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STRENGTHENING THE BTWC THROUGH LABORATORY BEST PRACTICES AND BIOSECURITY

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I. INTRODUCTION

In the context of international security, biosafety and biosecurity converge at the nexus of science and security and of health and security. This convergence has the potential to generate not only new opportunities, but also novel and unforeseen biological threats. Since the end of the cold war the security agenda has increasingly taken into account a number of non-military issues, including organized crime, transnational terrorism, political extremism, illicit immigration, and drug and human trafficking, as well as the implications of climate change, natural disasters and public health issues. Much of the focus of security concepts has shifted from protecting the state to ensuring the safety of citizens. Compared to the cold war period, non-state actors are perceived as a greater security concern than the threats that states may pose.

The European Union (EU) has gradually elaborated its concept of security, and its recent draft internal security strategy emphasized creating 'a safe environment in which people in Europe feel protected'. The EU aims to extend the same degree of safety to EU citizens whether they are in Europe, travelling elsewhere or are in a virtual environment, such as the Internet. Internal security has therefore also acquired an external dimension that requires collaboration and cooperation with partners around the world in order to achieve the level of security that exists within the EU.[1]

Working with pathogenic microorganisms, including genetically modified microorganisms (GMOs), requires developing health and safety measures that adequately protect laboratory workers and others, and also the environment. Implementing biosafety

[1] Council of the European Union, 'Draft internal security strategy for the European Union: towards a European security model', 5842/2/10, 23 Feb. 2010.

SUMMARY

The Biological and Toxin Weapons Convention (BTWC) remains the cornerstone of the regime to prevent the use of biological weapons, embodying the norm against biological weapon proliferation. The inherent challenges and complexities of the fight against biological weapons are best addressed by a multilayered approach that combines top-down and bottom-up actions and initiatives. The 2001 anthrax attacks, which caused widespread panic and disruption, highlighted the need to take into account the threats posed by both state and non-state actors. These events also led to more thorough consideration of one of the most difficult threat to deal with, the threat from inside.

In this context, enhancing biosafety and biosecurity measures and raising awareness at the laboratory level have been identified as in accordance with the aims and objectives of the convention. This paper considers how to strengthen the BTWC and focuses specifically on the involvement of the life sciences community and the need to engage scientists and laboratory workers, as well as on the role of the European Union.

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and biosecurity measures can contribute to reducing the full spectrum of natural and man-made biological risks, including those that fall within the purview of the 1972 Biological and Toxin Weapons Convention (BTWC). This paper focuses on increasing laboratory biosafety and biosecurity as a way to strengthen the BTWC—Article IV of which requires states parties to take the necessary measures to prevent the misuse of biological agents and toxins.

II. THE IMPORTANCE OF ENHANCING BIOSAFETY AND BIOSECURITY

Recent trends and events have exposed vulnerabilities related to the prevention and management of biorisks, alerting the public and underlining the need for adequate biosafety and biosecurity measures. Many governments have developed biopreparedness and crisis management plans to address a range of threats: a potential bioterrorist attack; the re-emergence of diseases that were thought to have been eradicated; outbreaks of new infectious diseases, such as severe acute respiratory syndrome (SARS), H5N1 and H1N1; pandemic disease outbreaks; and antibiotic-resistant bacterial strains of disease, such as multi-drug-resistant tuberculosis (MDR-TB). They have launched research and development programmes that focus on these threats in order to create and improve medical countermeasures and to enhance knowledge about pathogens and have also allocated the necessary human and financial resources to attain these goals. Consequently, new biosafety level (BSL) -3 and -4 laboratories have been or are being built.[2] While the number of BSL-4 laboratories is known, more uncertainty exists about the existence in some countries of BSL-3 laboratories.[3] Moreover, a number of these laboratories are located in countries where best practices and regulations in the fields of biosafety and biosecurity are not infrequently underdeveloped and inadequate.

Broadly speaking, biosafety and biosecurity are different approaches to ensuring the containment of hazardous biomaterial that share the end goal of minimizing the risk of exposure to or release of pathogens or toxins. However, while biosafety focuses on the accidental loss of containment, biosecurity focuses on the loss of containment as the result of a deliberate act. At the practical level, biosafety and biosecurity share a number of elements, such as inventory control, access restriction, accountability and compliance, incident reporting, evaluation and revision of a facility's operating procedures, and education and training.[4]

More people are gaining access to laboratories and a larger number of people are developing expertise in the life sciences, while new, infrastructures designed for work with potentially hazardous biomaterials are also being built. These developments can alter the risk–benefit ratio: while they lead to improvements in public health systems and contribute to progress in the life sciences, they also raise new safety and security challenges, including proliferation concerns.

Laboratory-acquired infections

Incidents and cases of laboratory-acquired infections in the past decade highlight the need to assess laboratory safety procedures and strengthen their effectiveness. Following the SARS epidemics, the LAIs that were reported in China, Singapore and Taiwan drew attention to the human factors behind a biosafety crisis, because the procedures and practices at facilities, not the level of containment, were responsible for the epidemics, which led to improvements in these countries.[5] More recently, in April 2011, the US Centers for Disease Control and Prevention (CDC) reported that students and employees had become ill in a multi-state outbreak of *Salmonella Typhimurium* infections that were linked to exposure in clinical and teaching microbiology laboratories.[6] These incidents prompted

[2] Butler, D., 'European biosafety labs set to grow', *Nature*, 12 Nov.2009, pp. 146–47.

[3] US Government Accountability Office (GAO), *High-Containment Laboratories: National Strategy for Oversight Is Needed*, report GAO-09-574 (GAO: Washington, DC, Sep. 2009), pp. 25, 38. Accurately estimating the number of BSL-3 laboratories is complicated, all the more so as they vary greatly in terms of capacity, design, function and operation. Moreover, some BSL-2 and BSL-3 labs have been enhanced to become, respectively, BSL-2+ and BSL-3+ labs. However, some BSL-3 labs do not actually meet all criteria. In order to assess biological risks, considering the work performed in these labs is more appropriate. Nevertheless, the GAO report highlights this concern, stating that 'no federal agency knows how many such laboratories exist in the United States', because no federal agency has the mandate to track their expansion and regulate biosafety.

[4] Clevestig, P., *Handbook of Applied Biosecurity for Life Science Laboratories* (SIPRI: Stockholm, June 2009), p. 4.

[5] Ling, A. E., 'Editorial on laboratory acquired incidents in Taipei, Taiwan and Singapore following the outbreak of SARS Coronavirus', *Applied Biosafety*, vol. 12, no. 1 (2007), p. 17.

[6] US Centers for Disease Control and Prevention (CDC), 'Investigation announcement: multistate outbreak of human *Salmonella Typhimurium* infections associated with exposure to clinical and

a survey to identify areas where biosafety and laboratory safety training could be enhanced. Public reports related to incidents in the United States are also informative in this regard.[7] A 2009 Government Accountability Office report, for example, analysed safety violations related to a series of incidents in 2006 at BSL-3 laboratories at Texas A&M University, and 2007 and 2008 power failures at the CDC's high-containment laboratories.[8] A perceived lack of transparency in these incidents helps to explain why people may be reluctant to have a high-containment laboratory situated near them.

A 2006 study identified 1448 cases of symptomatic LAIs between 1979 and 2004 that led to 36 deaths, including abortions resulting from maternal exposure to an LAI.[9] Most of these infections occurred in diagnostic or research laboratories. However, these incidents appear to be under-reported, especially when they result from a lack of compliance and some US experts, such as Kamaljit Singh, assistant director of clinical microbiology at Rush University Medical Center in Chicago, Illinois, have called for centralized registries.[10] This is a cause of concern because investigating LAIs and other incidents is crucial to assessing the effectiveness of biosafety and to further adapting and improving procedures.[11] Accidents in high-containment laboratories are rare, but they can usually be linked to human error or system failure. Thus, the higher the BSL classification, the lower the safety concern usually (but the higher the security concern).

Accidents in veterinary laboratories can also have serious consequences. In 2007 in the United Kingdom several outbreaks of disease among cattle and sheep resulted from the accidental release of the highly contagious foot-and-mouth disease virus, which was linked to a poorly maintained drainage system.[12] Not all laboratory accidents can be avoided, but implementing adequate safety measures minimizes risk.

Bioterrorism

The most well-known bioterrorism event remains the 2001 *Bacillus anthracis* case (anthrax spores in letters) in the USA, which was followed by numerous hoaxes worldwide. The US Department of Justice identified a microbiologist at the US Army Medical Research Institute of Infectious Diseases as the sole perpetrator, based on the investigative findings of the US Federal Bureau of Investigation (FBI).[13] A 2011 US National Academy of Sciences report concluded that the scientific basis for this conclusion was insufficient, but the case nevertheless highlights the risk posed by a lone terrorist (e.g. a scientist acting inside a sensitive facility) and thus the need to develop and improve security at the laboratory level. In response, the US Army took measures to develop its own policies in order to enhance security and implement more efficient procedures for controlling access to select agents and toxins. It also issued a series of interim guidance messages, starting in December 2001, and in 2004 implemented draft Army Regulation 50-X, the Army Biological Surety Program. The programme relies on four areas or pillars: physical security, biosafety, agent accountability and personnel reliability (according to the Biological Personnel Reliability Program, persons with access to select agents have to be 'mentally alert,

teaching microbiology laboratories', 28 Apr. 2011, <http://www.cdc.gov/salmonella/typhimurium-laboratory/042711/index.html>.

[7] Greenberg, M., Kovacs, T. and Mike, M., 'Governance and biosecurity: strengthening security and oversight of the nation's biological agent laboratories', *DePaul Journal of Health Care Law*, vol. 13, no. 1 (summer 2010).

[8] Kaiser, J., 'Texas A&M to pay $1 million for biosecurity breaches', ScienceNOW, 20 Feb. 2008, <http://news.sciencemag.org/sciencenow/2008/02/20-01.html>; and US Government Accountability Office (note 3), pp. 60–62.

[9] Harding, A. L. and Byers, K. B., 'Epidemiology of laboratory-associated infections', eds D. O. Fleming and D. L. Hunt, *Biological Safety: Principles and Practices*, 5th edn (ASM Press: Washington, DC, 2006).

[10] Singh, K., 'It's time for a centralized registry of laboratory-acquired infections', *Nature Medicine*, vol. 17, no. 8 (2011), p. 919.

[11] Kimman, T. G., Smit, E. and Klein, M. R., 'Evidence-based biosafety: a review of the principles and effectiveness of microbiological containment measures', *Clinical Microbiology Reviews*, vol. 21, no. 3 (July 2008), pp. 403–25.

[12] British Health and Safety Executive (HSE), *Final Report on Potential Breaches of Biosecurity at the Pirbright Site 2007* (HSE: [n.p.], 2007). High precipitation at the time, and people and vehicles carrying contaminated mud from the site were presumably also involved.

[13] The US Congress and others continue to consider this issue. See Committee on Review of the Scientific Approaches Used During the FBI's Investigation of the 2001 *Bacillus anthracis* Mailings, Board on Life Sciences, and Committee on Science, Technology, and Law, *Review of the Scientific Approaches Used During the FBI's Investigation of the 2001 Anthrax Letters* (National Academies Press: Washington, DC, 2011); US Federal Bureau of Investigation, 'Amerithrax or anthrax investigation', <http://www.fbi.gov/about-us/history/famous-cases/anthrax-amerithrax>; US Department of Justice, 'Amerithrax documents', Feb. 2011, <http://www.justice.gov/amerithrax/>; and Public Broadcasting Service, Frontline, 'The anthrax files', 21 Oct. 2011, <http://www.pbs.org/wgbh/pages/frontline/anthrax-files/>.

mentally and emotionally stable, trustworthy, and physically competent').[14]

The possibility that a researcher or student with access to expertise, equipment and microorganisms might be recruited by a terrorist group cannot be ignored. Deliberate malicious acts relate not only to bioterrorism, but can also be more broadly characterized as biocrimes (e.g. carried out for purposes of extortion or to harm an employer or colleague out of a sense of grievance). Political extremism can also pose a biosecurity threat. For example, groups and individuals opposed to the use of live animals in research mount frequent attacks on facilities.

Rapid developments have occurred in the life sciences, such as in the fields of synthetic genomics and synthetic biology. The reconstruction and synthesis of genes or whole genomes in recent years, including a virus that had the biochemical and pathogenic characteristics of poliovirus, the 1918 Spanish influenza pandemic virus and a *Mycoplasma genitalium* genome, have already sparked controversy and aroused fear.[15] Scientific and technological developments are expected in various sub-fields of biotechnology, with synthetic and systems biology, genomics, proteomics and bioinformatics demonstrating the growing convergence between several disciplines—especially biology and chemistry.[16]

Advances in the life sciences

Keeping pace with and taking into account advances in the life sciences is one of the key challenges for the future of the BTWC. Enhancing knowledge and understanding of pathogenicity and virulence, infectivity and transmission, and toxicity offers new perspectives in terms of medical treatment but is also a cause for concern. Proteomics and genomics cover the study of genetic information and of proteins, respectively, in an organism. On the one hand, it could facilitate the engineering of new biological agents or the identification of alternative means of obtaining. On the other hand, this contributes to the development of countermeasures such as new therapeutics and vaccines or more efficient diagnostics. Attention is also being focused on synthetic genomics and biology, and fear has been expressed that known pathogens (e.g. smallpox virus) could be recreated or that specific organisms could be designed for malicious purposes. Improvement of targeted drug delivery systems, especially thanks to nanotechnology, and the development of modelization techniques (showing biological dispersion) could also lead to misuse.

The rapid pace and expanding scope of the development of biotechnology creates new safety and security challenges because it involves a wide spectrum of actors with various backgrounds, some of whom may not have adequate awareness regarding biothreats and the need for caution. On the other hand, debate and practical initiatives have been launched within the scientific and industrial communities about new biosafety and biosecurity issues, centring on both the risks of unintended consequences on human health and environment and the potential for misuse.[17]

When considering biosecurity and biosafety, a new phenomenon is worth monitoring: namely, the emergence of 'do it yourself (DIY) biology' (also referred to as 'garage science'). The reduced cost and wider availability of specialist equipment and the spread of information have allowed citizen scientists and amateur biologists to practise biology outside traditional professional settings, including extracting and building synthetic DNA sequences in makeshift laboratories. Online networks such as DIYbio.org and OpenWetWare.org provide information and facilitate communication in ways that can lead to innovation, but that also represent a new challenge in terms of awareness, best practice and regulation. Even if openness and safety are among the values

[14] Demmin, G. L., 'Biosurety', ed. Z. F. Dembeck, *Medical Aspects of Biological Warfare* (US Army, Office of the Surgeon General and Borden Institute: Washington, DC, 2007).

[15] E.g. Cello, J., Paul, A. V. and Wimmer, E., 'Chemical synthesis of poliovirus cDNA: generation of infectious virus in the absence of natural template', *Science*, 9 Aug. 2002, pp. 1016–18; Taubenberger, J. K. et al., 'Characterization of the 1918 influenza virus polymerase genes', *Nature*, 6 Oct. 2005, pp. 889–93; Tumpey, T. M. et al., 'Characterization of the reconstructed 1918 Spanish influenza pandemic virus', *Science*, 7 Oct. 2005, pp. 77–80; and Gibson, D. G. et al., 'Complete chemical synthesis, assembly, and cloning of a *Mycoplasma genitalium* genome', *Science*, 29 Feb. 2008, pp. 1215–20.

[16] McLeish, C. and Nightingale, P., 'Biosecurity, bioterrorism and the governance of science: the increasing convergence of sciences and security policy', *Research Policy*, vol. 36, no. 10 (2007), pp. 1635–54.

[17] Hart, J. and Trapp, R., 'Science and technology developments and challenges: reflections on possible EU contributions to the Seventh Review Conference to the Biological and Toxin Weapons Convention', Paper presented at the EU Council Working Party on Global Disarmament and Arms Control (CODUN), Brussels, 26 May 2011; and Hart, J. and Trapp, R., *Science and Technology and their Impact on the Biological and Toxin Weapons Convention: a Synthesis Report on Preparing for the Seventh Review Conference and Future Challenges* (SIPRI: forthcoming).

promoted in well-meaning communities, projects may involve people without the relevant training and academic background. Some 'biohackers' are more security conscious than others. In the USA the members of Genspace opened what they consider to be the first not-for-profit community biological laboratory in December 2010, to promote science as a leisure activity for both adults and children. Genspace offers courses that teach biotechnology techniques and 'how to manipulate life' using standardized genetic parts (biotechnology crash course and synthetic biology course).[18] Genspace has developed biosecurity guidelines in consultation with the FBI and in July 2011 co-hosted the FBI–DIYbio Workshop.[19] The FBI is involved in outreach activities towards community groups and, since 2009, has sponsored the International Genetically Engineered Machine competition, an undergraduate synthetic biology competition that aims to build biological systems and operate them in living cells. Student teams receive a kit of biological parts from the registry of Standard Biological Parts and then work at their own schools.[20] Like universities that offer to host such a team, this example demonstrates the advantage of a collaborative effort to prevent the movement from going 'underground'. In this respect, in June 2011 the US National Science Advisory Board for Biosecurity (NSABB) published a report on strategies to educate amateur biologists and scientists in non-life science disciplines about dual-use research in life sciences.[21]

The discussion above illustrates that in the fields of laboratory biosafety and biosecurity even the definition of a laboratory is not fully demarcated.

III. THE SCOPE OF LABORATORY BIOSECURITY AND BIOSAFETY

Definitions and consequences

The lack of an agreed universal definition of biosecurity, combined with the different priorities that states allocate to public health and security issues, explain the coexistence of several definitions of quite different scope and conceptualization.[22] It is tempting to propose the harmonization of terminology, which would improve understanding and communication. However, some countries have already legislated on the basis of their existing definitions and harmonization would therefore present a major challenge.

In some languages, including Russian, the same word covers both biosecurity and biosafety. Consequently, the use of the terms can vary depending on the country, and also on the field of expertise (e.g. public health, animal health and agriculture, or arms control). In some cases, biosecurity has a broader meaning for security experts than activities in the laboratory (encompassing all issues and measures related to security in the biological field). In some countries and scientific communities the term 'biosecurity' has been used for some time in the context of agriculture and the environment to describe measures to prevent or limit transmission of pathogens in crops and breeding. This definition has been broadened to include threats resulting from alien invasive microorganisms that can have an economic and environmental impact.

Other definitions distinguish clearly between risks (natural and accidental) and threats (intentional), and the documents of the World Health Organization (WHO) give useful guidance and offer a common basis for understanding and discussion.[23] According to the WHO's 2006 *Biorisk Management: Laboratory Biosecurity Guidance*, laboratory biosafety deals with containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release. Laboratory biosecurity describes protection measures, control and accountability for valuable biological materials (VBMs) within laboratories that are dedicated to the prevention of unauthorized access,

[18] Genspace: New York City's Community Biolab, 'Projects@ Genspace', [n.d.], <http://genspace.org/projects>.

[19] The Implementation Support Unit for the BTWC participated in such a workshop in July 2010.

[20] International Genetically Engineered Machine (iGEM), 'Synthetic biology based on standard parts', [n.d.], <http://2011.igem.org/Main_Page>.

[21] US National Science Advisory Board for Biosecurity (NSABB), 'Strategies to educate amateur biologists and scientists in non-life science disciplines about dual use research in the life sciences', June 2011, <http://oba.od.nih.gov/biosecurity/pdf/FinalNSABBReport-AmateurBiologist-NonlifeScientists_June-2011.pdf>.

[22] Koblentz, G. D., 'Biosecurity reconsidered: calibrating biological threats and responses', *International Security*, vol. 34, no. 4 (spring 2010), pp. 96–132.

[23] World Health Organization (WHO), *Laboratory Biosafety Manual*, 3rd edn (WHO: Geneva, 2004); and WHO, *Biorisk Management: Laboratory Biosecurity Guidance* (WHO: Geneva, Sep. 2006).

loss, theft, misuse, diversion or intentional release of agents and toxins.[24] On laboratory biosecurity the WHO Manual states that 'in summary, security precautions should become a routine part of laboratory work, just as have aseptic techniques and other safe microbiological practices'.[25]

The WHO guidelines have become a widely used point of reference, for example in the EU and in BTWC documents. In 2007 the Organisation for Economic Co-operation and Development (OECD) published similar documents, the *OECD Best Practice Guidelines for Biological Resource Centres* and the *OECD Best Practice Guidelines on Biosecurity for BRCS*.[26]

The containment of intangible technology developed in dual-use research as part of laboratory biosecurity may also be of interest. Public availability of genomic sequence data that is potentially linked with a risk of misuse (e.g. involving gene encoding virulence factors) becomes, for example, more of an issue as capacities for synthesis steadily increase. The definition of biosecurity proposed by the NSABB has been broadened to take into account techniques and technologies that could be diverted to create biological agents or active compounds. The NSABB defines dual-use research of concern 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'.[27] This paper draws on the WHO's definitions of laboratory biosafety and biosecurity, as well as on the dual-use perspective.

[24] According to the WHO's *Biorisk Management: Laboratory Biosecurity Guidance*, VBMs are 'Biological materials that require (according to their owners, users, custodians, caretakers or regulators) administrative oversight, control, accountability, and specific protective and monitoring measures in laboratories to protect their economic and historical (archival) value, and/or the population from their potential to cause harm. VBM may include pathogens and toxins, as well as non-pathogenic organisms, vaccine strains, foods, genetically modified organisms (GMOs), cell components, genetic elements, and extraterrestrial samples'.

[25] *WHO Biorisk Management: Laboratory Biosecurity Guidance* (WHO/CDS/EPR/2006.6), p. 48.

[26] Organisation for Economic Co-operation and Development (OECD), *OECD Best Practice Guidelines for Biological Resource Centres*, 2007; and *OECD Best Practice Guidelines on Biosecurity for BRCs*, 2007, <http://www.oecd.org/document/36/0,3746,en_2649_34537_38777060_1_1_1_1,00.html>.

[27] US National Science Advisory Board for Biosecurity (NSABB), 'Frequently asked questions', [n.d.], <http://oba.od.nih.gov/biosecurity/nsabb_faq.html#NSABB_FAQ001>.

Biosafety and biosecurity: the need for an integrated and balanced approach

Given the trend towards an 'all-hazard' approach to biological threats, from natural events to intentional ones, and the aspects that safety and security share at a practical level, it is necessary to see biosafety and biosecurity in an integrated manner.[28] Consequently, biorisk assessment and management, tailored to each specific facility, should address both safety and security issues simultaneously, taking into account actual concerns and avoiding redundant and unnecessary measures, in a cost-benefit approach.

In reality, biosecurity is apparently often not taken into account sufficiently at facilities, and the main causes for concern and attention in risk mitigation are accidental exposure and negligence. As regards biosafety, measures should be identified following risk assessment. If there has not been adequate communication to raise awareness, biosecurity measures may be perceived as an unwelcome and unnecessary constraint at a facility and barely understandable from the point of view of a scientist. For example, the ideas that the authorization of research should be subordinated to an analysis of the scope of the project and an assessment of participating personnel may be controversial for some scientists.

Biosecurity cannot be considered and implemented without biosafety because they are complementary and mutually reinforcing. However, a global approach that integrates the biosafety and biosecurity dimensions based on risk assessment is essential since some measures may still conflict. For example, limiting unauthorized access for security purposes must not hinder emergency response in case of an accident. Information on biohazard signs in BSL-3 and BSL-4 laboratories must be sufficient to implement required safety measures but, for security reasons, should not precisely identify the nature and location of dangerous agents.

This is not only a question of regulations and resources. Developing a biosafety and biosecurity culture among laboratory workers, based on responsibility, is crucial and decisive to achieve effective implementation. Questioning and openness

[28] Taylor, T., 'Safeguarding advances in the life sciences: the International Council for the Life Sciences is committed to becoming the authoritative source for identifying and managing biological risks', *EMBO Reports*, vol.7, Special issue (2006), pp. 61–64.

must be encouraged, including for reporting incidents.[29]

IV. INTERNATIONAL REGULATION AND REGULATORY FRAMEWORKS

Many developed countries have adopted a regulatory framework for biosafety, but the specific measures and the arrangements for compliance (including monitoring compliance) may differ from country to country. In the EU, mostly work environment laws and regulations address biosafety.[30] In many developing countries biosafety regulations are more limited. However, public health threats linked to past outbreaks and fear of pandemics, together with scientific and technological progress, the changing economic context and an emphasis on internationalization have all promoted transfers of technology and the evolution of global pharmaceutical and biotechnology companies, through which biosafety standards have also been disseminated. This evolution may nonetheless also be cause for concern in terms of biosafety and biosecurity.

In comparison, few countries have developed particular regulations that address biosecurity. Australia, Denmark, France, the UK and the USA are notable exceptions. However, it cannot be assumed that measures or initiatives falling under the scope of biosecurity do not exist in other countries.

Most is known about the US system. The Public Health Security and Bioterrorism Preparedness Response Act of 2002 requires all persons possessing 'select agents' or toxins to notify the Department of Health and Human Services.[31] In the case of livestock pathogens and toxins that pose a severe threat, they must notify the Department of Agriculture.[32] Facilities possessing, using and transferring these agents or toxins have to be registered.

In Australia, securing biological agents of concern is achieved through implementation of the Security Sensitive Biological Agents Regulatory Scheme, which builds on Australia's obligations under the BTWC and UN Security Council Resolution 1540.[33] It is described in the National Health Security Act 2007 and the National Health Security Regulations 2008, and the Department of Health and Ageing acts as the administrative body.

In France the authorization regime governing activities that involve specific microorganisms and toxins was created in 2001 and addresses possession, use, importation, exportation, acquisition, transfer and transport. Biosafety and biosecurity regulations have been reviewed and are currently being implemented during a 2010–12 transition period.[34] The Agence française de sécurité sanitaire des produits de santé is the key administrative body.[35] Authorization requests must be accompanied by a technical file that includes information related to biosafety and biosecurity management.[36]

[29] A controversy at the Synthetic Biology Engineering Research Center (SynBERC) illustrates some of the difficulties and misunderstandings which may hinder the implementation of biosecurity measures. Disagreement about security and preparedness recommendations led to the resignation of Paul Rabinow, an anthropologist hired to assess security and ethical issues in relation with this centre. See Gollan, J., 'Lab fight raises U.S. security issues', *New York Times*, 22 Oct. 2011.

[30] For a 2008 assessment of existing European legislation see 'Implementation of legislation and measures related to biosafety and biosecurity in EU member states', submitted by Germany on behalf of the European Union, BWC/MSP/2008/MX/WP.16, BWC Meeting of Experts, Geneva, 12 Aug. 2008. This may evolve with the implementation of the EU CBRN Action Plan.

[31] Public Health Security and Bioterrorism Preparedness and Response Act of 2002, H.R.3448, <http://www.gpo.gov/fdsys/pkg/BILLS-107hr3448enr/pdf/BILLS-107hr3448enr.pdf>.

[32] National Select Agent Registry, <http://www.selectagents.gov/>.

[33] Australian Department of Health and Ageing, 'Health emergency preparedness and response: security sensitive biological agents', [n.d.], <http://www.health.gov.au/SSBA>; and UN Security Council Resolution 1540, 28 Apr. 2004.

[34] Regulation applies to microorganisms, infectious or non-infectious, and toxins, active or inactive, that are listed in 'Arrêté du 30 juin 2010 fixant la liste des micro-organismes et toxines prévue à l'article L. 5139-1 du code de la santé publique' [Law of 30 June 2010 establishing the list of microorganisms and toxins in Article L. 5139-1 Code of Public Health], Legifrance.gouv.fr, <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000022415130>. It also covers genetically modified organisms that are derived or include DNA sequences from these microorganisms or toxins; production of these microorganisms from their genetic materials; synthesis of toxins, genetic or antigenic material (or part of it) related to these microorganisms, genetic material (or part of it); coding for these toxins or one of their subunits; and samples including these microorganisms and toxins. See also 'Décret no. 2010-736 du 30 juin 2010 relatif aux micro-organismes et toxines' [Decree no. 2010-736 of 30 June 2010 on micro-organisms and toxins], <http://legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000022415024&categorieLien=id>.

[35] Agence française de sécurité sanitaire des produits de santé (AFSSAPS), 'Micro-organismes et toxines hautement pathogènes (MOT)' [Highly pathogenic microorganisms and toxins], 2011, Legifrance.gouv.fr, <http://www.afssaps.fr/Dossiers-thematiques/Micro-organismes-et-toxines-hautement-pathogenes-MOT/Micro-organismes-et-toxines-hautement-pathogenes-MOT/(offset)/0>.

[36] See 'Décision du 20 octobre 2010 fixant le contenu du dossier technique mentionné à l'article R. 5139-3 et accompagnant la demande d'autorisation prévue à l'article R. 5139-1 du code de la santé publique' [Decision of 20 October 2010 fixing the contents of the technical dossier referred to in Article R. 5139-3 and accompanying the application for authorization referred to in Article R. 5139-1 Code of Public Health],

In the UK the 2001 Anti-Terrorism, Crime and Security Act addresses biosecurity issues.[37] Managers of laboratories and other premises are required to notify the police if they possess microorganisms or listed toxins, must comply with reasonable security requirements and, on request, have to provide information on persons who have access to these agents and toxins.

Denmark has gone farther, creating the Centre for Biosecurity and Biopreparedness, by act of parliament, in pursuance of UN Security Council Resolution 1540.[38] The centre is part of the Statens Serum Institut, and serves as the national authority that issues licenses to allow research institutions and laboratories to work with dual-use agents.

Regulation at the international level

Preventing the proliferation of biological weapons and related biorisks relies on a multilayered approach. At the international level, several instruments address biosafety and biosecurity issues.

The primary instrument that focuses on biosafety is the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.[39] The 1993 Convention on Biological Diversity is the main international instrument to address biodiversity issues. The Open-ended Ad Hoc Working Group on Biosafety was established in 1995 at the second meeting of the conference of the states parties to the Convention on Biological Diversity, and its work resulted in adoption of the Cartagena Protocol in 2000 and its entry into force in 2003. The protocol is based on Article 19, paragraphs 3 and 4, and articles 8 and 17 of the Convention on Biological Diversity. While recognizing the great potential offered by modern biotechnology, the protocol takes into account the need to enhance the safety of biotechnology through the development of appropriate procedures. It established a mechanism, the Biosafety Clearing-House (BCH), to exchange information on living modified organisms and to assist parties in complying with their obligations under the protocol. The BCH relies on voluntary national reports.

There are currently 161 parties to the protocol, but several important exporters or actors, such as Argentina, Australia, Canada, Russia and the USA, have neither signed nor ratified it. When the European Commission deposited its instrument of ratification, it noted that it already had adopted instruments that are legally binding for EU member states and covering matters under the scope of the protocol.

Other international instruments also deal with biosafety and biosecurity. UN Security Council Resolution 1540, which was adopted under Chapter VII of the UN Charter and is therefore legally binding, requires states to refrain from providing any form of support to non-state actors that attempt to develop, acquire, manufacture, possess, transport, transfer or use nuclear, chemical or biological weapons and their means of delivery. To give effect to this requirement states must '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'. In the case of biological weapons this would require controls over pathogens and toxins. To that end, states are obliged to 'Develop and maintain appropriate effective measures to account for and secure such items in production, use, storage or transport' and to 'Develop and maintain appropriate effective physical protection measures'.[40]

The WHO also plays a role through its biorisk reduction management programme and its updated International Health Regulations (IHR), a legally binding instrument for the 193 WHO member states and the Holy See.[41] These regulations aim to contribute to global public health security 'by providing a new

Legifrance.gouv.fr, <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000022993011>. According to this decision, the technical file must include the following information: essential equipments and materials contributing to biosafety and biosecurity (with their location), identification of sources of risks, risk analysis in terms of biosafety and biosecurity, risk assessment, risk control and an assessment of acceptability of global residual risks.

[37] See British National Archives, Anti-terrorism, Crime and Security Act 2001, 'Part 7, security of pathogens and toxins', legislation.gov.uk, <http://www.legislation.gov.uk/ukpga/2001/24/contents>.

[38] Danish Statens Serum Institut, Centre for Biosecurity and Biopreparedness, <http://www.ssi.dk/English/PublicHealth/Biosikring%20og%20beredskab.aspx>.

[39] Article 1 states, 'the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements'. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, adopted on 29 Jan. 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on 11 Sep. 2003, <http://bch.cbd.int/protocol/>.

[40] UN Security Council Resolution 1540 (note 33).

[41] World Health Organization (WHO), *International Health Regulations (2005)* (WHO: Geneva, 2005).

framework for the coordination of the management of events that may constitute a public health emergency of international concern, and will improve the capacity of all countries to detect, assess, notify and respond to public health threats', irrespective of the sources of these risks.[42] The WHO requires state parties to have minimum core public health capacities to implement the IHR. The 'checklist and indicators for monitoring progress in the development of IHR core capacities in state parties' provide 28 indicators.[43] This framework is not legally binding but nevertheless represents 'a consensus of technical expert views drawn globally from WHO Member States, technical institutions, partners, as well as from within the WHO'.[44] One of these indicators for annual reporting (no. 13) states that laboratory biosafety and biosecurity (biorisk management) should be in place.

International standards for the transport of dangerous goods have been developed in a number of specialized forums. The International Maritime Dangerous Goods Code includes toxic and infectious substances as one of the classes of dangerous goods. Developed under the auspices of the International Maritime Organization, the code lays down basic principles and makes detailed recommendations on good operational practice for things like packing, labelling, stowage, segregation and handling, and emergency response action.[45] The International Air Transport Association has played a similar role in facilitating the development of guidelines for transport of infectious substances by air.[46] The Sub-Committee of Experts on the Transport of Dangerous Goods of the UN Economic and Social Council has prepared Recommendations on the Transport of Dangerous Goods, including carriage by road and rail. The UN Economic Commission for Europe subsequently elaborated regional agreements for Europe, translating guidelines into standards applicable to transport by road, rail and on inland waterways.[47]

Biosafety and biosecurity in Europe

While global processes have played a valuable role in establishing principles, creating legal obligations and setting standards, it is at the regional level that adherence can be promoted by raising awareness and facilitating experience sharing. There are examples of regional processes being established in different parts of the world. For example, the Biosafety and Biosecurity International Conference (BBIC) aims to promote national and regional capability building in the Middle East and North Africa.[48]

The European Committee for Standardization (Comité Européen de Normalisation, CEN) is an international non-profit organization set up under Belgian law that links together the national standards authorities of 31 European countries. Under the CEN, different types of voluntary European technical standards can be developed, one type of which is called a Workshop Agreement. The European Commission advises the CEN about the regulatory implications of standards and about public interest in standards in a particular technical area.[49]

In 2007 a CEN Workshop Agreement on laboratory biorisk management was prepared as a public reference document that was agreed by the CEN's national standard bodies. It examplified a voluntary standard that is applicable internationally, but which does not have the force of a regulation. The definitions of biosecurity and biosafety that were used were derived from the WHO's 2006 *Biorisk Management: Laboratory Biosecurity Guidance*.[50] Representatives from the WHO, the European Biosafety Association, the American Biological Safety Association and the Asia-Pacific Biosafety Association were also involved in the process.

The European Union

The EU provides a common regulatory framework for biosafety through directives adopted by the Council

[42] World Health Organization (WHO), 'About the IHR', <http://www.who.int/ihr/about/en/>.

[43] World Health Organization (WHO), 'IHR monitoring framework: checklist and indicators for monitoring progress in the development of IHR core capacities in states parties', <http://www.who.int/ihr/checklist/en/>.

[44] World Health Organization (WHO), 'IHR monitoring framework: checklist and indicators for monitoring progress in the implementation of IHR core capacities in states parties', <http://www.who.int/ihr/Processes_of_IHR_Monitoring_framework_and_Indicators.pdf>.

[45] On the IMDG Code see the IMO's website, <http://www.imo.org/Pages/home.aspx>.

[46] The guidelines on carriage of infectious substances are available at International Air Transport Association, <http://www.iata.org/whatwedo/cargo/dangerous_goods/Pages/infectious_substances.aspx>.

[47] UN Economic Commission for Europe, 'Dangerous goods', <http://www.unece.org/trans/danger/danger.html>.

[48] Biosafety and Biosecurity International Conference, <http://www.bbic-2011.org/>.

[49] European Committee for Standardization , <http://www.cen.eu/cen/pages/default.aspx>.

[50] WHO, *Biorisk Management: Laboratory Biosecurity Guidance* (note 23).

of the European Union and the European Parliament, with a focus on safety at the workplace and during transport. An EU directive is not a self-executing regulation but requires implementation by the EU member states through their national legislation. As a result, the national regulations on biosafety may look different in the EU member states but share a common minimum standard that is set out in the various directives. Seeking to establish minimum requirements regarding safety and health, in 1990 the Council adopted Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work. Directive 2000/54/EC, which is safety oriented and does not deal with biosecurity, codifies Directive 90/679/EEC. At national level, compliance is verified through control measures, such as inspections. Other directives and decisions specifically address GMOs, with for example Directive 2009/41/EC on the contained use of GMOs, adopted on 6 May 2009 repealing Directive 90/219/EEC.

Many of the safety and security guidelines for transport of dangerous goods have been translated by the EU into laws and regulations that member states must apply. Transport by road falls under the scope of Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the member states with regard to the transport of dangerous goods by road and Directive 95/50/EC on uniform procedures for checks on the transport of dangerous goods by road, amended by Directive 2008/54/EC. Transport by rail is regulated by Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the member states with regard to the transport of dangerous goods by rail, as adapted.

The export control law that governs all member states is Regulation 428/2009 of 5 May 2009 'setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items'. Dual-use means that items can have both military and civil purposes. The list of controlled items relies on control lists from multinational export control regimes, including the Australia Group.

Unlike biosafety, the EU provides no framework for biosecurity at the moment, even if actions and initiatives have been launched. In 2007 the European Commission prepared a Green Paper (a consultation document) on the issue of biopreparedness.[51]

[51] European Commission, 'Green Paper on bio-preparedness', COM(2007)399, 11 July 2007.

Subsequently, the recommendations that arose from the paper and the public consultation around it led to the elaboration of part of the chemical, biological, radiological and nuclear (CBRN) Action Plan that is intended to reduce the risk to public safety and security from a range of potentially hazardous substances and activities.[52] The CBRN Action Plan is discussed further below.

V. THE INVOLVEMENT OF NON-STATE ACTORS

Non-state actors, including non-governmental organizations (NGOs), professional associations and universities, have also been proactive and currently participate in the debate about biosecurity and biosafety, including developing and implementing biosecurity measures on their own.[53] Discussion and debate in the scientific community, especially in the national academies of sciences, led to publication of several proposals and recommendations. In 2005 the Interacademy Panel (IAP) on international issues, a global network of science academies, released the IAP Statement on Biosecurity. Recalling the prohibition norm embodied in the BTWC, the statement provided a set of principles related to awareness, safety and security, education and information, accountability and oversight to guide individual scientists and local scientific communities that may wish to define a code of conduct for their own use. Regarding safety and security, it further specified that '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 common practice'.[54]

In 2004 the US National Academies report, *Biotechnology Research in an Age of Terrorism*, known

[52] European Commission, 'Communication from the Commission to the European Parliament and the Council of 24 June 2009 on strengthening chemical, biological, radiological and nuclear security in the European Union—an EU CBRN Action Plan', COM(2009) 273 final, 24 June 2009.

[53] According to an EU definition, 'non-State Actors encompass non governmental organisations, grassroots organisations, cooperatives, trade unions, professional associations, universities, media and independent foundations. Their common feature lies in their independence from the State and the voluntary basis upon which they have come together to act and promote common interests'. European Commission, Development and Cooperation:EuropeAid, 'Civil society, a vital development partner', <http://ec.europa.eu/europeaid/who/partners/civil-society/index_en.htm>.

[54] Interacademies Panel (IAP) 'IAP Statement on Biosecurity', 2005, <http://www.interacademies.net/10878/13912.aspx>.

as the Fink Report, explored ways to minimize biothreats from states and terrorists, without hindering advances in the life sciences.[55] The recommendations included: (*a*) educating the scientific community about the nature of the dual-use dilemma in biotechnology and the responsibility of scientists; (*b*) reviewing plans for experiments; (*c*) reviewing at the publication stage, thus involving self-regulation; (*d*) creating the National Science Advisory Board for Biodefense (the National Science Advisory Board for Biosecurity, advisory committee, was established in 2005); (*e*) adding elements for protection against misuse, including physical containment and trained personnel; (*f*) ensuring a role for the life sciences in efforts to prevent bioterrorism and biowarfare; and (*g*) harmonizing international oversight.

In 2006 another US National Academies report, *Globalization, Biosecurity and the Future of Life Sciences*, known as the Lemon report, recommended: (*a*) establishing policies and practices promoting free and open exchange of information in the life sciences; (*b*) adopting a broader perspective on the 'threat spectrum'; (*c*) strengthening and enhancing the scientific and technical expertise within and across the security communities; (*d*) adopting and promoting a common culture of awareness and a shared sense of responsibility within the global community of life scientists; and (*e*) strengthening the public health infrastructures and existing response and recovery capabilities.[56]

In 2006 the British Council for Science and Technology, a scientific advisory body to the office of the prime minister, elaborated a universal code of ethics for scientists.[57] In 2007 the Biosecurity Working Group of the Royal Netherlands Academy of Arts and Sciences published a report integrating a 'code of conduct for biosecurity', which was intended to raise awareness about biosecurity among scientists. The code defined responsibilities, and terms of reference for governance and, if need be, sanctions. In 2008 the French Academy of Sciences produced a report, *Les Menaces Biologiques, Biosécurité et responsabilité des scientifiques*, that proposed guidelines for inter-academy commitments, organization of a national conference, creation of a scientific committee to monitor biosecurity, international policies and debates, and establishment of obligations and codes of conduct for biologists.[58]

Ethical codes and codes of conduct are primarily awareness-raising tools to remind scientists that they should consider the potential consequences of their research. Such codes can also play a role in undergraduate and postgraduate education as part of a programme to prepare students to consider the consequences of their activities, including any foreseeable negative side effects.

Laboratory biosecurity depends on the engagement of the scientists and technicians working in laboratories. Convincing laboratory workers of the need for safety is not a problem, but the same may not hold true for biosecurity. Some security measures may create adverse reactions and be viewed as impeding scientific research or restraining individual freedom. The question remains of how best to supplement existing ethical and accountability practices and raise the awareness of scientists and laboratory workers about biological security issues, without ignoring the issue of responsibility. The scientific community has already dealt with a similar dilemma regarding GMOs, and in that instance scientists themselves launched the debate and took the first steps in the policy process. On the initiative of biochemist Paul Berg, scientists gathered at Asilomar in 1973 to discuss the issue and then, in the framework of the Gordon Research Conference on Nucleic Acids, addressed safety and the prevention of environmental contamination by calling for a worldwide voluntary moratorium on recombinant DNA experiments.[59] In 1975 a subsequent Asilomar Conference on Recombinant DNA Molecules gathered scientists, lawyers, physicians, journalists and government representatives and lifted the voluntary moratorium. Instead, strict guidelines were proposed

[55] National Academies, National Research Council, Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, *Biotechnology Research in an Age of Terrorism* (National Academies Press: Washington, DC, 2004).

[56] National Academies, Institute of Medicine and National Research Council, Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, Institute of Medicine, *Globalization, Biosecurity, and the Future of Life Sciences* (National Academies Press: Washington, DC, 2006).

[57] British Council for Science and Technology, 'Universal ethical code for scientists', 2006, <http://www.bis.gov.uk/cst/cst-reports#Ethics>.

[58] Korn, H., Berche, P. and Binder, P., *Les menaces biologiques: Biosécurité et responsabilité des scientifiques* [Biological threats: biosecurity and responsibility of scientists] (PUF: Paris, 2008).

[59] Institut scientifique de santé publique, '1990–2010: 20 années d'évaluation des risques des OGM et pathogènes' [1990–2010 : 20 years of risk assessment of GMOs and pathogens], Brussels, 2010, <http://www.biosafety.be/Book/PDF/SBB_20ansBiosecurite_FR_HR.pdf>.

to ensure the safety of recombinant DNA technology, and the first such guidelines were published by the National Institutes of Health in 1976.[60]

It is essential to find a balance between openness and transparency, on the one hand, and security, on the other. NGOs and industry have demonstrated interest and developed initiatives in the field of synthetic biology, creating two industrial consortia that are dedicated to enhancing biosafety and biosecurity—the International Consortium for Polynucleotide Synthesis and the Industry Association of Synthetic Biology.[61] Although discussions continue, two approaches have emerged: self-regulation or external regulation.[62] The first option raises the issue of providing incentives for compliance, while the second focuses on scope and feasibility.

VI. STRENGTHENING THE BTWC PROHIBITION NORM THROUGH BIOSECURITY: LESSONS FROM EU AND EU MEMBER STATES' EXPERIENCES

The relationship of biosecurity and biosafety issues to the BTWC and the biological weapon prohibition norm that it embodies is worth considering. Linking safety and security is mandatory from the perspective of biorisk assessment, but the linkage goes beyond non-proliferation to engage scientists who would not normally concern themselves with security requirements. The BTWC was drafted during the cold war to achieve biological weapon disarmament and non-proliferation and is directed to states. However, non-state actors are not excluded from its scope, a bottom-up approach that mostly contributes to reducing the potential for misuse by non-state actors.

Articles III and IV and intersessional processes

Articles I–IV of the BTWC delineate national implementation obligations. Article I embodies the prohibition norms and includes the so-called general purpose criterion. Article III stipulates that states parties have an obligation not to transfer to any recipient, or in any way to assist, encourage or induce any entity to manufacture or acquire biological weapons. Under Article IV, states must adopt and implement 'any necessary measures' to prohibit and prevent proliferation of biological weapons, 'within [their] territory, under [their] jurisdiction or under [their] control anywhere'. As stated in the final declaration of the sixth review conference, the article covers legislative, administrative, judicial and other measures, including penal legislation. Preventing unauthorized access and theft by ensuring the safety and security of biological agents in laboratories and other facilities and during transport is explicitly mentioned. UN Security Council Resolution 1540 gave new momentum to this article, overlapping with and reinforcing the obligations of the BTWC.

The reconvened fifth review conference of the BTWC, in 2002, approved a proposal for annual meetings on specific topics: the intersessional process. In 2003 an intersessional meeting focused on national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins. At the sixth review conference in 2006 the states parties agreed to address several topics during the second intersessional process, including: '(iii) National, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogen and toxins; (iv) 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.'[63]

In 2008 the BTWC expert's meeting summarized the biosecurity and biosafety approach: 'biosecurity comprises measures that minimize the possibility of biological agents being deliberately used to cause harm. This distinguished it from biosafety, which involves measures aimed at protecting people and

[60] US National Institutes of Health, Office of Biotechnology Office, 'About DNA Recombinant Advisory Committee (RAC)', <http://oba.od.nih.gov/rdna_rac/rac_about.html>.

[61] Bhattacharjee, Y., 'DNA synthesis: Gene-synthesis companies join forces to self-regulate', *Science*, 22 June 2007, p. 1682.

[62] In 2006 a coalition of 38 NGOs signed an open letter asking scientists to withdraw from the self-governance approach, and stating that they 'believe that this potentially powerful technology is being developed without proper societal debate concerning socio-economic, security, health, environmental and human rights implications'. 'An open letter from social movements and other civil society organizations to the Synthetic Biology 2.0 Conference May 20–22, 2006, Berkeley, California concerning the "Community-wide vote" on Biosecurity and Biosafety resolutions', Etc Group News release, 19 May 2006, <http://www.etcgroup.org/en/node/8>.

[63] Sixth Review Conference 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, Final document, BWC/CONF.VI/6, 2006, p. 21.

the environment from the unintentional impact of biological agents, and includes workplace health and safety issues and the prevention of the accidental release of such agents'.[64] Considering the intersessional process from a biosafety and biosecurity angle, the main issues are whether it is possible to go further with this format, whether the process itself should be amended to bring added value, or whether other means of improvement should be employed to advance these issues. The most significant indication of progress was gaining the participation of actors traditionally not involved, or less involved, in the BTWC, such as scientific and public health organizations. It is important that the convention continues to serve as a forum enabling communities and actors from various backgrounds to meet and share experiences and best practices, in order to promote discussion on issues such as biosafety and biosecurity.

The EU's involvement in biosafety and biosecurity

In December 2003, the Council adopted the EU Strategy against Proliferation of Weapons of Mass Destruction, the main component of EU external relations policy in this field.[65] It identified the potential for misuse of dual-use technology and knowledge, which is considered to be 'increasing as a result of rapid developments in the life sciences'. Regarding biothreats, the strategy relied on a biological all-hazards approach and underlined the necessity to improve 'the security of proliferation-sensitive materials, equipment and expertise in the European Union against unauthorized access and risks of diversion'. The strategy was updated in 2008 with the 'New lines for action by the European Union in combating the proliferation of weapons of mass destruction and their delivery systems'.[66]

Addressing biosafety and biosecurity in the framework of the BTWC is an important issue for the EU, as testified by the EU paper on biosafety and biosecurity that was presented at the sixth review conference by Germany on behalf of the EU member states. By recalling the obligation to develop 'necessary measures' under Article IV, the main proposal was to develop and maintain an up-to-date systematic catalogue of biosafety and biosecurity, during the 2007–10 intersessional process. The paper also proposed that assistance be provided to develop national measures. In response, the Council adopted Common Position 2006/242/CFSP, which explicitly states that the EU shall promote among others issues 'strengthening, where necessary, national implementation measures, including penal legislation, and control over pathogenic micro-organisms and toxins in the framework of the BTWC'; compliance with obligations under UN Security Council Resolution 1540, including those contributing to prevent terrorist access to materials, equipment and knowledge; and the G8 Global Partnership programmes focusing on disarmament, control and security of sensitive materials, facilities and expertise.[67]

The EU has launched several initiatives and relies on specific instruments to carry out biosafety and biosecurity objectives. In 2008 the Council adopted Joint Action 2008/307/CFSP in support of the WHO's activities in the area of laboratory biosafety and biosecurity in the framework of the Strategy against the proliferation of weapons of mass destruction.[68] It noted the outcomes of the sixth review conference of the BTWC, including the decision to promote common understanding and action in the fields of biosafety and biosecurity, at the national, regional and international level. The joint action was intended to contribute to implementation of these decisions, with two objectives: '(a) ensuring the safety and security of microbial or other biological agents or toxins in laboratories and

[64] For this meeting the ISU produced a background document listing the various meanings of both terms, depending on the context in which they are used. It also summarized biosecurity proposals made in the framework of the BTWC in 2003. These proposals covered the scope and content of biosecurity arrangements and the means of enhancing domestic cooperation. 'Biosafety and biosecurity', Background paper for the 2008 Meeting of Experts and Meeting of the States Parties submitted by the Implementation Support Unit, BWC/MSP/2008/MX/INF.1, 24 June 2008.

[65] Council of the European Union, 'Fight against the proliferation of weapons of mass destruction: EU Strategy against Proliferation of Weapons of Mass Destruction', 15708/03, 10 Dec. 2003, <http://www.consilium.europa.eu/showPage.aspx?id=718>.

[66] Council of the European Union, 'Council conclusions and new lines for action by the European Union in combating the proliferation of weapons of mass destruction and their delivery systems', 15708/03, 17 Dec. 2008, <http://trade.ec.europa.eu/doclib/docs/2008/december/tradoc_141740.pdf >.

[67] Council Common Position 2006/242/CFSP of 20 March 2006 relating to the 2006 Review Conference of the Biological and Toxin Weapons Convention (BTWC), *Official Journal of the European Communities*, L88, 25 Mar. 2006.

[68] Council Joint Action 2008/307/CFSP of 14 April 2008 in support of World Health Organisation activities in the area of laboratory bio-safety and bio-security in the framework of the European Union Strategy against the proliferation of Weapons of Mass Destruction, *Official Journal of the European Union*, L106, 16 Apr. 2008.

other facilities, including during transportation as appropriate, in order to prevent unauthorised access to and removal of such agents and toxins; (b) promoting bio-risk reduction practices and awareness, including bio-safety, bio-security, bioethics and preparedness against intentional misuse of biological agents and toxins, through international cooperation in this area'.

To achieve these two objectives, the joint action intends to rely on outreach workshops, consultations and training for competent authorities, in order to promote biorisk reduction management. It also made provision for assistance to a selected country to strengthen its public health response capability and its security and laboratory management practices. Oman was selected as a recipient country in 2009.

Seeking to reduce risks from dangerous biological materials and pathogens, the Commission launched a process of consultation based on the 2007 Green Paper on Bio-preparedness, raising such issues as security and biological research, and professional codes of conduct.[69] Based on the 2009 final report of the CBRN Task Force, established in 2008 by the Commission, in November 2009 a new policy package, the EU CBRN Action Plan, was presented, with 133 measures and characterized by a multidisciplinary and multi-agency approach. It promoted a risk-based approach to security and prioritization of security measures, set up a plan for implementation of the various actions and established a CBRN Advisory Group to review the implementation of those actions. The latter falls under the responsibility of the EU member states and stakeholders, with support from the Commission. The *ex-ante* impact assessment showed that while addressing security issues largely depends on national competence, the subsidiarity principle is still respected given the potential transnational dimension of biological threats and their consequences. The CBRN Action Plan identified a number of actions that are relevant for enhancing biosafety and biosecurity (see appendix A). Most of these relate to preventive actions to enhance the security of high-risk materials and facilities, participate in the development of a high security culture of staff, and improve the security of transport and of information exchange. Others relate to specific training and personnel security.

The EU contributes to biosafety and biosecurity in non-EU countries through several development and cooperation financial instruments.[70] The most important one as regards biosafety and biosecurity is the Instrument for Stability, which was established in 2006. One of its objectives is to contribute to capacity building against CBRN threats. The EU thus supported in 2008 a project in Russia and Central Asia that focused on strengthening biosafety and biosecurity through training. It also plans to strengthen biosafety and biosecurity capabilities in Ukraine through projects implemented by the Science and Technology Center in Ukraine by helping to strengthen physical protection at the Ukrainian anti-plague station and by training scientists in the South Caucasus and in Central Asian countries.[71]

The recent creation of CBRN Centres of Excellence is a crucial step to meet the objective of building the capacity to address CBRN threats. By providing comprehensive, tailored assistance packages and mobilizing national, regional and international resources, the centres will contribute to enhancing national CBRN policies in countries that are not EU members. Five regional secretariats for CBRN Centres of Excellence are expected to be operational before the end of 2011, in Bangkok for South-East Asia; in Amman for the Middle East; in Tbilisi for South-East Europe, Ukraine and the South Caucasus; in Rabat for West Africa; and in Algiers for North Africa. Three others are planned to be set up in 2012, in Central Asia, sub-Saharan Africa and the Gulf Cooperation Countries.[72]

The Commission has funded projects that deal with biosecurity and biosafety in the Sixth and Seventh Framework Programme for research (FP6 and FP7), such as BIOSAFETY-EUROPE (Coordination, Harmonization and Exchange of Biosafety and Biosecurity Practices within a Pan-European Network),[73] SYNTH-ETHICS (Ethical and regulatory challenges raised by synthetic biology), ERINHA

[69] European Commission (note 51).

[70] 'European Union cooperative initiatives to improve biosafety and biosecurity', submitted by Belgium on behalf of the European Union, BWC/MSP/2010/MX/WP.5, BWC Meeting of Experts, Geneva, 12 Aug. 2010.

[71] Weaver, L. M., 'Biosafety and biosecurity activities of the International Science and Technology Center in the republics of the former Soviet Union: accomplishments, challenges and prospects', *Applied Biosafety: Journal of the American Biological Safety Association*, vol. 15, no. 2 (2010), pp. 56–59.

[72] European Commission, 'CBRN Centres of Excellence: an initiative of the European Union', <http://www.cbrn-coe.eu/>.

[73] Biosafety-Europe Consortium, 'Final considerations: coordination, harmonisation and exchange of biosafety and biosecurity practices within a pan-European network', Nov. 2008, <http://www.biosafety-europe.eu/FinalConsiderations_171208.pdf>.

(European Research Infrastructure on Highly Pathogenic Agents), EURONET-P4 (European Network of Biosafety-Level-4 laboratories) and SYNBIOSAFE (Safety and Ethical Aspects of Synthetic Biology).

For the EU member states, the implementation of actions defined under the CBRN Action Plan is ongoing. As mentioned above, Denmark, France and the UK have already adopted specific biosecurity regulations. In the UK, although its scope is broader than life sciences and biosecurity, the Academic Technology Approval System, which replaces the Voluntary Vetting System, is an interesting measure that was adopted to tackle the problem of intangible knowledge and skills that could contribute to proliferation of mass destruction. It concerns post-graduates students and focuses on sensitive subjects, not on country of origin or background, and is under the jurisdiction of the Foreign and Commonwealth Office. It was introduced by amending immigration rules and not through new regulations.

Some important programmes have been launched at the university level. The Research Group for Biological Weapons and Arms Control at the University of Hamburg, has developed a two-year project dedicated to the identification and comparison of control, safety and security measures that are applicable in European high-containment laboratories. The Department of Peace Studies of the University of Bradford is deeply involved in awareness raising and dual-use education for scientists and has developed and proposed educational tools.[74]

VII. BEYOND THE SEVENTH REVIEW CONFERENCE: A ROLE FOR THE EU?

The EU operates at a unique level and is able to contribute to the overall state of affairs of its member states through its CBRN Action Plan. The subsidiarity principle is definitely respected since the weakness of some member states could directly affect the security of others. Assessing the response to the requirements of the CBRN Action Plan and identifying the problems encountered, which will vary from country to country, may provide useful information about countries' experiences and benefit other countries.

As experts on biosafety and, particularly, biosecurity have reiterated, raising awareness is central to success.[75] Two such experts, Malcolm Dando and Brian Rappert, have found during seminars with life scientists and university students around the world that there is little evidence that the attendees 'regarded bioterrorism or bioweapons as a substantial threat, considered that developments in the life sciences research contributed to biothreats, were aware of the current debates and concerns about dual-use research, or were familiar with the BTWC'.[76] This situation is not changing significantly.

The key issue is devising an effective way to engage scientists. Inserting a module in university educational programmes for life sciences, medical, and pharmaceutical students that is dedicated to biosafety and biosecurity would prove beneficial and should be mandatory and part of the core curriculum at graduate and postgraduate levels. Laboratory workers and biosecurity experts who are able to clarify proliferation concerns and the risks of misuse should be involved. In order to provide a true picture, it is important that the right arguments are presented and that misunderstandings and misperceptions are avoided.

In the Fink Report the NSABB defined seven categories of dual-use research that are of concern. They encompass experiments that can: (*a*) enhance the harmful consequences of a biological agent or toxin; (*b*) disrupt the immunity or the effectiveness of an immunization without clinical and/or agricultural justification; (*c*) confer to a biological agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic intervention against that agent or toxin or facilitate their ability to evade detection methodologies; (*d*) increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin; (*e*) alter the host range or tropism of a biological agent or toxin; (*f*) enhance the susceptibility of a host population; or (*g*) generate a novel pathogenic agent or toxin or reconstitute an eradicated or extinct biological agent.[77]

This raises the issue of developing periodic reviews of research during the full cycle of a project—from proposal to dissemination of results, through

[74] Dando M. 'Dual-use education for life scientists?', *Disarmament Forum*, no. 1 (2009), pp. 41–44.

[75] Whitby, S. and Dando, M., 'Effective implementation of the BTWC: the key role of awareness raising and education', Review Conference Paper no. 26, University of Bradford, Nov. 2010, <http://www.brad.ac.uk/acad/sbtwc/briefing/RCP_26.pdf>.

[76] Dando, M. and Rappert, B., 'Codes of conduct for the life sciences: some insights from UK academia', Briefing Paper no. 16 (second series), University of Bradford, May 2005, <http://www.brad.ac.uk/acad/sbtwc/briefing/BP_16_2ndseries.pdf>.

[77] National Academies (note 55).

publication or oral communication—and is especially true of unclassified research. The researcher should be the first to assess his or her proposal for possible dual-use concerns, which implies a certain level of awareness on the part of the researcher and also that institutions and authorities have provided both education and guidelines. Access to an advisory board can be important in this regard. The next logical step, when dealing with experiments of potential concern, is evaluation at the institutional level by an institutional peer review mechanism. If a committee that deals with biosafety issues exists, it can also be tasked with considering the biosecurity aspects of a proposal, thus building on an existing framework in an integrated approach. An institutional mechanism must rely on guidelines. In this context, promoting the development of networks of experts can add value by sharing expertise and best practices. However, the efficiency of such a review mechanism may be impeded by diverging opinions or by the lack of adequate and available expertise that is able to evaluate a proposal or its dual-use dimension. A national authority or advisory board could thus prove useful and be given the tasks of authorizing specific experiments and supplying guidance and recommendations. However, not every country has such an entity. Authorities should also be involved in the review process, for example by developing guidelines, ensuring compliance and acting on notification by an institution or by scientists of a biosecurity breach. An effective mechanism should also include enforcement measures that could be used in the event of violations.

This issue could also be tackled by a compliance review that obliges research teams and institutions to abide by specific rules in order to be eligible for funding. Accreditation of research teams could also be made a prerequisite for the granting of funds.

Additionally, issues related to publishing, such as secrecy versus openness or censorship versus dissemination of results, can be and have already been the subject of controversy and disagreement.[78] Moreover, publishing may be considered crucial for career advancement. Addressing proliferation concerns without hindering research or its publication presents a dilemma.[79] Due to these conflicting aspects, self-regulation by scientists may not be a realistic or adequate approach, and researchers may also lack the expertise to make a proper security assessment.[80] In addition to the assessment made by the researcher, the editors of scientific publications rely on their own review process. However, in order to serve as an effective control mechanism the review process must involve reviewers who possess relevant expertise, including on dual-use issues, which may be difficult for some smaller journals to implement. The existence of an advisory board that can be consulted may be helpful. Guaranteeing that research has been carried out using best practices and with proper attention to ethical and security concerns could become a requirement for publishing in peer-reviewed journals. The challenge is to determine which independent entity should be responsible for granting approval.

Bioethical codes of conducts have also been suggested as a means of control. Brian Rappert has proposed applying a matrix of codes, including codes of ethics (aspirational codes), codes of conduct (educational or advisory codes) and codes of practice (enforceable codes).[81] Some have expressed skepticism about the effective impact of codes of ethics and conduct. Nevertheless, the process of developing such codes directly involves scientists and scientific associations, which contributes to raising awareness and promoting best practices, and thus the development of a culture of responsibility. Administrative and social culture may also influence the effectiveness of such an approach. An EU code of conduct would also be possible.

Identifying the best ways to disseminate information about biosecurity measures and best practices to the intended recipients is crucial. While an EU website dedicated to the purpose would be useful, relying on scientific, professional and industrial associations and organizations would provide an efficient approach. The EU can play a role by engaging the stakeholders and involving them in discussions about biosecurity, as was done through the BTWC's intersessional meetings. Several FP7 projects that deal with biosecurity and biosafety issues have been funded. The results of these

[78] Check, E., 'US officials urge biologists to vet publications for bioterror risk', *Nature*, 16 Jan. 2003, p. 197.

[79] Suk, J., 'Introduction to special issue on biosecurity governance: containing biological weapons, constraining biological research?', *Science and Public Policy,* vol. 35, no. 1 (2008), pp. 2–4.

[80] Selgelid, M. J., 'Governance of dual-use research: an ethical dilemma', *Bulletin of the World Health Organization,* no. 87, (2009), pp. 720–23.

[81] Rappert, B., 'Towards a life sciences code: countering the threats from biological weapons', Briefing Paper no. 13 (2nd series), University of Bradford, Sep. 2004, <http://www.brad.ac.uk/acad/sbtwc/briefing/BP_13_2ndseries.pdf>.

projects should be thoroughly assessed and analysed for their recommendations and to identify possible additional research activities, such as education about the dual use of research. The EU can also make a constructive and effective contribution through its external action policy and instruments and can continue to organize outreach activities and provide assistance to countries that are not EU members, especially via the Instrument for Stability. The CBRN Centres of Excellence will be at the core of EU efforts and following their progress will thus be important.

EU member states can also have a coordinated approach in the framework of the BTWC. The Council may adopt Council Decisions in support of the BTWC (e.g. Council Decision 2011/429/CFSP).[82] Moreover, Commission papers, such as the 2006 Paper on Biosafety and Biosecurity, can also be proposed for the consideration of other state parties.

At the most recent BTWC review conference, the EU proposed the creation of a catalogue of biosafety and biosecurity measures. In a similar approach, at the April 2011 meeting of the preparatory committee of the seventh review conference, the JACKSNNZ (Japan, Australia, Canada, (South) Korea, Switzerland, Norway and New Zealand) group presented a paper co-authored by Australia, Japan and Sweden (non-JACKSNNZ) that dealt with biosecurity education and the promotion of biosafety and biosecurity measures as part of national implementation activities, with the possibility to report experiences through the confidence-building measure mechanism. Two possible approaches to implementing these proposals can be explored: giving additional resources to the ISU to manage a database, or soliciting the support of an NGO or other relevant body.

VIII. CONCLUSIONS

The implementation of laboratory best practices and biosecurity measures provides a means to strengthen the BTWC. Given the complexity of biological threats and of setting up effective biosafety and biosecurity measures, public–private partnerships would provide the best basis for regulation.[83] Prevention relies on a multilayered or network approach that functions at supranational, national and subnational levels. The way in which the BTWC review conference in December 2011 addresses the biosafety and biosecurity issue will be informative.

Currently, accidental exposure and negligence are the main causes for concern, and facilities fail to adequately consider biosecurity issues, including proliferation. Engaging laboratory workers in biosecurity is challenging because of the potential for abuse. Moreover, the most difficult threat is that of the insider. A number of objectives should be pursued to enhance biosafety and, particularly, biosecurity in the framework of the BTWC.

1. Continue to promote capacity building and compliance in terms of biosafety and biosecurity through outreach activities at the regional level, such as organizing workshops or cooperation and exchange programmes. Ensure coordination with other relevant initiatives or instruments. The EU's CBRN Centres of Excellence will play a key role in these efforts.

2. Seek ways to continue to involve non-state actors, especially those in the scientific community, in the BTWC's development by providing them with a forum in which to discuss with security and arms control experts, and by enabling them to share their experiences and best practices related to biosecurity. Additionally, scientific experts can contribute to assessing the consequences of advances in the life sciences in terms of biosecurity, for example by the creation of an advisory panel.

3. Promote the development of a culture of biosecurity among laboratory workers as a long-term objective. Include education about dual-use in the core curriculum at universities, which is unusual at present and remains a major challenge. Developing a biosecurity code of conduct should be encouraged as a means to initiate debate and involve scientific and academic organizations, life scientists and laboratory workers.

[82] Council Decision 2011/429/CFSP of 18 July 2011 relating to the position of the European Union for the Seventh Review Conference 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 (BTWC), <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:188:0042:0046:EN:PDF>.

[83] Sanni Yaya, H., 'Les partenariats privé–public comme nouvelle forme de gouvernance et alternative au dirigisme étatique : ancrages théoriques et influences conceptuelles' [Public–private partnerships as a new form of governance and an alternative to state intervention: theoretical bases and conceptual influences], *La revue de l'innovation*, vol. 10, no. 3 (2005).

4. Assess new biosecurity challenges, such as DIYbio and ongoing initiatives that aim to develop biosecurity, in this context.

5. Promote the development of national and institutional review procedures and compliance mechanisms for the full life cycle of a research project, including dissemination of results. Reviewing existing mechanisms would also be useful. The advisory panel mentioned above could provide guidance regarding the scope of research and potential risks, especially when a national authority does not exist.

6. Collect information about national biosafety and biosecurity measures, for example with the creation of a specific database or by allowing an evolution of compliance-building measures.

APPENDIX A. MAIN RELEVANT ACTIONS FOR BIOSAFETY AND BIOSECURITY IN THE EU CBRN ACTION PLAN

This appendix extracts goals and actions dealing with biosecurity and biosafety for each thematic cluster of the EU CBRN Action Plan.

1. Prevention

Goal 2. Enhance the security of high risk CBRN materials and facilities

Action H.3. The Member States and the Commission should develop criteria on assessing security arrangements at high-risk CBRN facilities. This should be done in the form of a good practice document.

Action B.1. The Commission should assist the Member States in the proper implementation of applicable procedures at "the laboratory bench level" and in developing mechanisms for assessing and monitoring its correct implementation.

Action B.2. The Member States should establish:

- a secure registry of facilities possessing any of the substances on the EU list of high risk biological agents and toxins within each Member State while allowing access to law enforcement;
- a process to verify and if necessary to enhance security arrangements of facilities, including diagnostic laboratories handling and possessing any of the EU list of high risk biological agents and toxins;
- a mechanism within facilities storing biological agents and toxins on the EU biosecurity list to regularly review the need of such biological agents and toxins while keeping a good record of stored materials.

Action B.3. The Commission and the Member States should support:

- a process whereby facilities (clinical, diagnostic, university, etc) would avoid keeping clinical samples containing any of substances on the EU list of high risk biological agents and toxins unnecessarily;
- the identification and development of good practices on handling clinical samples containing any of the substances on the EU list of high risk biological agents and toxins;
- progress in creating collaborative networks of facilities working on substances on the EU list of high risk biological agents and toxins while taking into account existing networks.

Action B.4. The Commission and the Member States should ensure that:

- a comprehensive overview of the relevant standards at hand and their relevance to biosecurity and biosafety is achieved;
- facilities possessing substances on the EU list of high risk biological agents and toxins consider as appropriate the implementation of the CEN Workshop Agreement (CWA 15793), WHO Laboratory Biosecurity Guidance or their national equivalent standards;
- appropriate standards are met as part of a national authorisation or accreditation process or as a condition for issuing licences for work with substances on the EU list of high risk biological agents and toxins. Regular control over the adherence to and implementation of such standards should also be ensured.

Goal 4. Contribute to the development of a high security culture of staff

Action H.4. The Member States and the Commission should identify, develop and spread good practices in security training and education of persons working with/having access to or handling high-risk CBRN materials. Consideration should also be given to developing EU guidelines for minimum security training requirements for persons working with,

having access to, or handling such materials, based on the national experience across the EU 27. This could be done by way of a peer review process through which experts from the Member States would visit each other with a view to learning from their experience and exchanging best practices in specific fields.

Action H.5. The Member States should develop and implement specific training programmes for private security staff (in particular those involved in guarding specific high risk CBRN materials).

Action B.5. The Commission and the Member States shall encourage professional and other relevant associations working on bio-issues to develop and adopt codes of conduct for their Members.

Action B.6. The Member States and the Commission should define requirements for biosafety officers (roles, competences and training).

Goal 6. Enhance the security of the transport

Action H.8. The Commission should organize workshops on transport security with regard to CBRN materials. These workshops should bring together experts from the transport sector, the security services and law enforcement authorities. The workshops should address the following issues:

- assess whether existing transport security rules fully cover all CBRN materials;
- identify and exchange good practices in the Member States concerning the transport of CBRN materials (e.g. limited quantities in one transport; or tracking systems);
- identify and exchange current good practices in terms of tracking CBRN materials;
- requirements for the development of tracking and tracing systems for the transport of CBRN materials;
- identify and exchange good practices concerning the implementation of current ADR (and RID and ADN) and IMDG Code (class 7-radioactive materials) requirements such as the development of security plans.
- identify security requirements for logistics enterprises;
- consider establishing a notification system for the international transport of high risk CBRN materials;
- consider the feasibility and costs/benefits of introducing a requirement that only licensed transporters would be used for the transport of high risk CBRN materials. These licensed transporters would be obliged to follow agreed minimum security requirements;
- assess the possible negative impact of strict requirements for transport on transporters of high risk substances and examine potential remedies.

This work should feed into existing processes such as the UNECE Ad-Hoc Working Group.

Action H.9. The Member States and the Commission should ensure that links between law enforcement authorities and transporters of CBRN materials are enhanced.

Action H.10. The Member States should ensure that the training of transport staff concerning existing legislative requirements on the security of CBRN materials is improved where appropriate. Regular exercises on transport security should be organized.

Action B.7. The Commission and the Member States should initiate the creation of an EU capability and mechanism to rapidly and safely transport biological samples, in accordance with international regulations, within the EU and into the EU.

Goal 7. Improve information exchange

Action H.11. The Member States should analyse whether potential problem areas exist in the horizontal and vertical flow of information among the entities dealing with high-risk CBRN materials both within and across the individual Member States. Each Member State should assess whether relevant need-to-know information about changing threat levels reaches license holders.

Action H.12. The Member States should ensure that each party within the supply chain informs without delay the relevant national authority in the event of any theft or loss of any high-risk CBRN materials. The relevant national authorities should inform without delay the relevant law enforcement authority responsible for gathering and responding to this information where this has not already been done by the party concerned within the supply chain.

Action H.13. The Member States should ensure a high level of information exchange between relevant actors by having a clearly established notification mechanism which would allow anyone to inform the relevant authorities about a loss/theft of high-risk CBRN materials or about a suspicious transaction. As a minimum requirement, facility security managers should have the necessary contact information for relevant local law enforcement authorities.

4. Actions applicable to CBRN prevention, detection and response

Goal 3. develop improved information tools for CBRN security

Action H.46. The Commission should establish a forum in which good-practices on security could be shared. The use of existing systems should be explored in this regard.

Action H.47. The Commission should establish a library of resources which could be used by the relevant authorities (in particular the law enforcement community and public health authorities). The library would contain applicable information on the nature of CBRN agents and their handling. This library could include national contributions from the Member States. In light of the potentially sensitive content of such a reference library, the need for classification and thus restricted access will be considered.

Action H.48. The Member States and the Commission should establish a law enforcement Early Warning System (EWS) for incidents related to high risk CBRN materials, taking account of existing systems and experiences. Such a mechanism would include information on immediate threats, losses/thefts, and suspicious transactions and would in any case need to be accessible to the law enforcement authorities and relevant emergency responders of the Member States and to Europol. As a first step, the extension of the existing G6 system should be considered. The system should be without prejudice to the exchange of information on public health issues.

Goal 4. Improving training

Action B.18. Member States and the Commission should identify and spread:

- good practices on well targeted training for and education of individuals working with, having access to or handling substances on the EU list of high-risk biological agents and toxins;
- good practices on academic training on biosafety, potential misuse of information and biological agents and toxins, and bio-ethics for undergraduate, graduate and postgraduate students;
- good laboratory practices.

Action B.19. The Member States and the Commission should consider and develop:

- guidelines at the EU level for minimum training requirements for persons working with, having access to, substances on the EU list of high-risk biological agents and toxins;
- in conjunction with universities and professional associations, minimal requirements for academic training on biosafety, potential misuse of information and biological agents and toxins and bio-ethics for undergraduate, graduate and postgraduate students.

Goal 5. Strengthening personnel security

Action H.51. The Member States and the Commission should analyze the need to establish a system of mutual recognition of security vetting processes for certain categories of personnel.

Action H.52. The Member States and the Commission should develop and introduce common graduated criteria for background checks and vetting requirements in relation to personnel having access to materials on the EU list of high-risk CBRN materials along the whole chain of production, storage, distribution and use. These common criteria should be based on a graduated approach. In the course of the recruitment process, the recruiting organisation should ensure that the credentials of the candidates are properly checked and assessed. The Commission should launch a study concerning existing background check procedures and requirements within the CBRN industry.

Action H. 53. The Member States and the Commission should identify and exchange good practices on approaches to security of non-EU visiting staff and students; Member States should aim at common procedures across the EU.

Action B.20. The Member States should ensure that each Member State and/or organization has a secure registry of personnel having access to or information on substances on the EU list of high risk biological agents and toxins (along the whole chain of production, storage, distribution and use). Law enforcement should have access to such a registry.

Action B.21. The Member States and the Commission should identify and exchange good practices on robust management structures at commercial, industrial and research facilities possessing substances on the EU list of high risk biological agents and toxins ensuring regular appraisal of the staff and its monitoring.

Source: European Commission, 'Communication from the Commission to the European Parliament and the Council of 24 June 2009 on strengthening chemical, biological, radiological and nuclear security in the European Union—an EU CBRN Action Plan', COM(2009) 273 final, 24 June 2009.

ABBREVIATIONS

BCH	Biosafety Clearing-House
BSL	Biosafety-level
BTWC	Biological and Toxins Weapons Convention
CBRN	Chemical, biological, radiological and nuclear
CDC	Centers for Disease Control and Prevention
CEN	The European Committee for Standardization
EU	European Union
FBI	Federal Bureau of Investigation
FP7	Seventh framework programme
GMO	Genetically modified microorganism
IAP	Interacademy Panel
IHR	International Health Regulation
JACKSNNZ	Japan, Australia, Canada, (South) Korea, Switzerland, Norway and New Zealand
NGO	Non-governmental organization
NSABB	National Science Advisory Board for Biosecurity
OECD	Organisation for Economic Co-operation and Development
UNECE	United Nations Economic Commission for Europe
WHO	World Health Organization

EU Non-Proliferation Consortium

The European network of independent non-proliferation think tanks

A EUROPEAN NETWORK

In July 2010 the Council of the European Union decided to create a network bringing together foreign policy institutions and research centres from across the EU to encourage political and security-related dialogue and the long-term discussion of measures to combat the proliferation of weapons of mass destruction (WMD) and their delivery systems.

STRUCTURE

The EU Non-Proliferation Consortium is managed jointly by four institutes entrusted with the project, in close cooperation with the representative of the High Representative of the Union for Foreign Affairs and Security Policy. The four institutes are the Fondation pour la recherche stratégique (FRS) in Paris, the Peace Research Institute in Frankfurt (PRIF), the International Institute for Strategic Studies (IISS) in London, and Stockholm International Peace Research Institute (SIPRI). The Consortium began its work in January 2011 and forms the core of a wider network of European non-proliferation think tanks and research centres which will be closely associated with the activities of the Consortium.

MISSION

The main aim of the network of independent non-proliferation think tanks is to encourage discussion of measures to combat the proliferation of weapons of mass destruction and their delivery systems within civil society, particularly among experts, researchers and academics. The scope of activities shall also cover issues related to conventional weapons. The fruits of the network discussions can be submitted in the form of reports and recommendations to the responsible officials within the European Union.

It is expected that this network will support EU action to counter proliferation. To that end, the network can also establish cooperation with specialized institutions and research centres in third countries, in particular in those with which the EU is conducting specific non-proliferation dialogues.

http://www.nonproliferation.eu

FONDATION pour la RECHERCHE STRATÉGIQUE

FOUNDATION FOR STRATEGIC RESEARCH

FRS is an independent research centre and the leading French think tank on defence and security issues. Its team of experts in a variety of fields contributes to the strategic debate in France and abroad, and provides unique expertise across the board of defence and security studies.
http://www.frstrategie.org

PRIF Peace Research Institute Frankfurt — HSFK Hessische Stiftung Friedens- und Konfliktforschung

PEACE RESEARCH INSTITUTE IN FRANKFURT

PRIF is the largest as well as the oldest peace research institute in Germany. PRIF's work is directed towards carrying out research on peace and conflict, with a special emphasis on issues of arms control, non-proliferation and disarmament.
http://www.hsfk.de

IISS

INTERNATIONAL INSTITUTE FOR STRATEGIC STUDIES

IISS is an independent centre for research, information and debate on the problems of conflict, however caused, that have, or potentially have, an important military content. It aims to provide the best possible analysis on strategic trends and to facilitate contacts.
http://www.iiss.org/

sipri

STOCKHOLM INTERNATIONAL PEACE RESEARCH INSTITUTE

SIPRI is an independent international institute dedicated to research into conflict, armaments, arms control and disarmament. Established in 1966, SIPRI provides data, analysis and recommendations, based on open sources, to policymakers, researchers, media and the interested public.
http://www.sipri.org/