Biosafety professionals as stakeholders in the BTWC

Gary Burns, Karen Byers, Teck Mean Chua, Heather Sheeley and Brad Goble

Biosafety, biosecurity and the BTWC

Gary Burns

This article is rather unusual, as it comprises contributions from five authors. It includes articles provided by the American Biological Safety Association (ABSA), the Asia-Pacific Biosafety Association (A-PBA), the European Biosafety Association (EBSA), the International Federation of Biosafety Associations (IFBA) and the private sector. Each author provides content on two areas: first, an introduction of the organization and how it operates, then some thoughts on a specific aspect of how biosafety associations are important stakeholders in the Biological and Toxin Weapons Convention (BTWC). The President of ABSA, Karen Byers, focuses on the role played by biosafety associations. Teck Mean Chua, President of the A-PBA, addresses how the views of biological associations and the roles they play differ around the world. The relationship between EBSA and the security sector is the focus of Heather Sheeley, who was President of EBSA from 2008 to 2009. Brad Goble, Senior Project Manager for the IFBA, examines the benefits of strengthening the working relationship between the two communities of biosafety and the BTWC. The remaining text linking these contributions together and providing an additional perspective from the private sector is from Gary Burns, Global Biosafety and Biosecurity Manager at AstraZeneca.

A sensible place to start is to examine the terms that appear throughout this article. Several terms have meanings that vary depending on the context. For example, both the terms biosafety and biosecurity have different meaning in different settings. In the context of the BTWC:

Biosafety refers to principles, technologies, practices and measures implemented to prevent the accidental release of, or unintentional exposure to, biological agents and toxins, and *biosecurity* refers to the protection, control and accountability measures implemented to prevent the loss, theft, misuse, diversion or intentional release of biological agents and toxins and related resources as well as unauthorized access to, retention or transfer of such material.¹

Gary Burns is Global Biosafety and Biosecurity Manager at AstraZeneca, a biopharmaceutical company. Karen Byers is President of the American Biological Safety Association. Teck Mean Chua is President of the Asia-Pacific Biosafety Association. Heather Sheeley was President of the European Biosafety Association from 2008 to 2009. Brad Goble is Senior Project Manager at the International Federation of Biosafety Associations. Opinions expressed in this article are those of the authors and not necessarily those of the organizations they represent or the United Nations.

The procedures and practices used for biosafety and biosecurity both seek to contain biological agents to fixed locations. However, they differ in that biosafety seeks to protect humans and the environment from biological agents, whilst biosecurity seeks to protect biological agents from those seeking to use them to cause harm. The associated risks are collectively referred to as "biorisk". Without effective biosafety measures, it would be virtually impossible to implement effective biosecurity provisions. In many respects, effective biosecurity is a natural progression from good biosafety practices. For the remainder of the article, a reference made to biosafety also refers to biosecurity.

Biosafety professionals work to ensure that biological agents are not accidentally released or diverted from their intended purposes. Since the security sector and biosafety professionals share a goal in preventing the accidental or deliberate release of biological agents, how do they work together in pursuit of their joint objectives? Representatives of the security sector and biosafety professionals cooperate in a broad range of activities. They contribute to each other's literature—this article is but one example. Articles on the BTWC have been published in the journals of biosafety associations. Members of both communities have also taken part in each other's meetings and appeared together on panels.

The role of biosafety associations

Biosafety professionals are found in both the public and private sector and play an important role in biotechnology, from research and development through to production and manufacturing, and in transportation, disposal and decontamination. Many of these individuals are members of professional associations which represent their interests and play an important role in the development of their discipline. This section explores what these associations do and how they operate alongside the convention.

There has been a rapid increase in the number of biosafety associations in recent years. What were once comparatively small groups of individuals from a few developed states are now international bodies that span the world. Such a dramatic increase in the number and coverage of biosafety associations demonstrates the growing importance of biosafety. There is now an active global community of experts with technical knowledge of direct relevance to the BTWC. This community could be an invaluable resource for work related to the convention. States parties and biosafety professionals both share an interest in ensuring that biological agents are not accidentally or deliberately released. Members of biosafety associations span the gap between those who manage facilities and those who work in them. Furthermore, associations are found in countries which are not active participants in the BTWC. These shared interests would seem to provide fertile ground for a mutually beneficial relationship.

So what do biosafety associations do? They play a distinct role in community building, facilitate the exchange of experiences and best practices, help to build professional practice, publish important information and represent the views of their members. How biosafety professionals

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currently work alongside the convention, and how they could work in the future, is now explored in more depth.

The American Biological Safety Association

Karen Byers

Founded in 1984 as a non-profit organization, ABSA supports activities within the framework of the BTWC to promote biosafety as a scientific discipline, and to serve the needs of the growing US and international biosafety community by providing a forum for the exchange of biosafety information.

ABSA has been engaged in many key international activities of particular relevance to the BTWC. We have participated in Asia-Pacific, African, European and IFBA biosafety conferences, and in 2008 we participated in the BTWC Meeting of Experts. In addition, we have sponsored workshops on the laboratory biorisk management standard² and on biosafety professional competence.³ We have provided testimony to various government committees⁴ and contributed to the development of technical standards.⁵ The 1500 members of ABSA include not only international members but also members in the United States. ABSA has also formed alliances with organizations and agencies that share a commitment to biosafety and biosecurity.⁶

In 2010 ABSA hosted a seminar designed to share biosafety association management skills.⁷ In addition to presentations, discussions gave participants the opportunity to share their successes and challenges—all of which were broadcasted on the Internet. In the same year we co-sponsored a seminar on developing a plan for appropriate medical responses to laboratory biosafety issues.⁸ Twice a year ABSA offers a five-day interactive "Principles and Practices of Biosafety" course for new practitioners. ABSA also offers a seminar series and a certification review course for advanced training, as well as around 30 topic-specific courses.

The annual ABSA conference is a leading international event where experts in biosafety, biosecurity and related sciences can exchange information, best practices and develop working relationships. Past conferences have included participants from all over the world, and in response to a growing need, ABSA held an additional conference in 2003 entitled "Biosecurity: Challenges and Applied Solutions for Our Future Needs". In 2011 ABSA will present, in partnership with the Agricultural Research Service, the research arm of the US Department of Agriculture, the first conference dedicated to animal (livestock, aquaculture and wildlife) health issues associated with agricultural research, diagnostics and response.

ABSA provides a range of accredited courses, at all levels, on biosafety and biosecurity. We offer accreditation as either a "Registered Biosafety Professional" or as a "Certified Biosafety



Professional". We are authorized by the International Association for Continuing Education and Training to provide continuing education credits. Our programme is a sign of our commitment to continuing education and community service. In 2010 ABSA appointed a task force to review the ABSA credentialing process for international members.

Among our publications is a multi-volume series *Anthology of Biosafety*, and the journal *Applied Biosafety*. Many articles in Applied Biosafety support the general goals contained in the BTWC, and are publicly available on the Internet two years after publication. However, some articles have a specific focus on the convention.⁹

Views and opinions often differ around the world. The role, views, motivations and activities of biosafety associations vary between regions and countries. What may be accomplished in a highly developed country is different to what may be possible in a developing country. The following contribution from the A-PBA provides a different regional perspective, one more attuned to the views of developing countries.

Gary Burns

The Asia-Pacific Biosafety Association

Teck Mean Chua

The A-PBA was founded in 2005 with the objective of promoting biosafety and biosecurity in the Asia-Pacific region. It is a not-for-profit professional organization that aims to provide a forum for biosafety professionals in the region to share their experiences and knowledge in biosafety and biosecurity. A key goal of the A-PBA is to foster the growth of a regional biosafety community to share a collective responsibility towards improved biosafety and biosecurity, as no single state can be effective in its response to an outbreak of disease if neighbouring states are ill prepared. The A-PBA sees biosafety and biosecurity as addressing a collective risk. Given that all states confront the same risk, we all share a responsibility to manage it effectively. This requires working together to prevent accidents and incidents. The A-PBA was established to foster such collective action in the Asia-Pacific region.

As the regional forum for biosafety and biosecurity, the A-PBA works with and draws upon the efforts of national associations. For example, the A-PBA has had a long-standing history of cooperation with the Japanese Biosafety Association and the Korean Biological Safety Association. Recent years have seen the formation of several new associations in our region.¹⁰ It is clear that our efforts to foster recognition of biological safety as a distinct scientific discipline are proving successful, and that there is growing interest and demand in the region for a forum for the dissemination and continued exchange of information on biosafety and biosecurity.

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Promoting the safe and secure management of biological resources and processes

The A-PBA uses a range of approaches and activities to further its objectives. However, the centrepiece of the A-PBA's efforts is the regional biosafety conference. It provides a focal point for ongoing activities, gathers expertise from the region and provides a unique setting to share experiences. The conferences are held in different countries in the region to encourage cooperation. They also help to build capacity as any money left over after the conference is used as a seed fund to assist the host state in developing its own national biosafety association.

The most recent conference took place in Seoul, the Republic of Korea, in May 2010 and focused on advancing biosafety technology and national legislation in the Asia-Pacific region. Both the private and public sector participated, and the conference was attended by members of regional and national biosafety associations from around the world. Topics of the conference included: national regulations and legislation in the region; advances in biocontainment technology; international and regional partnership and collaboration; biorisk management and accreditation; dual-use research; and applied biosafety.

Together with topic-specific training courses, such as a course on biosafety management in January 2011,¹¹ the A-PBA also supports online training and distance learning, such as the interactive online training courses on the packaging and shipping of biological agents. A quarterly newsletter helps build a greater sense of community and keeps our members informed of news and events. It also provides a valuable medium to share technical information on approaches and practices.

On the global stage the A-PBA represents the views and expertise of biosafety specialists from the Asia-Pacific region, and has been an active participant in workshops to set international standards for biorisk management and biosafety practices.¹² In 2008 the A-PBA participated in the Meeting of Experts, within the framework of the BTWC, and recommended a "common platform for training, networking and promotion of biosafety and biosecurity".¹³

If we look around the world today, we see that the issues of biosafety and biosecurity have evolved differently in different countries and regions. In developed countries biosafety and biosecurity are sufficiently well established that concerns have shifted from a focus on the day-to-day operational aspects to a debate on the possible need for regulation and controls of scientific activities that have the potential for abuse or misuse.

In developing countries the focus remains primarily on the fundamentals of biosafety and biosecurity—how to safely and securely manage micro-organisms and the products of biological processes. Shortcomings in capacity, equipment and human resources can pose a weak link in that chain of control against the misuse and abuse of infectious agents. Informing those who work with biological agents and processes about the core concepts and procedures is a significant challenge. The A-PBA is working hard to build human capacity. We help raise



awareness, share experiences and best practice and conduct training. The Implementation Support Unit (ISU), together with meetings and publications within the framework of the BTWC, can make a direct contribution to raising awareness. Even more importantly, the framework of the convention can encourage states parties to foster national and regional biosafety associations and through them help to ensure that those who work in biological facilities around the world do so safely and securely.

Many of the facilities handling infectious agents in developing countries were built more than 10 years ago, with little or limited provision for biosafety and biosecurity in terms of both design and practice. The conditions found in the majority of these facilities are far below the standard of laboratories in developed countries. Efforts need to be made to improve the quality of facilities in which our members work. The framework of the BTWC could play an important role in building such capacity.

There is uncertainty in many of the communities which have just started to develop a more structured approach when it comes to biosafety and biosecurity. They often receive conflicting advice, which sometimes can lead to confusion. A great deal of work needs to be done to harmonize and simplify messages. Over the last five years there have been excellent papers and data on biosafety and biosecurity which support programmes to promote biosafety and biosecurity. The challenge now is to implement these programmes in a systematic and sustainable fashion when faced with limited resources and infrastructure. The next step forward is to identify and establish partners and channels that can assist in the implementation of these programmes. The framework of the BTWC can play a role here too.

The A-PBA regards itself as a partner in all these initiatives. A-PBA stands ready to support the activities of the World Health Organization (WHO) and other the organizations within the framework of the BTWC, and enhance biosafety and biosecurity in the Asia-Pacific region as well as around the world.

The A-PBA utilizes a range of resources to promote biosafety and biosecurity in the Asia-Pacific region. The organization is not alone in its efforts. The following contribution examines the methods of the European Biosafety Association and includes examples of relevant activities.

Gary Burns

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How the European Biosafety Association contributes to the BTWC

Heather Sheeley

EBSA was founded in 1996 and aims to provide a forum for discussion and knowledge exchange for a diverse range of people in the life sciences in academia, research, veterinary, health, and supporting technologies and services. EBSA, which has over 370 members from academia, governments and private organizations from 32 states, has attended meetings within the framework of the BTWC to actively promote excellence in biosafety and biosecurity and the responsible conduct of science.

The EBSA council and its members have supported the initiatives of other biosafety associations by giving presentations, running training sessions and attending meetings that cover biosafety and biosecurity, including bioethics and dual-use. EBSA has attended meetings within the framework of the BTWC, participating both as a Guest of the Meeting and as an observer. Members of the association have been participants at both intersessional and informal meetings. In addition, members have participated on panels with members of the ISU to raise awareness of the importance of biosafety and biosecurity. Similarly, guest speakers have also attended and presented at EBSA conferences and to national biosafety groups allied to EBSA.

EBSA initiated and has been the driving force behind a workshop to write and approve a consensus document on biosafety professional competence.¹⁴ The document was made available in December 2010 and following a 60-day public comment period, it will be approved in May 2011. The aim is to set a benchmark for competent advice on issues of biosafety and biosecurity.

Within the European Committee for Standardization (CEN) framework, EBSA has also been a main contributor to a document on laboratory biorisk management.¹⁵ The document sets the standard for effective biorisk management programmes and has been used to assess the adequacy of arrangements in several countries. In January 2011 the document was made available for the 60-day comment period, and a final meeting is planned in May 2011.

EBSA also coordinates biosafety efforts in Europe by holding meetings and providing an electronic platform for sharing information. EBSA has been supporting and sponsoring activities in Eastern Europe, with the goal to foster and strengthen biosafety in the region. In addition, EBSA members provide direct input on biosafety in these states. Within the European Union, EBSA is involved in the consultation process of documents relating to security and preparedness, and its members continue to participate in biosafety relevant initiatives, EBSA members also participate with international organizations such as the WHO, the IFBA, the European Centre for Disease Prevention and Control, and the Organization for Economic Cooperation and Development—across a broad range of issues related to chemical, biological, radiological and nuclear weapons.



It is clear that both biosafety professionals and those directly involved with and active in the BTWC are already engaged in a wide range of joint activities. There is clear support for closer cooperation— demand for joint activities outstrips supply. Are the joint interests of these communities close enough to warrant further efforts to strengthen working ties? The following article on the IFBA examines this question and provides an unequivocal answer.

Gary Burns

International Federation of Biosafety Associations

Brad Goble

Laboratory diagnostic and surveillance capacity are central to the global fight against outbreaks of infectious disease, whether naturally occurring or deliberately caused. However, many laboratories lack the capacity to safely and securely handle dangerous biological agents. These challenges are not unique to the global health community, and there is growing recognition that the global health and security communities must come together to address the full spectrum of biological risks.

Founded in 2001, the IFBA has actively promoted dialogue and collaboration among the global community of scientists, laboratory personnel, architects, engineers, academics and policymakers—all of whom share our common goal of advancing biosafety and biosecurity practices through increased collaboration among national and regional biosafety organizations. Together with our partnerships with biosafety associations, non-governmental organizations, governments and international agencies, the IFBA is uniquely positioned to assist states worldwide and deliver sustainable biosafety capacity building programmes where they are needed most.

The IFBA encourages and supports local, practical and sustainable biosafety capacity building around the world by reinforcing and promoting biosafety and biosecurity awareness, sharing best practices and expertise, and building strategies to strengthen biosafety programmes. Our emphasis is on delivering sustainable capacity-building programmes where they are needed most—and we do so within the broader context of strengthening global public health and security.

Looking to the future, the IFBA and more than 50 of its member states recognize the unique opportunity we have in strengthening our engagement and collaboration with BTWC stakeholders as an important partner in achieving our complementary goals across the world. Our task is to help ensure that all states have the biosafety, biosecurity and biological non-proliferation knowledge and tools they require. Collaboration with international, regional and national biosafety associations provides a direct channel with those who actually run the

facilities that conduct biological research. Ours is a community with expertise in safety and security issues specific to biological agents and toxins.

There is also a growing recognition of the synergies between our two missions. Biosafety associations are focused on strengthening the profession of biosafety, while the convention aims at preventing disease from being used to deliberately cause harm. In the age of biorisk management there is an increased need to harmonize efforts to achieve our common goals. However, with resource constraints being a constant challenge for all, working together not only makes sense, it is critical for future success.

The IFBA and the Elizabeth R. Griffin Research Foundation¹⁶ have chosen 2011 to be "the year of growing international biosafety communities". With its first international conference,¹⁷ in Thailand, in February 2011, the IFBA is well positioned to help identify and address key areas of biosafety and biosecurity concern.

However, there are still many ways in which to improve relations between biosafety professionals and the BTWC:

- 1. The biosafety community should work with states parties on practical projects to build biosafety and biosecurity capacity in developing countries—with a particular focus on raising awareness among biosafety professionals about the convention and dual-use issues.
- 2. The biosafety community can act as a useful bridge between governments and the private sector, and become an influential partner in generating greater buy-in and encouraging closer engagement within the framework of the convention.
- 3. States parties should establish a structured mechanism to incorporate the contributions and expertise offered by the biosafety community.
- 4. States parties should provide the resources necessary to support the work of biosafety associations, including a central archive of biosafety and biosecurity best practices and standards.
- 5. States parties and biosafety professionals should work together to provide the ISU with the support and resources necessary to expand its role in engaging with the biosafety community.

The upcoming Seventh Review Conference can be used as a setting for cooperation and action. The combination of the IFBA's partnership with front-line biological research and leading expertise and ISU's engagement with states parties can help to better tackle the issues of biosafety and biosecurity within the framework of the BTWC.



Perspectives from the private sector

Gary Burns

Many companies in the pharmaceutical and biotechnology sector carry out work involving biological agents. A significant number are involved in research to discover new medicines to prevent or treat infectious diseases, such as malaria and tuberculosis, which are a particular problem in the developing world. As is the case for life science research, some work may be categorized as dual-use according to criteria established by the US National Science Advisory Board for Biosecurity. The work may involve organisms which pose a security concern under national legislation, such as the US select agents list or UK anti-terrorism laws.¹⁸

There is a clear link between dual-use research and the BTWC for companies involved in vaccine production. As part of the confidence-building measures within the framework of the BTWC, states parties are required to provide information on all national vaccine manufacturing facilities. Many states parties, including the United States and the United Kingdom, have placed this information in the public domain and have posted it on both the publicly accessible pages of the ISU Internet site and also on its restricted access pages.

Companies that work with biological agents have strict biosafety and biosecurity programmes to address associated risks, and depending on the size and complexity of the organization, employ biosafety professionals to support those programmes. Compliance with national and international legislation is a strict requirement, but many large multi-national organizations within the sector often go beyond this and apply global minimum standards.

Biosafety professionals from leading pharmaceutical companies are generally members of national biosafety organizations, but they are also represented on the Pharmaceutical Biosafety Group (PBG), an industry group with a strong emphasis on cross-sector benchmarking and sharing of best practice. Like the biosafety associations that have contributed to this article, the PBG is also a member of the IFBA.

There have been many calls for the private sector to engage further in biosafety and biosecurity. A publication by the US National Security Council stated that the US private sector would be encouraged to undertake the following:

Conducting organizational assessments regarding potential vulnerabilities that could give aid to those seeking to develop or use biological weapons and taking all reasonable measures to reduce their risk of exploitation;

Ensuring that all reasonable measures are taken to promote the safety and security of high-risk pathogens and toxins within their possession;

Establishing and supporting robust participation in fora where sector colleagues and other stakeholders can discuss risks, raise awareness, and

explore community-based approaches and best practices for risk management; and

Maintaining productive working relationships with local, State, and Federal law enforcement agencies and reporting suspicious/illicit activities to appropriate authorities.¹⁹

Much of the private sector is already actively engaged in all these areas as individual organizations or through industry associations. A good example of such engagement is provided by two organizations which represent the main specialist genes synthesis companies. The International Association Synthetic Biology has adopted a code of conduct of best practices in gene synthesis, and the International Gene Synthesis Consortium has adopted a similar harmonised screening protocol for gene sequence and customer screening. Both of these measures go beyond current guidelines²⁰ and have been formally supported by at least one commercial organization in the pharmaceutical sector. The private sector has also provided a direct response to the consultation exercise on the Federal guidelines, for example through the Biotechnology Industry Organization.

While the private sector is clearly doing much to support the aims in the BTWC, the ISU has made clear to industry representatives that it would welcome further engagement aimed at raising awareness and understanding among governments of the perspectives, concerns and contributions of the pharmaceutical industry; exploring the potential for integrating industry activities with similar efforts in other sectors; and developing partnerships for practical action on reducing biological risks worldwide. In addition, there is a call for the development and implementation of standards on biosafety and biosecurity; education and awareness-raising for life scientists on the risks of misuse of biology; and capacity-building activities, particularly in developing countries.

Thoughts for the Seventh Review Conference

The various contributions in this article clearly lay out the synergies between the biosafety and BTWC communities. They seem to have much in common, and it is clear that much progress has been made in how they work together. The contributions highlight opportunities to improve this relationship and these may be of value to take forward at the Seventh Review Conference.

Notes

- 1. Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2008/5, 12 December 2008.
- 2. European Committee for Standardization (CEN), "Laboratory Biorisk Management Standard", CEN Workshop Agreement 15793, 2008.



- 3. European Committee for Standardization (CEN), "Biosafety Professional Competence", CEN Workshop 53, 2010.
- 4. Public Consultation Meeting of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, 8–9 December, 2008; National Science Advisory Board for Biosecurity Public Consultation on Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility at the Local Level, 5 January 2011; ABSA also gave testimony in 2010 and provided expert participants to serve on the US Federal Experts Security Advisory Panel.
- 5. We have provided representation on the American National Standards Institute Board for the development of containment laboratory standards, and also on the Association of Public Health Laboratories for the development of biosafety competencies for laboratory staff. We have participated with the Blue Ribbon Panel of the Centers for Disease Control and Prevention on clinical laboratory standards.
- 6. Some of which include: the American Association for Laboratory Animal Science; the American Public Health Association; the Campus Safety, Health, and Environmental Management Association; the Environmental Protection Agency; the US Occupational Safety and Health Administration; the Sandia National Laboratories' International Biological Threat Reduction Program; and the World Health Organization. The E.F. Griffin Foundation is an ABSA Principal Partner.
- 7. ABSA, "Affiliate and Biosafety Association Management Workshop", workshop, Denver, 7 October 2010.
- Eagleson Institute et al., "Preventing and Treating Biological Exposures: a Colloquium for Occupational Medicine, Infectious Disease and Emergency Medicine Professionals", conference, Cambridge, 14–15 June 2010.
- J. Domingo, "The Biological Weapons Convention (BWC) and Biosafety Diplomacy", Applied Biosafety, vol. 13, no. 2, 2008, pp. 86–88; P. Millett, "The Biological Weapons Convention: From International Obligations to Effective National Action", Applied Biosafety, vol. 15, no. 3, 2010, pp. 113–8.
- 10. For example, the Biosafety and Biosecurity Network (Thailand) was founded in early 2008 following an A-PBA conference in Bangkok. The A-PBA has been in communication with the Biological Safety Association of Pakistan and the Philippine Biosafety and Biosecurity Association. The A-PBA has also worked closely with the Biosafety Association for Central Asia and the Caucasus.
- 11. A-PBA, "Biosafety Management Course", training course, Singapore, 6–14 January 2011.
- 12. European Committee for Standardization (CEN), "Laboratory Biorisk Management Standard", CEN Workshop Agreement 15793, 2008; European Committee for Standardization (CEN), "Biosafety Professional Competence", CEN Workshop 53, 2010.
- 13. Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of Experts*, document BWC/MSP/2008/MX/3, 8 September 2008, p. 14.
- 14. European Committee for Standardization (CEN), "Biosafety Professional Competence", CEN Workshop 53, 2010.
- 15. European Committee for Standardization (CEN), "Laboratory Biorisk Management Standard", CEN Workshop Agreement 15793, 2008.
- 16. The Foundation promotes safe research practices in the area of zoonotic disease.
- 17. IFBA, "Global Biosafety and Biosecurity: Taking Action", conference, Bangkok, 15–17 February 2011.
- For further information see National Select Agent Registry, "HHS and USDA Select Agents and Toxins", 2008; and the United Kingdom, "Anti-terrorism, Crime and Security Act 2001, Part 7 Security of Pathogens and Toxins".
- 19. National Security Council, National Strategy for Countering Biological Threats, 2009, p. 22.
- 20. US Department of Health and Human Services, *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA*, no date.