miniscule and there was no evidence (at the time) that the programme had resulted in the deaths of anti-Apartheid activists. The denial of the state, and the fact that it chose to downplay the significance of the CBW programme, created an environment in which the scientific community could remain silent.

For many white South Africans it was easy to distance themselves from the actions of the Apartheid security forces after 1994, even if they had both benefitted from white minority rule and had done nothing to actively undermine the undemocratic state. This was, in some ways, a function of the success of the political transition in South Africa. After 1994 the national mindset and shared notions of morality of whites shifted so quickly and so dramatically that even a few years later the actions of the state and individuals who had served seemed hard to understand or relate to. In August 2001 the Centre for Conflict Resolution held a workshop with scientists and medical professionals that brought together those who had participated in the CBW programme with others to discuss and draw lessons from the past so as to prevent such a programme from emerging again (Gould 2001: 14). One of the participants, a prominent science administrator, found the exercise a dreadful waste of time, because for him the past was a period of insanity that could never be repeated. As such it was easy to sweep aside discussion about what motivated the scientists who had been involved in the programme because there was a firm perception that South Africa could not return to where it had been, either in terms of the threats to the state or to the absence of sufficient controls over the actions of those in power. The broader scientific community sought not to engage in any way with its complicity in the programme (Gould and Folb 2002). The gulf between 'then' and 'now' meant that the past experience of the involvement of scientists (many who were respected members of their professions) has not resulted in the scientific community being concerned, either privately or publicly, about what the programme may tell us about the future potential for scientists to participate in a programme of this nature again.

Both the past experience of a state chemical and biological weapons programme, and the anti-terrorism discourse that has informed much of the international (particularly US) discussion about the need for increased focus on 'biosecurity' has not provided the impetus for South African scientists to discuss dual-use concerns or the need for codes of conduct and oversight mechanisms. Rather they have resulted in a reluctance amongst many (although not all) in the scientific community to talk about the kind of issues that would inform increased awareness-raising within the community itself.

Moving into the future

While the scientific community sought to distance itself from the past CBW programme and the pall it cast over the conduct of science in South Africa, it was less possible to dismiss the public outrage that accompanied the biotechnology revolution that led to the widespread availability and production of genetically modified (GM) plants and foodstuffs. In South Africa, and several other countries in southern Africa, the public debate about genetically modified foods was highly polarised and many scientists have since commented that it damaged the public perception of science and the scientific community in the region.

In 2002, Zimbabwe led the way in rejecting GM maize as food aid from the United States. Mugabe's rejection of the maize was based on the concern that the import of whole kernel GM maize could contaminate the country's indigenous crop. Zimbabwe's rejection was repeated by Mozambique, Malawi, Lesotho, Swaziland and most notably Zambia – that unlike the other countries in the region, refused even to accept milled GM grain. All cited safety reasons 'human health and environmental damage – as well as trade-related issues, as justification for their rejection of GM maize' (Clover 2002).

The rejection by states of the GM food in the face of huge food shortages fuelled public fears about the dangers genetic manipulation posed to African agriculture. The arrogant rejection of African concerns as unfounded and uninformed by international organisations and states polarised the issue further (Anon 2002). Indeed, it is widely recognised that this rejection of agricultural biotechnology by politicians and the public hampered the development of science in the region as it was seen as a threat to society. This in turn appears to have fuelled concern that drawing attention to the dual-use risk of scientific development and thus the destructive use of science may again fuel an anti-science sentiment that could lead to a slowing down of scientific development.

At the biosecurity workshop organised by the Institute for Security Studies, previously referred to, and the Centre for International and Security Studies at Maryland in May 2008, the President of the Academy of Sciences of South Africa (ASSAF) (Professor Robyn Crewe) said that the Academy had been 'debating the issue of biosecurity for many years, the key issue being how to promote legitimate research while making scientists aware of the potential pitfalls in their discoveries'. In his statement the concern of the scientific community in South Africa about engaging in the biosecurity discourse was made evident. It is a debate precisely because there is concern that by focusing on the security concerns relating to the misuse of science the progress of science may be slowed. A reaction against science, based on dual-use concerns, would impede the advance of science and thus prevent science from being promoted as the anti-dote to underdevelopment. Crewe (2008) acknowledged the existence of the apartheid CBW programme, but sought to place it in the past as something that should not affect the way in which current concerns and threats are thought about, saying:

> The ASSAf has a particular context in which to think about these issues provided by the apartheid chemical and biological warfare programme. But we need to move forward from this perspective. Indeed, the main advances in science that would have made Project Coast more dangerous hadn't happened at that time. Since 1993 scientific developments mean that the threat is more serious and scientists have to take it more seriously.

Despite this, Crewe did place the Academy as a central player in future discussions about how 'biosecurity' concerns should be addressed saying that since the Academy is the 'brains trust' for the country 'it makes sense that the Academy would be used to investigate and find ways to address the issues – this is the role that the Academy would like to play'. The fact that Crewe sought to show that the Academy took the issue seriously and had plans to address dual-use concerns, is both a function of the mounting pressure by international science professional associations to make 'biosecurity' and dual-use a focus of discussion, debate and action and a function of the focus of the meeting he was addressing. This is not to say that the Academy does not believe that preventing the misuse of science is important, however there is disagreement within the scientific community about how prominent a place this discussion should take.

According to a staff member of the Academy, Simon Rambau (2008), the debate about whether and how the ASSAf should deal with the issue of biosecurity was initiated only after ASSAf became a signatory to the IAP *Statement on Biosecurity* (see the chapter by van der Bruggen) indicating the extent to which international, particularly western-led initiatives and activities can affect national priorities elsewhere. As he said:

> Towards the end of 2006, ASSAf received a questionnaire from IAP on the national impact of biosecurity initiatives which was

> supposed to be completed annually by all the signatories of the Biosecurity statement. When the first questionnaire was completed in 2006, there was not much done by ASSAf apart from being a signatory to the statement. It was against this background that the Academy deliberated on this matter to determine how the Academy could sensitise the country to biosecurity recommendations as listed on the statement. (Rambau 2008)

The Academy responded by putting the statement on its website and sending it around to members and government officials. But it could not go as far as to agree on whether it should be raising awareness about biosecurity issues through workshops and symposiums, nor was there agreement on whether to set up a task team to look at whether there was a need to review the existing regulatory framework or consider codes of conduct. Indeed, during 2008 a proposal put before the Council of the Academy to establish a standing committee on biosecurity failed. Rambau explained the Council's rejection of the proposal like this:

> The ASSAf Council noted that the proposal had placed too much emphasis on deliberate theft, or malicious use of high-consequence pathogens and toxins referred to as bioterrorism and biological warfare and less on unintentional and accidental release of biological agents, epidemics and emerging pathogens which are devastating Africa, South Africa included. The Council resolved that biosecurity issues as explained in the proposal were not top priority for South Africa. The ASSAF Project Officer was mandated to re-work the proposal and focus on the South African challenges such as bioethics, biosafety and bio-risks common in the country such as health threats and food security. The Council concluded that the proposal should be brought to the next Council meeting with more focus on health and food security issues, which are at the core of challenges facing South Africa and Africa as a whole.

In his presentation, under the heading 'The concerns of using the concept "Biosecurity"' Rambau wrote that '…the ASSAf Council adopted an approach of not using the concept of biosecurity because of its connotations to bioterrorism and biological warfare. Instead the Academy prefers to use a concept(s) that would clearly state the focus of the project as either health security, food security or bioethics.'

Rambau expressed two concerns in relation to the definition of biosecurity provided by Jonathan Tucker, namely 'that biosecurity denotes policies and procedures designed to prevent the deliberate theft, diversion, or malicious use of high-consequence pathogens and toxins'. These concerns are that the focus on biosecurity should not affect the acquisition of biotechnology by developing countries and that it should not result in a diversion of resources from actual problems to imagined, or non-existent problems. The extent to which dealing with biosecurity is regarded as a diversion of resources from important matters, to unimportant ones, is perhaps evidenced by the fact that when the Academy did try to recruit scientists (through a nomination process) to lead an investigation into biosecurity issues, they were unable to find any willing takers. While this may be an overly harsh assessment – in the light of the fact that there is a limited pool of senior scientists in South Africa and those identified as appropriate to lead the process are committed to other projects already – the fact is that this topic would certainly not entice a scientist from what they would regard, and perhaps quite rightly so, as more immediately pressing and important work.

The failure to reach consensus in the debate within the ASSAf has to do with the way in which the international biosecurity discourse has been framed as a response to threats posed by terrorist groups, that ignores the far greater threats faced on the African continent of food insecurity, pandemics and the incapacity of existing health systems or infrastructure to deal with large-scale human or animal disease outbreaks. The fear is that by accepting and emphasising the risk that science and the progress made in science poses to humanity, the development of scientific capacity (that is sorely lacking on the continent) both in human and infrastructural terms, will be compromised.

The fact that the US 'War on Terror' did not resonate in South Africa, and caused revulsion, meant that there was another excuse for not dealing with the issue – the fear that terrorists would develop biological weapons was seen by some (but not all) as silly – a Western obsession that would draw scientists away from the important jobs that they have dealing with the very real disease burden of Africa.

Notes

1 See for example: Address by Deputy Minister, Aziz Pahad, to the Spanish Foreign Ministry Seminar on Sub-Saharan Africa, Tenerife, Canary Islands, 12 May 2005.

2 Chandré Gould interview with Annalie Botha, Senior researcher on terrorism, Institute for Security Studies, Pretoria, 27 September 2008.
3 This became clear through the many interactions that the authors has had during the past ten years with South African scientists in the context of raising awareness about biological weapons prevention and dual-use issues.
4 Author's verbal communication with Professor Leslie London, University of Cape Town during 2000.
5 For a complete list of working papers submitted by South Africa to the Ad Hoc group meetings of the BTWC please see www.opbw.org

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11
Biosecurity in Argentina

Martin Lema

Introduction

General background on Argentina

Argentina is one of the most significant producers and exporters of food and agricultural products in the world. More than half of Argentinean export income is currently derived from agricultural products. Argentina also has large tracts of land planted with genetically modified crops; with 21 million hectares in the 2008/2009 season, it is second only to the United States (James 2009).

Compared to other developing countries, Argentina has reached a significant level of development in the fields of biotechnology and peaceful uses of nuclear energy, both in terms of knowledge production as well as civilian applications of these technologies. This capacity has however not been applied for military purposes. This is despite the fact that the Argentinean conglomerate of governmental factories collectively known as '*Fabricaciones Militares*' is a significant manufacturer of conventional weapons (FM 2008; Soldados 2008).

The following Argentinean bodies have a role in relation to biological weapons control, defence or non-proliferation:

- The Armed Forces Scientific and Technical Research Institute (CITEFA)
- The Directorate of International Security, Nuclear and Space affairs of the Foreign Office (DIGAN)
- The Chemical, Biological and Nuclear Defence Company of the Argentine Army 601st Engineer Battalion
- The National Administration of Health Institutes and Laboratories (ANLIS) that, among other relevant divisions, comprise a Biological Containment Unit

- The National Directorate of Disease and Risk Prevention, National Health Ministry (particularly its branches of Epidemiology and Sanitary Emergencies)
- The Bacteriology and Exotic Diseases divisions of the National Service of Agri-food Health and Quality (SENASA)
- The Virology Institute of the National Institute for Agricultural Technology (INTA)
- The Non-Economic Bans Division of the General Customs Directorate

In addition, a number of institutions belonging to the National Science and Technology System work with biological agents and dual-use technologies. This diverse group includes universities and research institutions under the National Scientific and Technical Research Council (CONICET). Finally, several biotechnology firms related to animal and human health and agri-food production are making use of sensitive biological materials and/or employing dual-use supplies/technologies for legitimate purposes.

The biological materials mentioned comprise several viruses, bacteria, fungi and toxins. A few of these agents are 'traditional' biological weapons agents, such as anthrax, salmonella, hantavirus, and mycotoxins. In addition, others (an illustrative list is not given for the sake of prudence) are local human pathogens or toxins, or significant animal and plant diseases, of potential dual-use. In terms of technologies, the situation is no different from any country with a significant level of development in biotechnology including *inter alia* genetic engineering, advanced immunology and microbiology, biosensing, bioprocessing, protein purification, particle nanotechnology, and so on.

Local use of terms

In considering 'biosecurity' issues in Argentina, the usage of relevant Spanish terms should be taken into account. While in English there are two distinct terms with different meanings: biosafety and biosecurity, in ordinary Spanish both 'safety' and 'security' are commonly translated into the same word 'seguridad'. As a consequence, in many Spanish-speaking countries such as Argentina, the word 'bioseguridad' can be used to mean biosafety or biosecurity, depending largely on the background of the person speaking or the context within which the word is used. Since the experts in non-proliferation, laboratory safety and food safety do not usually work together, there is little appreciation of the potential term confusion.

In Argentina, the word 'bioseguridad' is most frequently used to mean 'biosafety'. For instance, it may be used in connection with agri-food production, which is in line with definitions of the Food and Agriculture Organisation (FAO) of the UN. The FAO defines biosafety as referring to

> … the avoidance of risk to human health and safety, and to the conservation of the environment, as a result of the use for research and commerce of infectious or genetically modified organisms.
>
> … [and] …
>
> The safe use for human health and the environment of new biotechnologies … where 'new biotechnologies' would be a combination of 'modern biotechnology', other types of biotechnologies that would not occur naturally, the use of novel organisms with no history of safe use, and the use of alien or invasive organisms or species. (FAO 2006)

Nevertheless, even FAO documents can contribute to confusion, for instance providing a definition for biosecurity that is actually closer to the concept of biosafety:

> FAO defines 'biosecurity' as a strategic and integrated approach that encompasses the policies and regulatory frameworks that analyze and manage risks in the sectors of food safety, animal life and health, and plant life and health, including associated environmental risk. It is a holistic concept of direct relevance to the sustainability of agriculture and food production, food safety and the protection of the environment, including biodiversity and covers the introduction of plant pests, animal pests and diseases, and zoonoses, the introduction and release of genetically modified organisms (GMOs) and their products, and the introduction and management of invasive alien species and genotypes. (FAO 2006)

In Argentina the word 'bioseguridad' is often used in connection with risk management measures applied to genetically modified organisms of potential agricultural use, while still under field trials and safety assessment. This is also in line with the international trend after the entry into force, in 2003, of the Cartagena Biosafety Protocol (BSP). The BSP provides an international regulatory framework for the safe transfer, handling and use of Living Modified Organisms (LMO), as products of 'modern biotechnology', with a specific focus on trans-boundary movements of LMOs 'that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health' (BSP 2000).

On the other hand, the term 'bioseguridad' in Argentina is also used when referring to laboratory biosafety in the context of biological containment, or for general biological safety in research, industrial activities, or pharmaceutical production. Nevertheless, more general terms like 'seguridad e higiene de laboratorio' (laboratory hygiene and safety) are still ordinarily used, unless for laboratories working with very dangerous pathogens (BL3-BL4), or when the speaker intends to dramatise. Nevertheless, rarely does this concept of '*bioseguridad'* also include laboratory *biosecurity* in the way that, for instance, OECD has defined it:

> Institutional and personal security measures and procedures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens, or parts of them, and toxin-producing organisms … (OECD 2007)

In Argentina and other Spanish-speaking countries, the word '*bioseguridad*' is understood by most people to mean either laboratory or agri-food biosafety, i.e. frameworks encompassing policies, regulation, and management for safe use of biological entities, and as such only refers to 'legitimate' activities.

There have been some attempts to find a solution to the lack of two distinct terms. For instance, in FAO technical meetings it has been proposed to begin translating '*bioseguridad*' as '*bio-inocuidad*' (the literal back-translation would be 'bio-innocuousness' or 'bio-harmless') or '*gestión de riesgos biológicos'* (which would back-translate to 'management of biological risks'). Consequently, the term '*bioseguridad*' might be freed for switching its meaning to 'biosecurity'. In contrast, the term '*biocustodia*' (literally translated as 'bio-custody') has been agreed as a translation for 'biosecurity' among the Spanish-speaking delegations to the BTWC (consequently, the term '*bioseguridad*' would still mean 'biosafety'). Nevertheless, neither these nor other proposals have yet been widely adopted in Argentina, thus there is no common agreement on the use of these terms.

Argentina, is on the one hand an important food producer; on the other hand, it has reached a significant level of development in all branches of pharmaceutical, agricultural and industrial applied biosciences. In addition, the country actively contributes to and benefits from many relevant international forums. As a consequence, and mirroring the international situation, many regulatory, scientific and policy bodies have indeed been working for decades in 'bioseguridad', but for most this meant to dealing with 'biosafety' issues.

The historic lack of a second term was due to a lack of awareness amongst many regarding 'biosecurity' issues. Moreover, it also concealed the lack of cooperation between those few who were working on 'bioseguridad', but with a biosecurity meaning. This has now started to reverse, since biosecurity has suddenly become highly relevant at the global level and simultaneously in different fields of endeavour.

The national situation

State involvement in international non-proliferation

Argentina is active in many international counter-proliferation forums (Matías 2007). In 1969 Argentina acceded to the 1929 Geneva Protocol. Argentina also endorsed the Biological and Toxin Weapons Convention (BTWC) as soon as it was opened for signature in 1972, and ratified it in 1979 through the National Law no. 21978. Finally, in 1994 Argentina became a member of the Australia Group (established in 1985), and currently it is the only state from Latin America to do so.

The country is also an active member of other important non-proliferation regimes: the Chemical Weapons Convention, the Australia Group, the Missile Technology Control Regime, the Wassenaar Agreement, the Zangger Committee, and the Nuclear Suppliers Group (Argentina has reached an important technical capability in the civil uses of nuclear energy). Indeed, the Director-General of the OPCW (who has been consecutively elected for two terms spanning the years 2002–2010) is Ambassador Rogelio Pfirter, an Argentine diplomatic.

The underlying reasons for this level of involvement are straightforward: on one hand, Argentina has never been a proliferator,[1] therefore no national interests are affected by the bans. On the other hand, the repugnance for these kinds of weapons and Argentina's interest in ensuring that no other country takes advantage of them, also informs its active engagement in non-proliferation initiatives.

Argentina has also engaged in regional non-proliferation efforts. For example, in 1991 Argentina, Chile and Brazil signed a declaration including compromises in support of the chemical and biological warfare conventions; this happened in the Argentine province of Mendoza. The declaration was later adhered by Uruguay, Bolivia, Ecuador and Paraguay.

In 1998, a similar but updated declaration to strengthen the ongoing negotiations of the BTWC was signed by Argentina, Brazil, Chile, Colombia, Mexico and Peru.

More recently, Argentina has repeatedly endorsed the implementation of the UN Security Council Resolution 1540/2004. In 2005, an international meeting to this end was hosted in Buenos Aires and co-sponsored by the United Kingdom. In 2008 two other meetings were held in Buenos Aires, one of them to address the issue in the context of the Organization of American States and the other in the context of the weapons of mass destruction group of the Southern Common Market (MERCOSUR).

Also in 2008, an International Seminar on Technology Controls, including 'bioresponsibility' was held in Buenos Aires, as a part of the Argentina-United States bilateral agenda. The two main Argentine bodies involved in these negotiations and the enforcement of the confidence-building measures are the DIGAN and CITEFA.

In relation to the BTWC specifically:

- Argentina supported the 2002 agreement on the assembly of an intergovernmental expert group to identify measures aimed to strengthen compliance of the BTWC
- During the sixth review conference of the BTWC the delegations of Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, Guatemala, Mexico, Peru and Uruguay contributed several joint declarations and written submissions covering many issues, including confidence-building measures, follow-up mechanisms, scientific cooperation and technology transfer
- Argentina regularly submits annual Confidence Building Measures (CBM) reports
- Argentina has submitted technical papers to the *ad hoc* technical group of the BTWC on 'Methodology for the assessment of the feasibility of use of biological agents' and 'Classification and characteristics of biological agents' (Argentina, 1999)
- Argentina submitted recommendations for the adoption of codes of conduct, which were elaborated *ad hoc* by the Ethics Committee of the Ministry of Science and Technology[2] (CECTE 2005)

Finally, Argentine experts from CITEFA have participated as chemical and biological weapons inspectors of the special commissions created by the UN to ensure Iraq's compliance with policies concerning production and use of weapons of mass destruction after the Gulf War (UNSCOM and UNMOVIC).

Altogether these activities show sustained and clear State commitment to non-proliferation.

National legal framework

Penal liability

Article 189-bis of the Argentine Criminal Code is directly related to the internal implementation of the BTWC. This article, introduced in 2004, stipulates penalty of up to 15 years in prison for whoever acquires, produces, supplies or possesses bombs, materials or devices capable of releasing hazardous materials of biological origin (or substances or materials intended for their preparation), if there is an intention of committing felonies against public security, the sabotage of machinery or the manufacture of goods.

The same penalty can be imposed on anyone who gives instructions for the preparation of such substances or materials, knowing that he or she is contributing to this kind of felony. Besides, the possession of such materials, without proper legal authorisation or justification by domestic or industrial use, shall be punishable by a prison term of up to two years, and a fine.

Other relevant sections of the code are:

- Article 200 refers to the deliberate poisoning or adulteration of drinking water, foods or medicines (extended to anyone who knowingly distributes them by Article 201), providing a prison term of up to 25 years if it results in human death
- Article 202 specifies 15 years for anyone who purposely propagates a dangerous and contagious human disease
- Article 203 also incorporates lighter penalties if the situations under Articles 200, 201 and 202 are the consequence of reckless, negligent, unprofessional acts or omissions, or for not following the applicable norms
- A prison term of up to two years is requested by Article 205 for not complying with sanitary measures requested by competent authorities to avoid the initiation or the spread of an epidemic, while Article 206 provides for a term of up to 6 months in cases of incompliance with animal sanitary laws
- Article 186 stipulates up to ten years for whoever destroys crops, agricultural products or facilities; this can be raised to 20 years if the damage becomes proximate cause of a person's death
- Under Article 188, a term of up to six years in prison should be imposed on anyone who sabotages means of defence against disasters

- Article 189 provides up to a year if a disaster is produced because of reckless, negligent, unprofessional acts or omissions, or for not following the applicable norms. This can be raised to five years if it leads to the death of a person

To supplement previous articles devoted to actual damages or regulation defiance, article 211 refers to public intimidation. Anyone who threatens the population or raises an alarm to inspire fear should be imprisoned up to six years, or up to ten if 'related materials' (e.g. biological agents) are actually used to fulfil such purposes.

Finally, it is relevant to note that in August 2008 the former Military Code was repealed in Argentina, therefore the military personnel is currently fully under the ordinary justice and the Argentine Criminal Code.

Export/import control regime

A commission for coordinating the export policy for warfare materials was created by the 1097/1985 (Presidential) Decree. Later, a specific regime for the control of sensitive exports was created by the 603/1992 Decree, and the previously existing commission became the *National Commission for the Control of the Export of Sensitive and Warfare materials*. This regime so far has been complemented by Decrees 1291/1993, 102/2000 and 437/2000.

The lists of regulated materials are currently updated through joint resolutions by the Defence, Economy and Foreign Affairs Ministries. The first of these updates, in 1993, included biological agents and dual-use equipment for the first time. From 1998, the lists of chemical substances, biological agents and dual-use equipment were extended in order to match the Australia Group lists.

The current regime[3] controls the export and import of materials, equipment, technologies, technical assistance and services related to nuclear, chemical and biological dual-use technologies, as well as military and missile-related technologies; this is done through a requirement of prior authorisations whose applications are assessed on a case-by-case basis. In regards to biological materials, health and sanitary agencies also intervene in the control of transboundary movements.

Biosecurity awareness in life sciences research

There are no studies in Argentina on the awareness of 'biosecurity' issues in the context of life sciences laboratories. Nevertheless, results of a recent survey by Sandia National Laboratories on the state of laboratory 'biosecurity' in Latin America (Phipps *et al.* 2007) can be regarded as representative of the Argentine situation.[4] The study covered 19 countries and 160 respondents actually working with at least one pathogen from a standard list of biological agents compiled by the authors of the study. Among its findings, it can be read:

> Study respondents were generally more concerned with issues related to biosafety than biosecurity. ... Accidental contamination is a bigger worry than a breach of security ... <u>76 per cent are completely unconcerned about theft of samples</u> by either an employee or non-employee with intent to cause harm [emphasis added by the author].

In Argentina, most life science specialists have been adequately trained in microbiology, therefore they are familiar with biological hazards and biosafety standards to avoid them. Conversely, there is generally little to no institutional or individual concern regarding 'biosecurity' (i.e. prevention of the misuse of biological agents or technologies). In many universities, despite efforts of regulatory authorities, it might still be possible for a student or an outsider to enter a laboratory (or to reach a shared facility like a freezer in a public corridor); and once there steal a disease agent or a dual-use reagent. Furthermore, in some cases the theft may go unnoticed due to the lack of a tracing system for avoiding unlawful attempts.

Another interesting finding of the Sandia Survey is:

> ...a variety of research objectives and a diverse array of pathogens and toxins: nearly half of the respondents [also] work with agents not specified on the list provided, and there were over 50 agents listed under the 'Other, please specify' answer choice.

Current lists of sensitive agents have been compiled from the experience of western, northern-hemisphere countries. Many local diseases (i.e. potential agents) in the developing world, particularly in Latin America, are not widely known in other regions and therefore they fall 'outside of the radar'. This impacts on the efficacy of control regimes, since some of these agents may not be adequately monitored. On the other hand, the inclusion of these agents in 'international' lists may increase the difficulties of developing countries to study and ultimately find remedies for highly important health problems.

Recent experiences: 'Chantrax'

Perceptions of biological weapons threats skyrocketed in Argentina by the end of 2001. The term 'chantrax' is a mixture of the words '*chanta*' (local Argentine slang for 'cheater') and '*antrax*' (anthrax, in Spanish). It was coined by a major news magazine in Argentina as a headline to an article describing what happened during those months (Klipphan 2001).

Shortly after news that letters containing anthrax spores were sent to influential individuals in the United States, Argentina experienced a wave of mock anthrax letters. Unexpected correspondence (e.g. advertisements) from abroad, in particular from the United States, were considered potentially dangerous by the population. In addition, thousands of mail envelopes containing talcum, sugar, ashes or other ordinary clear powder were sent to schools, media, governmental offices, ballot vote locations, etc., along the whole country. They were probably sent spontaneously by different people, as practical jokes or with an intention of disrupting activities of the recipient organisations.

Some of these envelopes were dismissed by the recipients without raising alarm, but in many cases there were operations of varying professionalism to isolate and inactivate the material. When requested, first responders including police, firemen and ambulances intervened, usually with uncoordinated and dissimilar approaches for each episode. In a few weeks, the Muñiz Hospital and the Malbran Institute – the main laboratories for the diagnosis of exotic diseases in Argentina – received about 20,000 diverse objects for anthrax analysis (Klipphan 2001).

At the same time low flights of single-engine aircrafts over urban areas began to raise panic after journalists described how, hypothetically, anthrax could be dispersed by air.

People rushed to buy any kind of masks – most of which were not suitable to protect against biological agents – and antibiotics. Some specific products were imported or invented in the moment and sold out: sterilising aerosol cans to moisture envelopes and deactivate biological agents, small acrylic cabinets to open envelopes safely (like a small Class III biological safety cabinet), etc. Even INVAP (a public-private high tech company in the field of nuclear energy and space technology) considered the production of an apparatus for high-volume mail sterilisation by irradiation.

Some bureaucrats and politicians unnecessarily boosted this state of public anxiety, perhaps in order to increase their influence or budget. The Minister of Health, for instance, informed the population that laboratory results had confirmed that one of the letters actually contained anthrax. Later this was found not to be true, and the Minister was put on trial – and afterwards absolved – for the crime of 'public intimidation' (see previous reference to Article 211 of the Argentine Criminal Code).

During those final months of 2001, the Argentine Federal Emergency System (SIFEM) tried to coordinate the activities of first responders in regards to the perceived biological threats. SIFEM was created in 1999, it originally reported directly to the Chief of Ministers (the President's right hand) and its functions included articulating emergency response bodies at the federal level, and establishing protocols and networks with a focus on prevention, alert and monitoring.

Although SIFEM at that moment was a high-level bureau, its recent creation implied it still lacked the networking basis that was vital for coordinating an ordered response. SIFEM also begun to elaborate protocols for further biological incidents. Nevertheless, in December 2001 a major economic and political crisis hit Argentina, there was a sudden President change, and SIFEM activities were discontinued. The crisis also made the population forget about the threat perception, and afterwards there has been no significant hoaxes or panic incidents related to biological weapons.

Present state of preparedness and outreach activities

The Argentine intelligence and defence sectors are aware of biological weapons issues, as can be learnt from several publications of the relevant academic organisations by local authors (Espona 2003; Sarno *et al.* 2007; Valles *et al.* 2006). A battalion of the Argentine army has been trained and equipped for NBC (nuclear, biological and chemical) warfare; in addition, several ground vehicles (tanks, troop transporters) and ships (missile frigates) have been equipped to operate in a NBC environment.

There have been a few recent training activities and combined drills simulating a bioterrorism situation by Argentine first responders and security forces (police, gendarmerie, fire-fighters, public healthcare system, etc.); some of which have been arranged in collaboration with international organisations.

CITEFA is the main institution responsible for the technical aspects of non-proliferation in Argentina. It has a key role in the technical revision of the control lists of the sensitive exports regime, in gathering information for the Argentine national report to the BTWC, and in performing outreach activities involving other governmental institutions and the biosciences academic/productive sector.

The DIGAN has established a programme of activities including a working group of members from relevant national agencies regarding non-proliferation, in order to coordinate activities towards the implementation of the BTWC and related agreements.

There are several branches of legitimate research and product development activities related to dual-use biological agents; for instance those related to Argentine hemorrhagic fever, foot and mouth disease, mycotoxins, *datura* alkaloids, etc. There are a few biosafety Level 3 laboratories in the country, which are operated by public or private organisations for basic research or vaccine production.[5]

Nevertheless, there is a lack of proper discussion about 'biosecurity' issues in the curricula of relevant careers and the industry. The National University of Quilmes is one of a few exceptions, having introduced specific courses related to ethics, regulation and social impacts of biotechnology (which includes biosecurity issues since 1998). It has also released a popular science book on bioweapons and bioterrorism that has sold more than 50,000 copies in several Latin-American countries (Lema 2002).

Factors informing perceptions of threat

Argentina is a relatively peaceful and safe country. Nevertheless, its recent history includes several experiences of the kind that shape the field of international security. Such experiences also illustrate how the state, key individuals and the population perceive and respond to this kind of threats.

Wars, terrorism and organised crime

Argentina remained neutral during the first and second World Wars. Nevertheless, during WW I Germany intended to sabotage livestock shipments from Argentina to France and the United Kingdom. Covert agents and anthrax vials were sent through Spain, in order to infect the animals by feeding them with contaminated sugar cubes (Wheelis 1999). In fact, during the twentieth century Argentina only engaged in one conventional war: the South Atlantic conflict in 1982 between Argentina and the United Kingdom over the disputed Malvinas, South Georgia and South Sandwich Islands, a group of two large and several small isles in the South Atlantic Ocean east of Argentina. On the other hand, Argentine military forces have contributed to 20 United

Nations (UN) peacekeeping missions along the last 50 years (Mindef, 2008).

During the 1990s, the Argentine justice initiated two investigations regarding the smuggling of (conventional) war weapons from the Argentine national stockpile. In one of the cases the destination was Croatia, under a UN weapons embargo at the time. On the other, the destination was Ecuador during a period of war with Peru, Argentina being a member of the UN peace force for that conflict (Levit 1996).

In the same decade, there were two major terrorist attacks on Argentina. The first, in 1992, was targeted at the embassy of Israel in Buenos Aires. A vehicle driven by a suicide bomber and loaded with explosives smashed into the front of the embassy and destroyed the embassy itself, a Catholic church, and a school building. Most of the victims were Argentine civilians, including many children. The blast killed 29 and wounded 242. The second attack, in 1994, was similar in nature. It involved about 275kg of a shaped charge, high explosive that demolished the seven-floor building of the Argentine Israelite Mutual Association in Buenos Aires. Eighty-five people were killed and about 300 injured in this attack.

Both cases are still unsolved and there are several theories about who was behind the attacks. Early conjectures involved a reprisal for the Argentine contribution – which was quite limited and non-combative – to the UN coalition during the Persian Gulf War. Later, hypotheses suggested that the attacks were a retaliation against the Argentine government decision to suspend a nuclear cooperation programme with Iran, and/or revenge for the death of Hezbollah leaders by Israeli forces in the middle East. Suggestively, a young man has been granted a plaque in a square of southern Lebanon *'for his martyrdom on July 18, 1994'* – the date of the last bombing (Caistor 2007; Savoia 2005).

After the terrorist attacks in Argentina and the 9-11 attacks in the United States, a great deal of international attention was directed at the triple border between Argentina, Brazil and Paraguay. The triple border zone occupies 2 500 sq km with a combined population of 700,000 people. The three main cities in the area are the Brazilian *Foz do Iguaçu*, the Paraguayan *Ciudad del Este* and the Argentinean *Puerto Iguazu*. Two bridges connect the three cities that are crossed by 20,000 vehicles everyday; this hinders comprehensive border control. The Argentine contribution to the border area is minor relative to the other countries both in demographic and economic terms.

This zone is home to the second biggest population of people of Arab origin in South America, most of whom are traders of Lebanese heritage. The local leaders of Arab communities have spoken out against the 9-11 attacks, and have rejected allegations that there is a relationship between the local Arab communities and terrorism. There is no evidence to suggest terrorist activities take place in the area. There is however evidence of organised crime activities (particularly smuggling and counterfeit). As a consequence, some have argued, this might create an increased opportunity for the temporary support of terrorist activities from abroad through funding, smuggling of people and materials or recruitment of local aid (Bartolomé 2002; Oz 2008). As a consequence of this perception the United States increased intelligence surveillance in the area and extended offers of joint military exercises (Aliscioni 2005).

On the other hand it has been argued (Aliscioni 2005) that other strategic issues may inform foreign interests in the triple border region. This area provides immediate access to five South American countries (Uruguay and Bolivia are close), it is a gate to the heart of the Amazonia and other regions with high biodiversity assets, and is in the middle of the Guarani Aquifer, which is the largest single body of fresh, non-contaminated, underground water in the world.[6]

Toxin smuggling

A more recent episode points to the existence of potential future threats. This incident took place in 2006, when a mail package containing 500 milligrams of ricinine[7] was seized by the Argentine customs authorities in the National Ezeiza Airport.

The product, that had been bought by a French laboratory for USD 3000, was exported from France, through the United States and Brazil. The Argentine importer never showed up physically, but after the initial concern was raised by the *Maria* System (the Argentine Customs informatics system) he requested authorities, by email, to re-send the package to Spain. This request was denied.

At the time, the individual responsible for the attempted ricinine import was already under investigation for custom taxes fraud (he previously imported compact disks but declared a shipment of bricks). After the ricinine affair it was discovered that he earlier succeeded in introducing 250 milligrams of aconitine to the country (Villosio 2007). More recently, the same person is being investigated in connection with a case of drug dealing that involved ephedrine smuggling from Argentina to Mexico.

To date, no further findings on other persons implicated or the intended use of the ricinine or the aconitine have been reached. Given the broad range of activities displayed by the operator, probably he was just hired by someone else interested in gaining access to these toxins.

Some difficult issues

Other threats: Backfires on international trade

One of the earlier enforcements of the United States 2002 Bioterrorism Act affected an Argentine shipment of lemons. In July, 2004 an anonymous email was received by the United States Department of Agriculture; it warned that an incoming Argentine shipment of lemons was contaminated 'with a dangerous biological substance' (Longoni 2004a).

This resulted in the United States Coast Guard stopping a Chilean cargo ship approaching the port of Newark, which was transporting five containers with 125 tons of lemons from the Argentine province of Tucuman. The final destination of the cargo was Montreal, but the containers were intended to be transported by land from New York to Canada. The cargo ship was delayed a week, and the crew was quarantined. US customs, FBI and FDA also intervened in the operation.

The containers were never opened. They were frozen, then scanned during which suspicious horizontal lines were reported (later found to be cardboard boxes) and finally heated to 200°C to inactivate any (undetected) biological agent. The alarm was raised when a viscous yellowish liquid emerged from the containers and it was sent for analysis. The liquid was ultimately identified as caramelised lemon juice.

In this process, the Argentine exporter reported a Canadian importer as a potential author of the scare. That operator, after being dismissed for contract infringement, had been sending some intimidating messages to the Argentine exporter. Eventually, the FBI could confirm that the anonymous email was indeed sent from Canada.

The costs of this sabotage were high. The lost lemons were valued at USD 70,000. The Argentine exporter lost another USD 200,000 due to the subsequent cancellation of other shipments. Moreover, USD 700,000 were lost by the carrier due to the immobilisation of the ship, finally the destroyed containers were valued at USD 250,000.

The United States Department of State formally apologised following an official complaint by the Argentine government (Longoni 2004b).

The Bioterrorism Act was adopted in the United States after the anthrax letters of 2001. This law mostly address a scenario of biological agents being delivered from abroad, despite the fact that the evidence seems to indicate that those letters were sent from inside the United States territory (Willman 2008). It gives the United States authorities the license to destroy a foreign suspected shipment based on credible information. In this case, an anonymous email – in the absence of any analysis confirming the presence of a biological agent – seemed to represent 'credible information'.

In addition, the Bioterrorism Act enforces a strict tracing and notification regime. The costs of any emerging operation are to be covered by the owner of the product. Such increase in costs, delays and commercial risks may be considered disproportionate and a potential non-tariff barrier from the perspective of countries having a good record of food safety and non-proliferation, like Argentina. Even a specific neologism has been coined for such measures: 'bioprotectionism'.

The case of Junín virus vaccine

Argentine hemorrhagic fever (AHF), is a zoonotic infectious disease caused by the Junín virus (an arenavirus). The endemic area of AHF covers approximately 150,000sq/km, compromising the Argentine provinces of Buenos Aires, Córdoba, Santa Fe and La Pampa, with an estimated population at risk of five million people.

The vector, a small rodent known locally as corn mouse, suffers from chronic asymptomatic infection and spreads the virus through its saliva and urine. Disease can be caused by inhalation or contact of the skin or mucous membranes with infected particles. It is found mostly in people who reside or work in rural areas; the mortality of untreated AHF reaches 30 per cent. This disease was very influential in the creation of a National Institute of Human Viral Diseases (INEVH), named 'Dr Julio Maiztegui' after the head of the lead Argentine research team in this disease.

The Junín virus was isolated in 1958. An early attempt to create a vaccine almost succeeded in the sixties. During the seventies, a serum was produced which helped to reduce lethality but obviously did not contribute to prevent the disease.

Although the Argentine Government supported research on this disease for decades, the lack of adequate long-term policies translated into an irregular flux of resources that hampered the national development of a vaccine. On the other side AHF mostly affected poor people in the outskirts of cities, so it was not particularly interesting for the blooming Argentine pharmaceutical industry.

Only in 1985 did an Argentine scientist conclude the development of a vaccine (Candid#1) in the Fort Detrick laboratories of the United States Defence Department. Candid#1 is a derivative of a very virulent strain of AHF isolated from an Argentine patient, through an attenuation process that began in Argentina and was completed in the United States. Candid#1 was tested in a high-risk population in Argentina and was found to be 95 per cent effective (Maiztegui *et al.* 1998). Finally, the vaccine was produced in the Salk Institute, and became available in Argentina after 1990.

This experience begs the question – why was the United States defence sector interested in developing a vaccine for this local Argentine disease? In retrospect, it seems likely that the interest was sparked by intelligence information that the Soviet Union had supposedly collected virus samples in Argentina. This hypothesis is supported by the memories of a deserter of the soviet 'Biopreparat' programme (Alibek 1999).

It is sad to acknowledge that the Argentine society was not able to conclude obtaining a vaccine for a major public health problem among (poor) agricultural workers while, in contrast, the United States boosted its development just in case a foreign power could succeed in weaponising the virus.

This history has a macabre resemblance to current discussions on the access and sharing of benefits from genetic resources in the World Trade Organisation, the FAO, and other forums. Analysed in these terms, the Soviets could be accused of 'biopiracy' for stealing samples of the virus from Argentina, the 'centre or origin' of the 'biological resource'. Subsequently, the United States made use of the 'local knowledge' developed by Argentine scientists to produce a vaccine. Thereafter Argentina had (initially) to buy the vaccine from the foreign supplier that developed it on the basis of Argentine science investment and that had benefited from the availability of Argentine citizens for purposes of testing the vaccine. Finally, when the foreign provider lost interest in manufacturing the product, Argentina had to license the know-how before it could start local production of the vaccine (Camps 2006).

As in other international agreements tied to biological resources and technology development, the BTWC has an impact on the (usually opposing) global fluxes of primary materials and technologies. Therefore, as in other forums, the universal implementation of the BTWC would rely on a serious commitment of the developed countries to account for the legitimate needs of developing countries.

Conclusions

Argentina is unlikely to become a proliferator of biological or any other type of non-conventional weaponry in the foreseeable future. Moreover, it is one of the leaders in its region regarding the support of nonproliferation regimes. Nevertheless, Argentina shares many relevant elements with other countries where biosecurity is an issue: a high degree of development in the applied and basic life sciences; and abundance of material resources and personal capabilities. Consequently, Argentina should sustain efforts to further develop and maintain high biosecurity standards, in addition to developing pre-emptive tools like widespread specific ethics education.

In the international field, one of the pending issues is how to cope with the fact that conditions in Latin American countries can be quite different compared to the developed countries that currently shape biosecurity policies. Therefore, it would be an appropriate role for Argentina to develop and propose model policies (agent lists, transboundary biosecurity standards, etc.) that could be effective without hindering legitimate and necessary activities in developing countries. At the same time, it would also be important to avoid 'biosecurity' concerns from becoming a pretext for non-tariff trade barriers. Analogous measures have been already adopted to protect against food products from cattle treated with growth hormones or from genetically modified crops (WTO 2006) based on alleged concerns about *biosafety*.

Argentina has adopted adequate legal standards to implement the BTWC, with perhaps minor gaps (for instance, in regards to fault-based liability from the failure to the duty of due care in handling dual-use materials). It is now important to conduct sustained and comprehensive outreach to ensure full compliance in all relevant sectors.

Argentina also fulfils its commitments within the Australia Group related to export control. It is commendable that the ministries of Economy, Defence, Foreign Affairs and Production cooperate in this endeavour; while it would be advantageous if the recently created Science and Technology Ministry also begins to contribute. Conversely, as in other countries, one of the main transversal issues that can tangle with biosecurity is the smuggling of persons or dual-use materials in retail quantities.

In summary, Argentina has acknowledged the importance of 'biosecurity' and it is reacting adequately both internally and externally. Given its clean record, national interests, intermediate position and willingness to take action, it is called to play a significant role in the building of an effective international biosafety framework.

Disclaimer

The information and views contained in this article are the sole responsibility of the author, and they should not be ascribed to and do not necessarily represent the opinions or policies of any organisation, institution or government. This text is only intended for academic purposes.

Notes

1 Argentina's neighbours in the region are not and have not been suspected of biological weapons production, except for an unconfirmed report of a chemical and biological weapons program temporarily run under the government of Pinochet in Chile (Franklin 2006; X.M.V., 2006).
2 The report recognises that many scientific and technical advances can be misused to develop mass destruction weapons. Conversely, it states that scientific progress should not be interfered with, and asserts that excessive regulatory obstruction to the freedom of research can end up jeopardising defence capabilities. The report suggests that codes should be instructed during initial scientific training, but relevant institutions also should officially adopt them. At the international level, the report warns against the development of guidelines that may hamper multinational research, or create a division between countries that can or cannot afford the implementation of such standards; thus it proposes the creation of an international fund for reducing that gap.
3 In 2007 a Law Project was presented in the Argentine Legislative Congress, which would strengthen, enhance and update the current regime. This project is an improved version of an original proposal dated 2005. The Higher Chamber has already endorsed it, and it is currently under consideration by the Lower Chamber.
4 Despite the many similarities among Latin American countries, there is one area where Argentine researchers are in a clearly better position. Since Argentina is a member of the Australia Group, they can import dual-use materials more easily.
5 For instance, the ANLIS Biological Containment Unit (UOCCB) has a BSL3 and ABSL3 facility certified under NIH and WHO standards in 2008. It is currently beginning projects involving high-risk pathogens of public health relevance, ranging from research and diagnostics to small-scale production of biological agents.
6 The aquifer is located beneath the four original Mercosur countries (Argentina, Brazil, Paraguay and Uruguay). It is estimated to contain about 40,000 cubic km of water, with a recharge rate of 200 cubic km/year from precipitation. In addition to irrigation and drinking, its waters at high depths can also be employed for the generation of geothermal energy.
7 The main toxin of the ricin plant is a protein. In contrast, ricinine is an alkaloid of lesser toxicity, but is easier to use it in forensic analysis as a marker of poisoning with ricin plant extracts. From mice feeding studies it can be estimated that the amount of ricinine seized may, at best, be used in an anti-personal attack.

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12

Strategies to Prevent Bioterrorism: Biosecurity Policies in the United States and Germany

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The mailing of letters contaminated with anthrax spores through the US postal system in September–October 2001 resulted in the infection of 22 people, five of whom died, and caused expanding ripples of fear, social disruption, and economic damage. This crime called attention to the need for 'biosecurity' measures to prevent terrorists from acquiring the materials and know-how required to carry out biological attacks. Such measures include limiting access to dangerous pathogens and toxins, restricting the publication of sensitive scientific information, and overseeing dual-use research that is conducted with peaceful intent but could be misused for hostile purposes. Because biotechnology is spreading worldwide, national biosecurity laws and regulations should be harmonised to the extent possible.

This chapter compares how the United States and Germany each address biosecurity. Both countries are Western industrial democracies that rank among the top five in biotechnology, and both have a political system that divides governance responsibilities between the federal government and the states. Nevertheless, Washington and Berlin have taken quite different approaches to the prevention of bioterrorism, including pathogen security and the oversight of dual-use research.[2] A systematic comparison of US and German biosecurity policies should therefore shed light on the challenges involved in developing a harmonised set of international guidelines.

Background

Although biology is not the only science with potentially destructive applications, it poses a qualitatively different set of risks. Producing sufficient fissile material to build a nuclear bomb or enough chemical weapons to inflict mass casualties requires a large industrial base and, most likely, the financial and technical resources of a nation-state. But terrorists who managed to obtain and deliver a highly infectious, contagious, and lethal pathogen could unleash a deadly epidemic with a far smaller investment of time, money and effort.[3] Because of the potential destructive power that biotechnology puts in the hands of small groups and even individuals, it is essential to find ways of channelling biological research and development in beneficial directions while minimising the risk of its deliberate misuse for hostile purposes.

At least in the near term, the greatest threat is not from 'biohackers' tinkering in basement laboratories but rather from military scientists working in national biological warfare programmes. Such individuals read the scientific literature and are capable of directing basic research findings into new lines of offensive development. Although the current technical capabilities of terrorist groups such as Al-Qaeda are rudimentary, they may become more sophisticated over the next decade as powerful biotechnologies such as automated DNA synthesisers spread to countries around the world.

National strategies to prevent bioterrorism have focused primarily on measures to limit access to dangerous pathogens (Tucker 2002). Such efforts are consistent with Article IV of the 1972 Biological and Toxin Weapons Convention (BWC), which stipulates that each state party shall 'take any necessary measures to prohibit and prevent' the development, production, stockpiling, and transfer of biological and toxin weapons within its territory and any other location under its jurisdiction or control. Although Article IV does not refer to specific measures, it is generally understood to require member states to adopt implementing legislation making the prohibitions of the BWC binding on their citizens and imposing penal sanctions for violations. National biosecurity measures were discussed during the intersessional meetings of experts and BWC States Parties in 2003 and 2008 (see the chapter by Revill and Dando in this book). Although the participating countries exchanged a great deal of information, no effort was made to distill it into a uniform set of guidelines or 'best practices' for national implementation.

In April 2004, the development of national biosecurity measures received a new impetus from UN Security Council Resolution 1540, which requires all states to adopt 'appropriate' and 'effective' national legislation to prevent the proliferation of nuclear, chemical and biological weapons and related materials, especially for terrorist purposes (United Nations Security Council 2006).

As elaborated in the Introduction and previous chapters, biosecurity measures also extend beyond pathogen security to the more contentious issue of regulating dual-use research in the life sciences (Atlas and Dando 2006). Although recent advances in bioinformatics and molecular genetics promise great benefits for human health, state proliferators or sophisticated terrorists could potentially misuse the results of such research to develop more effective biological weapons (Tumpey *et al.* 2005; Van Aken 2006; Tucker and Zilinskas 2006).

A complicating factor for policymakers is that advanced biotechnology is no longer the exclusive purview of advanced industrial states such as the United States, Germany, and Japan. Countries such as Brazil, China, Cuba, India, Malaysia, Singapore, South Africa, South Korea and Taiwan are also making major investments in biotechnology and, in some cases, conducting cutting-edge research and development. It will therefore be necessary to develop internationally harmonised – or at least mutually compatible – biosecurity guidelines to prevent the emergence of a patchwork quilt of national regulations, with gaps and inconsistencies that proliferators and terrorists could exploit as targets of opportunity (Tucker 2003).

Domestic legislation on pathogen security

The term 'pathogen security' refers to measures to reduce the risk of bioterrorism by making it harder for would-be perpetrators to gain access to dangerous pathogens and toxins that have legitimate uses in biomedical research but could be misused for the development of biological weapons. Although the United States and Germany share this objective, they have taken divergent approaches to ensuring that only legitimate scientists have access to dangerous biological materials.

US legislation on pathogen security

The US Congress first introduced security controls on dangerous pathogens in the late 1990s, after an incident in 1995 revealed the lack of government regulation in this area. Larry Wayne Harris, a licensed microbiologist living in Columbus, Ohio, and a known neo-Nazi sympathiser, used a forged letterhead and the identification number of the laboratory where he worked to order three vials of freeze-dried plague bacteria through the mail from a major supplier, American Type Culture Collection (ATCC). After Harris aroused suspicion by making repeated calls to ATCC to check on the status of his order, he was arrested and convicted of one count of mail fraud for the use of the forged letterhead. Further prosecution was not possible, however, because no US law then in effect prohibited ordinary citizens from ordering pathogens for personal use (Stern 2000).

In response to the Harris case, the US Congress included a section in the Anti-Terrorism and Effective Death Penalty Act of 1996 regulating US domestic facilities that sell, transfer or receive dangerous micro-organisms and toxins. The Department of Health and Human Services, through its Centers for Disease Control and Prevention (CDC) and in consultation with other federal agencies, developed a list of 'select agents and toxins' of bioterrorism concern. The federal Select Agent Rule, promulgated in 1997, required anyone who shipped or received such agents to register with the CDC and file a report on each transaction. This regulation contained a major loophole, however, in that laboratories that merely possessed or worked with select agents, but did not transfer or receive them, did not have to register.

The autumn 2001 mailings of letters contaminated with anthrax spores had a major impact on the US Congress. Two Democratic Senators (Tom Daschle and Patrick Leahy) were targets of the letter attacks. Several other Senators and their staff were urged to take prophylactic antibiotics, and the Hart Senate Office Building was closed for nearly five months for decontamination. Not surprisingly, Congress responded to this traumatic experience with a flurry of new legislation. The USA Patriot Act, passed shortly after the incident, contained a provision making it a crime to possess a biological agent, toxin, or delivery system that 'is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose'. In addition, the Patriot Act defined several categories of 'restricted persons' who are prohibited from shipping, receiving, transporting, or possessing select agents. This ban applies to all individuals who have been convicted of a felony, diagnosed with a mental illness, convicted of using illegal drugs, or are citizens of countries that the State Department has designated as 'state sponsors of terrorism'.[4] No exceptions or waivers are allowed.

The Senate Judiciary Committee also held hearings on the anthrax letter attacks during which officials from the Federal Bureau of Investigation (FBI) admitted that because of the loophole in the 1997 Select Agent Rule, they could not identify all of the facilities in the United States that possessed stocks of anthrax bacteria. Seeking to close this loophole, Congress included a provision tightening the controls on select agents in the Public Health Security and Bioterrorism Preparedness and Response Act, which President George W. Bush signed on June 12, 2002. This law requires all entities in the United States that possess, use, or transfer human pathogens and toxins on an expanded Select Agent List to register with the CDC and implement enhanced laboratory security measures. Clinical laboratories are exempt from the registration requirement if they destroy medical specimens containing select agents within two weeks (USA 2003).

The Bioterrorism Act also mandated the Animal and Plant Health Inspection Service (APHIS) of the US Department of Agriculture to develop and maintain a list of pathogens and toxins that pose a severe threat to livestock or crops. Laboratories that possess or work with these agents must register with APHIS. At present, the Select Agent List contains 80 microbial and toxin agents that affect humans, livestock, or plants.[5] This list must be reviewed and updated every two years.

The primary aims of the strengthened Select Agent Rule are to track who has access to listed pathogens and toxins, what pathogens have been handled and studied, and where they have been used in order to reduce the risk of diversion for hostile purposes. Because of the variety of laboratories that work with select agents, the guidelines for upgrading physical security are not highly prescriptive. Instead, each affected institution must conduct a threat and vulnerability assessment and develop a comprehensive plan to secure and limit access to all areas containing select agents. The security plan must be approved by the US government, performance-tested, and updated periodically. CDC and APHIS officials conduct short-notice inspections of the registered laboratories to ensure that their security measures are effective. Upgrading physical security can be quite expensive; Louisiana State University in Baton Rouge, for example, spent approximately $130,000 on new security systems for its laboratories (Malakoff 2002).

According to the Bioterrorism Act, all scientists seeking to work with select agents and toxins must be fingerprinted and undergo an FBI 'security risk assessment' to verify that they do not have a criminal record or are listed on databases of known terrorists. The legal consequences for scientists who do not comply with the Select Agent Rule can be severe. Thomas Butler, a microbiologist at Texas Tech University, was arrested by the FBI in 2003 for failing to report 30 missing vials of plague bacteria. Although he was acquitted of this charge, he was later found guilty of 47 other counts, most of them involving fraud (Malakoff and Enserink 2003).

As of October 2006, 335 facilities in the United States had registered with the CDC to work with human select agents, including private research companies, universities and hospitals, and an additional 75 facilities had registered with APHIS to work with select plant and animal pathogens (Altimari 2006). Ironically, the expansion of select-agent research caused by the dramatic rise in federal biodefence spending has generated new safety and security risks. Many scientists working with select agents have little prior experience handling dangerous pathogens and were drawn to this area by the availability of research money. At the same time, the Select Agent Rule has caused a number of experienced researchers to leave the field. Microbiologists at Stanford University, for example, stopped working with select agents because the 'administrative and security burdens of the select agent rule outweighed the scientific need to maintain stocks on campus'(Gaudioso and Salerno 2004). Other institutions have destroyed valuable pathogen strain collections accumulated over many years.

The recent emergence of synthetic genomics also promises to complicate the Select Agent Rule by making it possible to resurrect extinct viruses or to create novel viruses that do not exist in nature (Synthetic Biology Working Group 2006). More generally, high-throughput DNA synthesisers will eventually bring the synthesis of large viruses and even small bacteria into the realm of feasibility. When that happens, strategies for pathogen security based on physical access controls will cease to be effective, and government policymakers will need to regulate the synthesis of dangerous viruses in the laboratory.

In contrast to select agents, the United States does not regulate recombinant DNA ('genetic engineering') research through legislation but rather through administrative rules that apply to scientists who receive grants from the National Institutes of Health (NIH). A major weakness of the NIH Guidelines is that they are not legally binding on the US biotechnology industry. Although some companies comply voluntarily with the guidelines, much industrial research and development involving recombinant DNA takes place outside the regulatory framework.

German legislation on pathogen security

Perhaps because Germany has never experienced a bioterrorist attack, the level of public awareness and concern about this issue is considerably less than in the United States. Shortly after the US anthrax mailings, Germany experienced a spate of anthrax hoaxes that raised anxiety but were quickly discovered to be false alarms. Partly for this reason, Germany did not respond to the events of autumn 2001 by introducing new biosecurity legislation. While the United States framed bioterrorism prevention as a security problem and responded by tightening controls on a targeted list of select agents and toxins that could be used as weapons, German officials viewed the risk of bioterrorism mainly in public health terms, as a subset of the broader challenge of infectious disease. Accordingly, whereas the US Select Agent Rule focuses narrowly on pathogens considered suitable for bioterrorist use, Germany relies on an extensive framework of 'biosafety' laws and regulations, which are designed to ensure the safe handling of dangerous pathogens by legitimate researchers and to minimise the risks to public health and the environment from research conducted for peaceful purposes.

The German term '*biologische Sicherheit*' is generally understood to mean 'biosafety'. There is no separate word for 'biosecurity' and German laws and regulations do not make a clear distinction between the two concepts. After 9/11 and the anthrax letter attacks, the German government examined its existing biosafety regulations to identify gaps that might be exploited by terrorists. Although some gaps were found, German officials concluded that they could be addressed without additional legislation.

German biosafety measures date back to 1900, when the Reich Epidemic Act (*Reichsseuchengesetz*) required scientists wishing to work with dangerous pathogens to meet certain educational prerequisites and to be licensed by the state. The list of current German laws related to biosafety includes the Genetic Engineering Act (*Gentechnikgesetz*) of 1993, the Health and Safety at Work Act (*Arbeitschutzgesetz*) of 1996, the Plant Protection Act (*Pflanzenschutzgesetz*) of 1998, the Regulation on Health and Safety Related to Activities involving Biological Agents (*Biostoffverordnung*) of 1999, the Infection Protection Act (*Infektionsschutzgesetz*) of 2000, and the Animal Infectious Disease Act (*Tierseuchengesetz*) of 2001. The War Weapons Control Act (*Kriegwaffenkontrollgesetz*) of 1961, as amended, makes it illegal to 'develop, produce or trade in biological or chemical weapons, to acquire them from or transfer them to another person, to import or export them, to transport them through or otherwise bring them into or out of federal territory, or otherwise to exercise actual control over them' (Federal Republic of Germany 2001; Rhode and Smith 2005). In addition, the Biological Weapons Convention Act of 1983 bans the development and production of biological and toxin agents for hostile purposes. All of these laws and ordinances impose penal sanctions for violations, including fines and imprisonment.

Because German biosafety legislation has been built up incrementally over more than a century, the responsibilities for implementation and oversight are scattered over multiple agencies. The federal ministries of health, interior, agriculture, labour, and consumer protection are involved in enforcing various aspects of the biosafety laws, and a non-governmental professional association for the chemical industry (*Berufsgenossenschaft der chemischen Industrie*) develops and oversees certain occupational health and safety rules. In addition, under Germany's federal system, many biosafety regulations are enforced by state (*Bundesland*) authorities, who have primary responsibility for healthcare, law enforcement, and civilian emergency management (*Katastrophenschutz*). Finally, as a member of the European Union (EU), Germany must harmonise its domestic biosafety legislation with common European norms. According to the principle of 'subsidiarity', the implementation of EU directives is delegated to the lowest appropriate level of each member government.

Germany has extensive tracking and manifest systems for dangerous pathogens and a well-developed infrastructure for inspection and training (Federal Republic of Germany 2003). The biosafety regulations are based on the inherent capacity of microorganisms to cause illness and death in humans, animals, or plants. All known microbial and toxin agents are classified into four Risk Groups based on characteristics such as infectiousness, contagiousness, virulence (ability to cause illness and death), and the availability of protective vaccines and therapeutic drugs. Risk Group 4 includes pathogens such as the Ebola virus that are lethal and incurable, and hence demand highly stringent (Biosafety Level 4) containment measures, whereas Risk Group 1 agents require only minimal safety precautions.[6] Because of this comprehensive approach, the total number of microbial and toxin agents covered by the German biosafety regulations is considerably larger than the US Select Agent List.

The Infection Protection Act of 2000 spells out the biosafety precautions that must be taken when working with dangerous or genetically engineered pathogens. This law requires the licensing of facilities that store and handle dangerous pathogens and the individual scientists who work with them. Permission for individual scientists to handle pathogens in Risk Groups 3 and 4 (along with several named pathogens in Risk Group 2) must be granted by local or regional public health authorities in the form of a personal use authorisation (*Umgangsgenehmigung*). Scientists who repeatedly violate the biosafety rules may have their license to work with dangerous pathogens revoked.[7]

Prerequisites for obtaining an authorisation to work with dangerous pathogens include possessing the proper academic credentials and, in some cases, undergoing a personal reliability check. This procedure was introduced after the events of autumn 2001 but was based on an existing law, the Security Vetting Act (*Sicherheitsüberprüfungsgesetz*) of 1994, which provides that 'a person who is to be entrusted with a security-sensitive position must first undergo a securityvetting'.[8] In the past, this law dealt mainly with government positions requiring access to classified information, but amendments introduced by the Counter-Terrorism Act of 2002 expanded the definition of 'security-sensitive position' to cover jobs at facilities deemed 'vital for public security', including entities that work with highly toxic substances or dangerous pathogens (Federal Republic of Germany 2008).

The 16 German Federal states each have their own security vetting laws, which closely resemble the federal statute but vary in their definition of biological facilities 'vital for public security'. Some of the state laws cover research laboratories that work with pathogenic microbes in general, while others focus more narrowly on those that handle highly dangerous pathogens or biological warfare agents. Individuals applying for a sensitive position that does not require access to classified materials are subject to the lowest of three levels of security vetting: they must make a personal declaration and undergo checks of their identity, references, qualifications, employment history and criminal record. Factors that may rule out eligibility to work with dangerous pathogens include prior conviction of a felony, evidence of anti-social behaviour or mental instability, extreme political views or membership in a subversive organisation that is monitored by the German Federal Office for Protection of the Constitution (*Bundesamt für Verfassungsschutz*).

Unlike the United States, Germany does not deny access to hazardous biological materials on the basis of nationality, although some sensitive research facilities are off-limits to non-citizens. Moreover, when foreigners apply to enter Germany for scientific training or to conduct research, the administrative rules for granting visas take into account the country of origin and the institution where the applicant is employed. Because the visa rules are not based on legislation, they can be readily modified in response to intelligence information. The purpose of this system is not to impede normal exchanges or collaborations between German and foreign scientists but rather to protect sensitive information.[9] Nevertheless, the visa-issuing authorities may lack the expertise needed to assess the intentions of scientists coming from countries of proliferation concern.

Permission (*Zulassung*) to conduct individual experiments is required for those involving genetic engineering, which are assessed solely from the standpoint of biosafety. Unlike the NIH Guidelines, which are not binding on private industry, Germany's Genetic Engineering Act of 1993 covers recombinant DNA research in academia, government and industry, without exception, and includes penal sanctions for violations. Depending on the nature of the proposed experiment, it must be reviewed either by the state authorities or by a federal body called the Central Commission for Biological Safety (ZKBS). The bio-containment level for genetic engineering experiments is determined by assessing whether the modified microbe is likely to be more dangerous than the wild type. If so, the experiment must be conducted at a higher level of containment.[10] The primary goal of the German genetic-engineering regulations is to ensure the safety of experiments rather than to prevent misuse. Although all scientists who receive a license to conduct recombinant DNA research must attend a three-day course on biosafety, the issues of laboratory security and biological weapons are not addressed in detail.

Despite their differences, the US and German approaches to pathogen security overlap extensively in practice. According to Dr. Volker Beck, a technical adviser to the German Foreign Ministry, 'The US prefers the term biosecurity, whereas Europe has long focused on biosafety. In fact, 80 percent of what is called biosecurity is actually biosafety'.[11] Nevertheless, the US and German paradigms differ in three important respects. First, the German biosafety regulations cover a much larger set of microbial and toxin agents, only some of which could be used as bioterrorist weapons. Second, whereas the German regulations on genetic engineering research are more stringent than those of the United States, the rules for working with natural pathogens are less so. Third, because the German biosafety regulations aim primarily to prevent accidental infections and releases, they focus on physical containment and good laboratory practice. US biosecurity measures, in contrast, seek to prevent the deliberate theft, diversion, and misuse of pathogens and therefore focus on physical security measures, access controls, and personnel reliability.

Restrictions on publication of dual-use research

Part of the debate over dual-use research in the life sciences has focused on whether or not security-sensitive findings should be published in the open scientific literature. The main concern is not that the scientists doing the work will engage in illicit activity but rather the possibility that someone else could misuse the research findings for malicious purposes. Scientists have traditionally viewed the acquisition of knowledge as an unalloyed good that contributes to an understanding of the natural world and leads to beneficial applications, yet some types of scientific information may be dangerous in the wrong hands. As bioethicist Arthur Caplan of the University of Pennsylvania has argued, 'We have to get away from the ethos that knowledge is good, knowledge should be publicly available, that information will liberate us… . Information will kill us in the techno-terrorist age' (Caplan quoted in Atlas 2002). Nevertheless, US and German policy-makers differ strongly on the issue of restricting the publication of basic research. While US officials may be willing in some cases to prevent the release of sensitive findings in the name of national security, their German counterparts are uncompromising in their defence of scientific freedom.

US approach to restrictions on scientific publication

In 2002, a research paper in the journal Science describing the laboratory synthesis of poliovirus outraged some members of Congress, who proposed legislation restricting the publication of dual-use research. Seeking to pre-empt congressional action, a group of editors of leading scientific journals issued a 'Statement on Scientific Publication and National Security' in which they declared that they were 'committed to dealing responsibly and effectively with safety and security issues that may be raised by papers submitted for publication, and to increasing our capacity to identify such issues as they arise'. In rare cases, they noted, 'an editor may conclude that the potential harm of publication outweighs the potential societal benefits. Under such circumstances, the paper should be modified, or not published' (Journal Editors and Authors Group 2003). This statement made clear, however, that the responsibility for any decisions to restrict scientific publication should remain in the hands of journal editors, publishers, and the affected researchers themselves and not delegated to government officials.

The US journal editors' statement did not include guidelines for how articles that pose security concerns should be reviewed before publication, and to date, no scientific papers have been rejected on security grounds (NSABB 2006(a): 21). In 2005, the public release of a paper containing a mathematical model of how terrorists might use botulinum toxin to contaminate the nation's milk supply was delayed after the US government requested that it not be published. Because the research had not been funded with public money, however, the federal government had no legal jurisdiction over the information and the journal went ahead with publication (Wein and Liu 2005).

In 2002, in response to the controversy over the Australian mousepox experiment, the National Research Council (the policy analysis unit of the US National Academies) assembled an expert committee chaired by biology professor Gerald Fink of the Massachusetts Institute of Technology to consider ways of preventing the misuse of biotechnology for hostile purposes without hindering progress in the life sciences. The Fink Committee's final report, released in late 2003, concluded that dual-use research posed a real threat and identified seven categories of potentially dangerous experiments that might warrant additional discussion or review (US National Research Council 2004).

One of the recommendations of the Fink Report was to establish a national panel of experts from the scientific and defence communities to advise the US government on how best to address the security risks associated with federally funded research in the life sciences. In response to this recommendation, the Bush Administration established the National Science Advisory Board for Biosecurity (NSABB), which met for the first time in mid-2005. Administered by the National Institutes of Health, the committee consists of up to 25 voting members, plus *ex officio* representatives from 15 federal agencies that conduct or support research in the life sciences. The mandate of the NSABB is to develop criteria for identifying dual-use research, draft guidelines for the review and oversight of such experiments, and suggest restrictions on scientific publication (Shea 2006: 7).

In July 2006, the scientific communications subcommittee of the NSABB proposed that universities conduct a risk-benefit analysis before approving the publication of research results that could be 'directly misapplied by others to pose a threat to human health, agriculture, plants, animals, the environment, or material'. The reviewers would decide whether the results should be published immediately, after a delay, with modifications or added contextual information, or not at all (NSABB 2006(b); Field 2006). Nevertheless, identifying which basic research findings are directly relevant to bioterrorism is far from obvious (Aldous 2006).

US critics have also argued against restricting scientific publication on several grounds. First, the restrictions would slow progress and deter research in the areas potentially subject to censorship. Second, classifying sensitive scientific information might delay its spread only temporarily. Although man-made plans can be kept secret forever, facts of nature could be rediscovered by investigators working outside of the control regime. Third, restricting the publication of scientific information would make it harder to monitor dual-use research and might hamper the development of medical defences against biological threats. For example, the discovery that poxviruses can be genetically modified to make them vaccine-resistant alerted the scientific community to the need for new anti-viral drugs to treat possible engineered strains (Carlson 2005).

German approach to restrictions on scientific publication

The findings and recommendations of the Fink Report have yet to attract much attention in Germany, where there is limited awareness of the problem of dual-use research. Those few German scientists and officials who are familiar with the issue oppose proposals to restrict the publication of basic research directly relevant to bioterrorism. They argue that scientific freedom is guaranteed by Article 5 of the German constitution, or Basic Law (*Grundgesetz*), and that any exceptions to this rule must be well-founded. The issue of restricting scientific publication is further complicated by the fact that many life-sciences journals are international, raising concerns that other countries could restrict the publication of German research.

In general, German scientists and officials believe strongly that scientific knowledge and ideas must remain freely available, regardless of their theoretical potential for misuse. Dr. Walter Biederbick, Director of the Federal Information Center for Biological Security at the Robert Koch Institute (the German equivalent of the CDC), questions whether a bioterrorist would go to the trouble of developing a genetically engineered pathogen when standard microbial agents obtained from nature, such as the anthrax bacterium, would be quite effective at killing or causing disruption. Biederbick also doubts the feasibility of controlling the advance of biotechnology. 'Stopping the spread of knowledge is very difficult', he says. 'It can be delayed for a time but not prevented entirely'.[12]

A German government working paper submitted to a 2005 BWC Meeting of Experts called proposals to restrict the publication of dual-use research 'unacceptable' because they 'violate central rules of scientific research' (Federal Republic of Germany 2005(a)). Another working paper prepared for the meeting stated, 'To aim at the exclusion of every possibility of misuse of data with respect to "dual use" would lead to an unacceptable situation: a major part of research in the fields of microbiology and infectious diseases, especially in molecular and cellular basic research, cannot be published anymore or just with major restrictions. The probable consequence would be to stop the accumulation and exchange of knowledge to fight [the] global emergence of old and new pathogens and infectious diseases produced by nature' (Federal Republic of Germany 2005(b)).

According to Dr. Alexander Kekulé, a microbiologist who heads the Biosecurity Working Group of the German Commission on Homeland Security, 'Terrorists are unlikely to be scientifically innovative in their own right. They may copy a scientific discovery or method that already exists, but to do so they would need step-by-step instructions that are simple enough to follow without a great deal of training or expertise'.[13] Kekulé worries that restricting scientific communication would be counterproductive because it would create a black or grey market in the forbidden information. If scientific publication remains unconstrained, he argues, the broad community of scientists with good intentions should be able to maintain a technical lead over the small minority with malicious intent. But if information is censored, highly motivated terrorists might find a way to access the restricted data while ordinary scientists would not, slowing the development of medical countermeasures and giving the terrorists a relative advantage.[14]

German experts acknowledge that in rare cases, the publication of dual-use information might have to be restricted if its public release could lead directly to the development of novel agents for hostile purposes. A German government working paper states that scientific editors and publishers 'should develop specific rules for this type of information' but that in general 'the exchange of ideas including publications should continue to be open on the national level as well as on the international level, taking the aspects of misuse into account' (Federal Republic of Germany 2005(c)).

Security reviews of dual-use research

Whereas US officials emphasise the need for a review and oversight mechanism to identify and oversee dual-use experiments that could be misused for hostile purposes, their German counterparts oppose such measures on the grounds that they would be ineffective and could have a chilling effect on important areas of scientific investigation.

US approach to security reviews of dual-use research

US government policy with respect to the review and oversight of dual-use research in the life sciences is currently in flux. The key tasks facing US policymakers are to devise criteria for identifying 'dual-use research of concern' and to prepare guidelines for the review and oversight of such projects to minimise the risk that the resulting knowledge could be misused for hostile purposes. In seeking to define dual-use research, the NSABB has set the threshold fairly high. First, the research must have the potential to be misapplied directly for hostile purposes, creating an immediate risk that warrants concern. Second, the potential misuse must have significant implications for public health. For example, creating a highly virulent organism that cannot be readily transmitted would not constitute a major threat (Kasper 2007: 19; WHO 2005: 16–17).

The NSABB has also recommended that whenever possible, security reviews should take place at an early stage, before a research proposal has been approved and funded by a government agency. One idea is to assign the task of reviewing research proposals to the more than 400 registered Institutional Biosafety Committees (IBCs) in the United States that currently perform risk assessments of research involving recombinant DNA technology. The overall effectiveness of the IBC system, however, has been called into question (Sunshine Project 2004(a)). Moreover, as currently organised, the IBCs focus narrowly on biosafety and do not appear capable of fulfilling the additional biosecurity functions envisioned by the NSABB. Not only are the existing committees overworked and staffed largely by volunteers, but they lack the expertise to assess the security implications of proposed research. Thus, a new set of local oversight committees may need to be created for this purpose.

Given the globalisation of biotechnology research, it is clear that any effective system of security review and oversight of dual-use research will have to be based on internationally harmonised rules and procedures. If, for example, other countries were to adopt guidelines that are considerably less stringent than those of the United States, US researchers and scientific journals would find themselves at a competitive disadvantage, and the expected biosecurity benefits of the tighter US regulations would not materialise (Shea 2006: 9).

In addition to national mechanisms for security review and oversight, the US government favours the development of professional codes of conduct to sensitise scientists to their obligations under the BWC and encourage them to report violations by others (Rappert 2004). Because biomedical research is so diverse; however, the United States contends that a 'one-size-fits-all' approach would be ineffective and that each organisation should develop its own code of conduct, tailored to its particular focus and the activities of its members (Mahley 2006).

German approach to security reviews of dual-use research

German government officials and scientists have yet to grapple systematically with the problem of dual-use research. Although some preliminary discussions of the issue have taken place, there are currently no plans to establish an NSABB-like commission to advise the federal government on biosecurity. The reason for this resistance is twofold: (1) a strong commitment to academic freedom, and (2) the perception that German science is already overregulated and that more government intervention would curtail scientific progress and national competitiveness in the fields of biomedicine, biology and biotechnology (Müller-Lissner 2006: 27).[15]

The German biomedical community stresses the importance of basic research on the mechanisms of pathogenesis and antibiotic resistance for combating infectious diseases and objects to the Fink Report's proposed restrictions on experiments that enhance the pathogenicity, transmissibility or host range of bacteria and viruses. German scientists contend that the world will be more secure if such research remains fully transparent and in the public domain rather than hidden behind walls of secrecy and classification. According to a German working paper prepared for a BWC experts' meeting, 'An open information exchange between scientists will allow a better understanding of risks arising from the handling of infectious or toxic material or genetic modifications of organisms. This will lead to generally accepted recommendations for risk management of dangerous pathogens and toxins' (Federal Republic of Germany 2005(d)).

In lieu of restrictions on dual-use research, the German government favours mandating laboratory best practices and educating graduate students and postdoctoral fellows about bioethics and biological arms control. A professional code of conduct for the life sciences would ideally 'promote awareness of the complex dual-use dilemma and at the same time obligate the research scientist to reflect on risk assessments and consider alternative approaches during the research process'. Germany objects, however, to codes banning 'research of any kind carried out with peaceful intent' (Federal Republic of Germany 2005(e)).

Some German scientists admit that certain hypothetical experiments should not be carried out because they could result in engineered pathogens or dual-use information that might endanger public health and national security. In such cases, however, scientists and not bureaucrats should be the ones deciding whether or not to proceed. Dr. Biederbick of the Robert Koch Institute observes that 'as soon as the state begins controlling information, it inadvertently creates incentives to circumvent those controls'.[16] Accordingly, German officials favour a self-governance mechanism that emerges from within the scientific community, rather than being imposed from above. Dr. Stefan Kaufmann, the director of the Max Planck Institute for Infection Biology in Berlin, supports efforts to raise the awareness of scientists about the potential for misuse so that they will agree to participate voluntarily in the oversight process. He acknowledges, however, that if scientists do not accept responsibility for reviewing dual-use research, the task may be taken out of their hands.[17]

Conduct of biodefence research

Although the BWC permits defensive research to protect soldiers and civilians from biological weapons, the line between defensive and offensive activities is defined largely on the basis of intent and can be difficult to distinguish clearly. For this reason, biodefence research projects should be sufficiently transparent to avoid provoking suspicions that they are a cover for offensive research and development. Germany appears to be more sensitive to this particular dual-use dilemma than the United States.

US approach to biodefence research

The US presidential directive 'Biodefense for the 21st Century', issued by the Bush Administration in April 2004, describes the basic elements of the US biodefence programme and defines the roles and responsibilities of various federal departments and agencies in implementing this strategy. A key pillar of the US biodefence programme is research on 'threat awareness, including BW-related intelligence, risk and net assessments, and anticipation of future threats' (White House 2004). To help define the nation's biodefence priorities, the Science and Technology Directorate of the Department of Homeland Security (DHS) conducts periodic threat and risk assessments of a broad set of biological agents. According to John Vitko, former Director of the Biological Countermeasures Portfolio at DHS, these assessments 'are performed with the best available information. However, there are large uncertainties, sometimes factors of ten to a hundred, in some of the key parameters and hence in the associated risks' (Vitko 2005).

To address these 'critical knowledge gaps', DHS conducts a programme of 'laboratory threat characterization research' that reportedly involves realistic tests with small amounts of weaponised pathogens and toxins, as well as genetically engineered microbes that might be used in a bioterrorist attack (Petro and Carus 2005). A maximum-containment laboratory for such research, the National Biodefense Analysis and Countermeasures Center (NBACC), has been constructed at Fort Detrick in Maryland. Some arms control experts have criticised this research programme because it appears to skirt or even cross the line of what is permitted by the phrase 'prophylactic, protective and other peaceful purposes' in Article I of the BWC and because some of the projects are classified (Leitenberg *et al.* 2004; Tucker 2004). Although DHS reviews the threat-characterisation experiments internally to ensure compliance with the treaty, the department does not intend to subject the research to a more objective interagency oversight process. According to an article in the *Washington Post*, 'The administration … [insists] that the work of NBACC is purely defensive and thus fully legal. It has rejected calls for oversight by independent observers outside the department's network of government scientists and contractors. And it defends the secrecy as necessary to protect Americans' (Warrick 2006).

German approach to biodefence research

The German term for biodefence is *B-Schutz*, meaning 'biological protection', avoiding the word for 'defence' (*Verteidigung*) because of its military connotations. During the 1950s, when West Germany was allowed to rearm as a member of NATO, the former Wehrmacht Chemical Troops (*Nebeltruppe*) were renamed the Nuclear, Biological and Chemical (NBC) Protective Troops (*ABC-Abwehrtruppe*). Military biodefence work is conducted by two research centres of the German Federal Armed Forces (*Bundeswehr*), the Institute for Microbiology in Munich and the Defence Research Institute for Protective Technologies in Munster, as well as by a number of civilian contractors.

The German biodefence programme is characterised by a strict policy of focusing on protective measures, reducing the likelihood that the research will result in dual-use findings. According to a German government statement, 'Activities with potential for offensive use, such as investigation of the [antibiotic] resistance of microorganisms, genetic manipulation of organisms and aerosol experiments, are avoided in principle' (Federal Republic of Germany 2005(f)). The *Bundeswehr* does not conduct laboratory threat-assessment studies that might be problematic from an arms control perspective (Sunshine Project 2004(b): 4). Further, the *Bundeswehr* eschews classified biodefence research and maintains the transparency of its activities by regularly publishing research findings and presenting them at national and international conferences.

German biodefence activities are also subjected to the following review and oversight mechanisms:

- Internal peer review of all research projects by the relevant *Bundeswehr* agencies
- Oversight by the responsible federal and state authorities of all projects involving the use of genetically-engineered organisms
- Submission of an annual BWC confidence-building measure declaration on the German biodefence programme to the United Nations Office for Disarmament Affairs
- Publication of the topics and goals of all medical biodefence research projects on the website of the Medical Service (*Sanitätsdienst*) of the *Bundeswehr*;[18] and
- Parliamentary oversight in the form of an annual declaration by the *Bundeswehr* to the Defense Committee of the German Parliament of

all biodefence research projects financed by the German Ministry of Defence that utilise genetic engineering techniques.

Conclusions

Although United States and Germany are close allies and have many values in common, their biosecurity policies differ in important ways for reasons of history, geopolitics and political culture. In the area of pathogen security, Germany relies on broad biosafety regulations rather than narrowly targeted biosecurity measures. The German biosafety regulations predated the US anthrax letter attacks of autumn 2001 and have changed little since then. The only area that has been expanded since 9/11 involves personal reliability checks of scientists who work with dangerous pathogens, and this vetting process draws on existing legislative authority. Unlike the United States, Germany does not deny access to dangerous pathogens strictly on the basis of nationality. According to political scientist Alexander Kelle, the German emphasis on biosafety rather than biosecurity 'reflects the limited extent to which public health has been securitised in the German political and expert discourse' (Kelle 2006: 21).

With respect to dual-use research, German officials have so far rejected restrictions on scientific publication and proposals for top-down government oversight. In the area of biodefence, the two countries have also taken quite different approaches. The United States has largely ignored how other countries view its laboratory threat-characterisation programme, which includes experiments that appear to skirt if not cross the red lines laid down by the BWC. Germany, in contrast, has sought to reassure other countries about the strictly protective nature of its biodefence programme by avoiding provocative experiments and striving for maximum transparency.

German experts are troubled by the rapid expansion of the US biodefence programme since 2001 and the claim by DHS officials that it may be necessary to create small quantities of weaponised biological agents in order to guide the development of countermeasures. This logic, German officials fear, could undermine the normative restraints embodied in the BWC and inadvertently lead to a new biological arms race. According to Dr. Beck, 'The Americans have a different concept of what can and should be done in biodefence research than the Europeans. So I think it will be difficult to agree on a common standard for what should be permitted'.[19]

The divergent biosecurity paradigms of Germany and the United States can be attributed to a variety of factors. First, the two countries differ in their assessments of the magnitude and urgency of the threats of biological warfare and bioterrorism. As a global power with military forces deployed around the world, the United States is more vulnerable to an asymmetric biological attack, whereas German officials assess the risk of bioterrorism in Europe as fairly low (Schutzkommission beim Bundesministerium des Innern 2001: 27). In addition, whereas US analysts tend to engage in worst-case assessments of the bioterrorism threat, their German counterparts are sceptical that terrorist groups could exploit discoveries at the cutting-edge of biology to create novel biological weapons.

Second, the German biosafety regulations are based on a strong cultural tradition of placing trust in the professional integrity of scientists and the self-governance of the scientific community. Germans take it as an article of faith that individuals with the right training and credentials will comply with the rules for good laboratory practice and effective biocontainment. Nevertheless, this assumption neglects the fact that scientists may be motivated by curiosity or ambition to cut corners and perform experiments that pose risks to society at large. The German biosafety regulations also fail to address scenarios in which trusted insiders deliberately acquire and release pathogens for malicious purposes.

Third, in reaction to the heavy-handed censorship and ideological distortion of scientific research (particularly in the field of human genetics) that took place during the Third Reich, German scientists and officials perceive scientific freedom as an inalienable right and strongly resist government intervention in this area. At the same time, the memory of the unethical experiments performed by Josef Mengele and other Nazi doctors has led Germany to be more stringent in regulating applied biotechnologies such as genetic engineering.

Unless the gap between the US and German approaches to biosecurity can be bridged, it will create impediments to scientific cooperation and joint efforts to combat bioterrorism. German scientists complain that since 2001, they have had difficulty exchanging select-agent strains with US scientists or ordering microbial cultures from American Type Culture Collection, the leading US supplier. In addition, the US Select Agent Rule has made it more difficult for American researchers to share data with colleagues from other nations. According to Dr. Bernd Appel, director of the biosafety division at the German Federal Office for Risk Assessment, exchanges of information on select agents between Germany and the United States have become a 'one-way street'.[20] For example, during the preparation of a European manual of laboratory methods for anthrax research, researchers at the Max Planck Institute for Infection Biology sought advice from US anthrax specialists, who refused to share information. The Institute's director, Dr. Kaufmann, observes, 'Having always assumed that scientists from different countries could talk freely, I found the reticence of my American colleagues both troubling and sad'.[21] Such restrictions on the sharing of sensitive information risk isolating US researchers from the international scientific community.

Notes

1 This chapter was originally published in the journal *Disarmament Diplomacy*, Issue No. 84, Spring 2007. With the exception of minor insertions and deletions, it remains unmodified. The work is reproduced with permission of *Disarmament Diplomacy*.

2 This finding is actually not that surprising. Professor Sheila Jasanoff of Harvard University has described how the United States and Germany took divergent approaches to the regulation of genetic engineering based on their different political cultures. Whereas US policymakers framed genetic engineering as a tool for making products whose risks could be assessed according to existing regulatory principles, German officials framed genetic engineering as a novel technological process for intervening in nature that entailed certain inherent risks and uncertainties, and thus required special precautions. See Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton, NJ: Princeton University Press, 2005).

3 This point was made by Gerald Epstein, in remarks during a panel discussion on 'Preventing the Misuse of Biotechnology', Carnegie International Nonproliferation Conference, Washington, D.C., 15 December 2002.

4 At the time of writing the US State Department list of state sponsors of terrorism included Cuba, Iran, North Korea, Sudan, and Syria.

5 An updated version of the US Select Agent List is available online at http://www.selectagents.gov/agentToxinList.htm

6 Germany currently has two BSL-4 laboratories for work with human pathogens, at the Bernard Nocht Institute for Tropical Medicine in Hamburg and the Philipps University in Marburg, and a third is under construction at the Robert Koch Institute in Berlin. A fourth high-containment facility, at the Friedrich Loeffler Institute on Reims Island in the Baltic Sea, studies highly contagious livestock pathogens such as foot-and-mouth disease.

7 The German biosafety regulations have a loophole with respect to clinical laboratories. The registration requirement applies only to facilities that perform 'targeted' (*zielgerichtete*) experiments with dangerous pathogens but not clinical labs that culture human specimens for purposes of diagnosis. Moreover, there is no requirement for clinical laboratories to subject their staff members to personal security checks or to ensure the physical security of patient specimens that may contain dangerous pathogens.

8 The original German text states: '*Eine Person, die mit einer sicherheitsempfindlichen Tätigkeit betraut werden soll (Betroffener), ist vorher einer Sicherheitsüberprüfung zu unterziehen'*.
9 Interview with Professor Reinhard Burger, Vice President, Robert Koch Institute, 28 September 2006.
10 When a foreign gene is inserted into a host organism, the experiment must be conducted at a level of biocontainment that corresponds to the Risk Group of the transferred gene or the host, whichever is higher.
11 Interview with Dr. Volker Beck, technical advisor to the German Federal Foreign Office, Berlin, 4 October, 2006.
12 Interview with Dr. Walter Biederbick, Robert Koch Institute, Berlin, 28 September 2006.
13 Interview with Dr. Alexander Kekulé, Director, Institute for Medical Microbiology, Martin Luther University, Halle-Wittenber, Germany, 24 October 2006. See also, German Commission on Homeland Security web site at http://www.schutzkommission.de
14 Interview with Kekulé.
15 Interview with Dr. Gabriele Kraatz-Wadsack, United Nations Office for Disarmament Affairs, New York City, 6 July 2006.
16 Interview with Dr. Biederbick.
17 Interview with Dr. Stefan Kaufmann, Max Planck Institute for Infection Biology, Berlin, 28 September 2006.
18 Website of the Medical Service of the German *Bundeswehr*, http://www.sanitaetsdienst-bundeswehr.de
19 Interview with Dr. Volker Beck.
20 Interview with Dr. Bernd Appel, German Federal Office for Risk Assessment, Berlin, 23 November 2006.
21 Interview with Dr. Stefan Kaufmann.

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13
Conclusion

Chandré Gould

If there is one thing that becomes clear from the contributions to this book, it is that the multiplicity of meanings associated with the term 'biosecurity' mirror the multiplicity of agendas of those who seek to strengthen it. This is perhaps one of the reasons that efforts both to 'mainstream' issues relating to biosecurity (such as preparedness to respond to deliberate disease, increase laboratory security, enhance the security of pathogens) and to move the discourse out of the strictures of a security framing have had limited success.

It is certainly the case, as noted in both the Introduction to this book and in several other chapters, that the stakeholders in 'biosecurity' discussions have increased rapidly in the past decade. However, while there have been efforts to disengage the concept of 'biosecurity' from the narrow focus on preventing bioterrorism or laboratory security, it is clear from the national case studies in Part II of this volume that such efforts at re-framing have had limited effect, certainly in relation to the general use of the concept of 'biosecurity'. For many governments, this discourse is synonymous with the terrorism discourse. The very word itself confines the discourse to concerns about security and threats, which is in many ways is oppositional to the framing of the purpose of the life sciences to enhance human well-being. The result is the creation of an uncomfortable space for scientists and policymakers to traverse. Nevertheless, despite the connotation of bioterrorism with the word biosecurity, Dando and Revill show how, at least in the context of the BWC, efforts have been made to unpack the issues of concerns to states and address those through the intersessional meetings that have been taking place in recent years.

Countless articles, papers and reports point to 9/11 and the anthrax mailings in October 2001 in the United States as the trigger for US and international level concern about the threat of biological weapons. Certainly these events triggered a massive US spending on biodefence, a response that has continued in the years since. In this period, international and intergovernmental organisations, professional associations, and others have also picked up on and contributed to the discourse by offering definitions, guidelines for responses, and forums for discussion. The BWC too has focused on issues such as disease surveillance; education and awareness raising; controlling dangerous pathogens and laboratory safety and security (see Chapter 2 by Dando and Revill) – yet at a national level the response by many states has been less emphatic.

The reason for this is simple, and is dealt with in some detail in the chapters of Part II (see the chapters by Gould, Furukawa, Lema and Dunworth): few states share the assessment that biological weapons – whether employed by states or non-state actors – present a significant threat. Gould demonstrates that biological weapons threats are not, and have not been included in South African military threat assessments, even after 2001. This is echoed by Furukawa who explains the relative lack of attention to biosecurity matters as a function of the far greater threat posed by nuclear and ballistic missiles to Japan from North-East Asia. The mere physical remoteness of New Zealand and its history of stringent measures to protect crops and animals from disease, means that biological weapons use is not perceived to be a threat in that country. That being the case, the benefit of allocating resources to counter the threat is unclear to states that share the view that biological weapons do not pose an imminent threat. This is despite the now trite observation that while the probability of biological weapons use is low – the consequence could be high, and thus an investment in prevention and protection is money well spent. Chapter 1 by Lentzos explores the prevention/protection discourse in some detail proving a useful framework of analysis for understanding the responses by states that follows in Part II.

The fact that biosecurity and its attendant issues remains the compartmentalised concern of a relatively small (albeit growing) community is no more clearly demonstrated than by the interactions at the 2008 Symposium on Science, Technology and Innovation in Africa that was held as a side event to the International Council for SU General Assembly in Mozambique. The Symposium was attended by African science and technology ministers, representatives from inter-governmental organisations, scientists and NGOs. At no point during the symposium was biosecurity mentioned (even relatively broadly defined), nor were related issues associated with biotechnology (such as dual-use concerns) given attention. Even the panel discussion on 'Global Environmental Change and Desertification in Africa and on Natural and Human-induced Hazards and Disasters in Africa', which would have been the obvious opportunity for these issues to be raised, focused on hydro-meteorological, geological, biological, technological and conflict-related disasters.[1] The potential for the misuse of the results of scientific research and other biosecurity-related issues were also not raised under the heading 'issues of general concern', despite the fact that several prominent science leaders from the continent who had participated in international meetings on biosecurity were present, and had previously stated the importance of the issues relating to biosecurity elsewhere.

For many reasons the silence on dual-use and biosecurity issues in this forum is unsurprising. Science is presented as the answer to the serious problems faced by the African continent, and indeed by the global community. Politicians regularly look to science to provide solutions to the problems of poverty, food insecurity, disease, climate change, and environmental degradation. Indeed, at the time of the final completion of this volume, US President Barack Obama allocated around USD 70 billion to science as part of the trillion dollar rescue package for the US economy, which will be shared between basic heath research and research into renewable power and energy efficiency. This demonstrates belief in the ability of science to deliver solutions to the major problems facing the globe. In this context many – particularly those in the developing world where science faces serious challenges – will balk at integrating a discussion of its benefits and security problems.

Yet, if society is to retain (or regain, as is the case certainly in many African countries) confidence in science, it is imperative that research is conducted in an ethical, accountable, safe and secure manner. For more attention to be paid to these issues at a global level it will have to be clearer to those who have not yet been engaged in the biosecurity discourse and who are not convinced of the threat/risk, what the benefits would be of increased attention to biosecurity.

An international group of scientists including Harvey Rubin, Kameswara Rao (Rubin and Rao 2009), Abdullah Daar, and Peter Singer present what they believe is a way of answering the question of who benefits from improving the ability of states to counter the effects of deliberate and natural disease. They propose an international compact that would combine preparedness to respond to disease outbreaks with improved laboratory and regulatory practices. The benefits of their proposed international agreement would include, amongst other things:

- Providing access to cheaper, more highly standardised specific therapeutics and vaccines;
- Ensuring better quality control of vaccines, therapeutics and diagnostics in the developing world;
- Providing access to and participation in high level research.

While such a compact would not deal with how to prevent states or non-state actors intent on using biological agents from doing so, it goes some way towards bringing the public health and security agendas closer together.

It is likely that more thinking along these lines, towards the objective of mainstreaming the security of the life sciences will take place in years to come. This volume is an important contribution to that discussion because it provides new insight into how a range of states from different continents understand the problem and its solutions. While it may be clear that the term biosecurity is not necessarily the most useful term to refer to efforts to reduce the potential for the misuse of science; the chapters in Part I provide a clear indication that there are many forums for discussion and places where a great deal of thinking and action is taking place towards the common goal of securing the world against biological threats.

Note

1 With 'hydro-meteorological being the most common and having the highest impact' (ICSU 2008: 11) higher even than the impact of disease.

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