

Strengthening the Biological and Toxin Weapons Convention: The Vital Importance of a Web of Prevention for Effective Biosafety and Biosecurity in the 21st Century

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1. Introduction

A 1997 article titled ‘The Complementary Role of Environmental and Security Biological Control Regimes in the 21st Century’ that appeared in the *Journal of the American Medical Association (JAMA)* argued that:

As we approach the 21st century, there is increased worldwide concern about disease, whether natural or deliberate, in humans, animals, and plants. There are 2 driving forces for multilateral biological control regimes: international/national security and environmental protection. With respect to deliberately caused disease, these seemingly disparate forces are mutually reinforcing as demonstrated by simultaneous moves to strengthen the Biological and Toxin Weapons Convention and the entry into force of the Convention on Biological Diversity. Future multilateral biological control regimes based on these developments will aid the security, prosperity, and health of the world community.¹

More than two decades later, it is evident that there remains a need to foster a web of policies, approaches, and measures that strengthen biological security: the successful minimising of the risks that the biological sciences may be accidentally or deliberately misused in a way which causes harm for humans, animals, plants or the environment.² The web of prevention, we argue, continues to be of vital importance in enhancing the health, prosperity, and security of the world community.

This article reviews the conclusions of the 1997 *JAMA* paper in the light of the dynamic international security context, on the one hand, and the rapidly evolving life science landscape, on the other, in order to develop a conceptual framework for promoting the

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¹ Graham S. Pearson, ‘The complementary role of environmental and security biological control regimes in the 21st century’, *Journal of the American Medical Association* 278:5, 1997, pp. 369-372.

² Simon Whitby et al. eds. *Preventing biological threats: what you can do*. (Bradford: University of Bradford, 2015), available at

[https://www.unog.ch/80256EE600585943/\(httpPages\)/0A20E57D9F8424B8C12581D8007EC32E?OpenDocument](https://www.unog.ch/80256EE600585943/(httpPages)/0A20E57D9F8424B8C12581D8007EC32E?OpenDocument) (accessed 24 October 2019).

implementation of biosafety and biosecurity policies, standards, regulations, and guidelines. The terms ‘biosafety’ and ‘biosecurity’ are used to denote the purpose of the different international instruments: biosafety instruments are those that seek to prevent the unintentional (accidental) release of pathogens and toxins, including naturally occurring disease, whereas biosecurity instruments are those that seek to prevent the deliberate release and misuse of pathogens and toxins. Section 2 of the paper examines the evolution of the spectrum of biological risks over the past two decades to account for the growing recognition of the complementarity of biosafety and biosecurity for effective biological risk management. The concept of a ‘web of prevention’ is introduced in Section 3 to develop a systematic classification of biosafety and biosecurity instruments by purpose. The article concludes in Section 4 by recommending steps to be taken for strengthening the web of prevention and upholding and strengthening the norms against accidental and deliberate disease.

2. The Spectrum of Biological Risks in the Twentieth-First Century

Disease outbreaks are classified as naturally occurring, accidental, and deliberate. Traditionally, each type of disease has been addressed by a different set of measures: public health measures are used to prevent naturally occurring disease; biosafety measures are used to prevent disease as a result of industrial and laboratory accidents and/or negligence; and biosecurity, including disarmament measures are used to prevent deliberate disease. Yet disease recognises no borders and the globalised systems of international travel, trade, and communication can turn a local event into a global crisis, as the 2004 SARS and 2014-2015 Ebola outbreaks have demonstrated. Antimicrobial resistance coupled with the impact of climate change on disease patterns and the re-emergence of vaccine-preventable diseases are symptomatic of the challenges that global public health faces.³ The progress of biotechnology over the past few decades promises to make a significant contribution to addressing some of these issues, for example, through the generation of novel drugs and therapeutics. At the same time, there are concerns that the global diffusion of cutting-edge life science capabilities, such as genome-editing and synthetic biology, both in and outside traditional research environments (e.g. emergence of community laboratories and ‘do-it-yourself’ biology movement) increases the risk of accidental and deliberate misuse of life science knowledge and materials against humans, animals, or plants. Against this backdrop, the need for reconciling the benefits that are likely to be accrued from the continuous advancement of the life sciences with the potential risks arising from the availability, accessibility, and

³ See, for example, Interagency Coordination Group on Antimicrobial Resistance, *No time to wait: securing the future from drug-resistant infections*, Report to the Secretary General of the United Nations, April 2019, <https://www.who.int/antimicrobial-resistance/interagency-coordination-group/final-report/en/> (accessed 24 October 2019); Derek MacFadden et al. ‘Antibiotic resistance increases with local temperature’, *Nature Climate Change*, 8: 21 May 2018, pp. 510-514, <https://www.nature.com/articles/s41558-018-0161-6> (accessed 24 October 2019); Anthony McMichael, et al. eds. *Climate Change and Human Health – Risks and Responses* (Geneva: World Health Organisation, 2003), <https://www.who.int/globalchange/summary/en/index4.html> (accessed 24 October 2019).

affordability of the knowledge, tools, and technologies necessary for conducting scientific work requires special attention.⁴

According to the report *Human Security Now* published by the Commission on Human Security in 2003, ‘good health is both essential and instrumental to achieving human security’.⁵ Around the same time, the World Organisation for Animal Health (OIE) coined the concept of ‘One Health’ which holds that ‘human health and animal health are interdependent and bound to the health of the [natural] ecosystems in which they exist’.⁶ More recently, this understanding of the human-animal-ecosystems interface has been incorporated in the UN 2030 Agenda for Sustainable Development that features 17 Sustainable Development Goals (SDGs), including:

- Goal 3: Ensure healthy lives and promote well-being for all at all ages;
- Goal 14: Conserve and sustainably use the oceans, seas and marine resources;
- Goal 15: Sustainably manage forests, combat desertification, halt and reverse land degradation, and halt biodiversity loss.⁷

Life science research and development (R&D) has an important role to play in achieving the SDGs by providing ‘breakthrough products and technologies to combat debilitating and rare diseases, stop the outbreak of infectious diseases, reduce our environmental footprint, relieve poverty, feed the hungry, use less and cleaner energy, provide clean drinking water, protect biological diversity on land and in our oceans, and have safer, cleaner and more efficient industrial manufacturing processes’.⁸ Hence, harnessing the potential of biotechnology for promoting economic growth through sustainable and socially responsible production and innovation has attracted considerable state and business investment.

Yet as life science knowledge and capabilities diffuse and multiply, so does the potential for an accidental or deliberate release of biological agents. Writing at the turn of the 21st century, Mathew Meselson noted that:

Every major technology – metallurgy, explosives, internal combustion, aviation, electronics, nuclear energy – has been intensively exploited, not only for peaceful

⁴ Terence Taylor, ‘Safeguarding advances in the life sciences’, *EMBO Reports*, 7:2006, pp. S61-S64.

⁵ Commission on Human Security, *Human security now* (New York: United Nations, 2003), <https://reliefweb.int/report/world/human-security-now-protecting-and-empowering-people> (accessed 24 October 2019).

⁶ World Organisation for Animal Health (OIE). *One Health “at a glance”*, 2019, <http://www.oie.int/en/for-the-media/onehealth/> (accessed 24 October 2019).

⁷ United Nations General Assembly, Resolution 70/1 *Transforming our world: the 2030 Agenda for Sustainable Development*, A/RES/70/1, 25 September 2015, United Nations, New York, https://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E (accessed 24 October 2019).

⁸ Hilary Stiss, ‘Biotechnology: a critical tool in achieving the UN Sustainable Development Goals’, *Biotech Now*, 27 March 2019, <https://www.biotech-now.org/international/2019/03/biotechnology-a-critical-tool-in-achieving-the-un-sustainable-development-goals> (accessed 24 October 2019).

*purposes but also for hostile ones. Must this also happen with biotechnology, certain to be a dominant technology of the twenty-first century?*⁹

In 2019, the US National Academies of Sciences, Engineering, and Medicine (NAEM) published a report that echoed some of Meselson's concerns:

*Synthetic biology expands what is possible in creating new weapons. It also expands the range of actors who could undertake such efforts and decreases the time required.*¹⁰

The report further observed that,

*[...] synthetic biology approaches also have the potential to be used in ways that could change the presentation of an attack, for example, by modifying the properties of existing microorganisms, using microorganisms to produce chemicals, or employing novel or unexpected strategies to cause harm. It is valuable for the U.S. government to pay close attention to rapidly advancing fields such as synthetic biology, just as it did to advances in chemistry and physics during the Cold War era. However, approaches modelled after those taken to counter Cold War threats are not sufficient to address biological and biologically enabled chemical weapons in the age of synthetic biology.*¹¹

The advent of enabling life science advances coupled with the emergence of illicit online markets (e.g. Darknet) and an open-access pool of scientific knowledge constitute a critical governance (and security) challenge that can hardly be addressed through a traditional disarmament approach alone. This trend has been recognised and acknowledged by the States Parties to the Biological and Toxin Weapons Convention (BTWC), the principal international agreement that prohibits the development, stockpiling, acquisition, and retention of biological weapons. The Fifth Review Conference of the BTWC held in 2002 agreed an Inter-Sessional Programme of Work to discuss and promote common understanding and effective action on the following topics:

- i. the adoption of necessary national measures to implement the prohibitions set forth in the Convention, including the enactment of penal legislation;*
- ii. national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;*
- iii. enhancing international capabilities for responding to, investigating and mitigating the effects of cases of alleged use of biological or toxin weapons or suspicious outbreaks of disease;*

⁹ Matthew Meselson, 'Averting the hostile exploitation of biotechnology', *The CBW Conventions Bulletin* 48, 2000, pp. 16-19, <http://www.sussex.ac.uk/Units/spru/hsp/documents/cbwcb48.pdf> (accessed 4 April 2018).

¹⁰ US National Academies of Sciences, Engineering, and Medicine, *Biodefense in the Age of Synthetic Biology* (Washington DC: National Academies Press, 2018), <https://www.nap.edu/catalog/24890/biodefense-in-the-age-of-synthetic-biology> (accessed 24 October 2019).

¹¹ US National Academies of Sciences, Engineering, and Medicine, *Biodefense in the Age of Synthetic Biology*.

- iv. *strengthening and broadening national and international institutional efforts and existing mechanisms for the surveillance, detection, diagnosis and combating of infectious diseases affecting humans, animals, and plants;*
- v. *the content, promulgation, and adoption of codes of conduct for scientists.*¹²

At the same time, the need for an integrated approach to countering natural, accidental, and deliberate disease has been underscored in the 2004 edition of the World Health Organisation guidance document titled *Public Health Response to Biological and Chemical Weapons* which recommended that ‘considerations for [countering] deliberate releases of biological or chemical agents should be incorporated into existing public health infrastructures, rather than developing separate infrastructures’.¹³

3. A Web of Prevention for Biosafety and Biosecurity

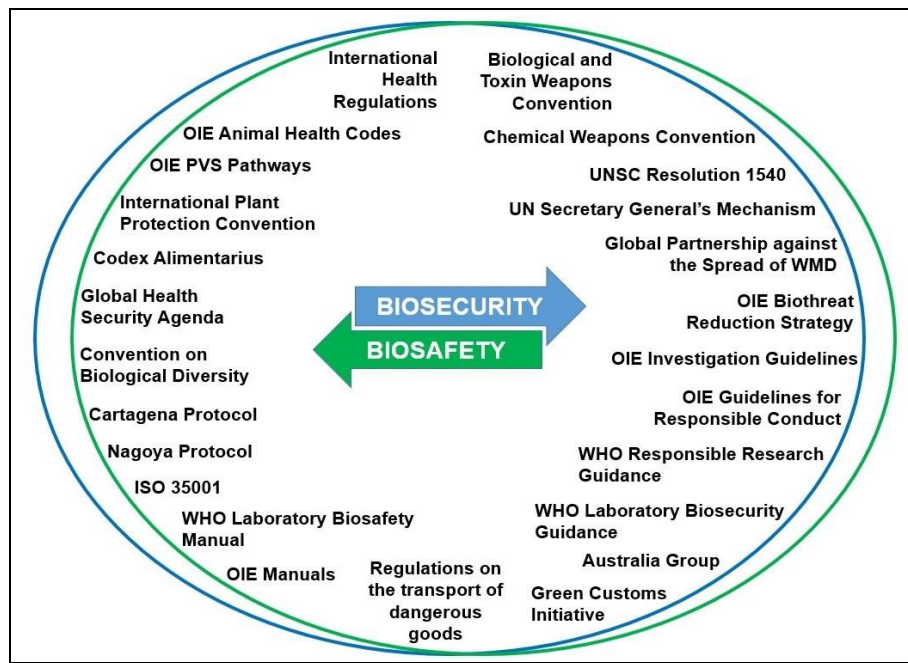
This section outlines a conceptual framework for the implementation of biosafety and biosecurity international regulations, policies, and guidelines for promoting a comprehensive and integrated approach to the management of biological risks in the twenty-first century. The framework is centred on the concept of a ‘web of prevention’ which originated in the early 1990s as the ‘web of deterrence’.¹⁴ The web of prevention refers to the different strands / lines of action that are required for effective biological risk management, regardless of whether biological risks occur naturally, or are accidentally or deliberately caused. The model proposed here groups the different strands of the web in two overarching categories: international biosafety instruments and international biosecurity instruments. The instruments are grouped based on their primary purpose, that is whether they aim to prevent the unintentional (accidental) release of biological agents and toxins, including naturally occurring diseases (biosafety), or whether they aim to prevent the deliberate release of biological agents and toxins (biosecurity). The model of a web of prevention is presented in Figure 1.

¹² Biological and Toxin Weapons Convention. Fifth 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.V/17, Geneva, Switzerland, 2000, [https://www.unog.ch/80256EE600585943/\(httpPages\)/2796BFD7ADDD08C9C125772800331B63?OpenDocument](https://www.unog.ch/80256EE600585943/(httpPages)/2796BFD7ADDD08C9C125772800331B63?OpenDocument) (accessed 24 October 2019).

¹³ World Health Organization, *Public health response to biological and chemical weapons* (Geneva: World Health Organization, 2004), <https://www.who.int/csr/delibepidemics/biochemguide/en/> (accessed 24 October 2019).

¹⁴ Graham S. Pearson, ‘Prospects for chemical and biological arms control: the web of deterrence’, *The Washington Quarterly* 16:2, 1993, pp. 145-162; Graham S. Pearson, ‘The idea of a web of prevention’, in Simon Whitby, eds. *Preventing biological threats: what you can do* (Bradford: University of Bradford, 2015), [https://www.unog.ch/80256EE600585943/\(httpPages\)/0A20E57D9F8424B8C12581D8007EC32E?OpenDocument](https://www.unog.ch/80256EE600585943/(httpPages)/0A20E57D9F8424B8C12581D8007EC32E?OpenDocument) (accessed 24 October 2019); Brian Rappert and Catriona McLeish eds. *A web of prevention: biological weapons, life sciences, and the governance of research* (London: Earthscan, 2007).

Figure 1: The Web of Prevention for Biosafety and Biosecurity



3.1 International Biosafety Instruments

Depending on their thematic focus, international biosafety instruments cover three areas: health and food security; biodiversity preservation; and safe handling, including shipment, transport, and transfer of biological agents and toxins.

Health and Food Security

The provision of accessible good-quality healthcare is an essential condition for the socio-economic and political stability of States. Maintaining a functioning and resilient healthcare system also enhances States' capacity for response to disease outbreaks and helps mitigate negative impacts, including the loss of lives. The International Health Regulations (IHRs) that were adopted in 2005 by the World Health Organization (WHO) and are binding on all States seek to 'prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade'.¹⁵ Under the IHRs, States are obliged to 'develop, strengthen and maintain [...] the capacity to detect, assess, notify, and report' biological events, as well as to 'develop, strengthen, and maintain [...] the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern'.

As observed in Section 2, public health is dependent on the health of natural ecosystems. It also requires safe and reliable food supply which in turn highlights the importance of

¹⁵ World Health Organization, *International Health Regulations* (Geneva: World Health Organization, 2005), <https://www.who.int/ihr/about/en/> (accessed 24 October 2019).

sustainable agriculture based on ecologically-friendly farming and stock-breeding practices. The World Organisation for Animal Health (OIE) *Terrestrial Animal Health Code* sets out the standards for the improvement of animal health and welfare and veterinary public health worldwide, including the safe international trade in terrestrial animals and their products.¹⁶ Likewise, the *OIE Aquatic Animal Health Code* sets out the standards for the improvement of aquatic animal health and welfare of farmed fish worldwide, and for safe international trade in aquatic animals.¹⁷ Both *Codes* provide information on the OIE-listed notifiable terrestrial and aquatic animal diseases that are being monitored in real-time through the World Animal Health Information System (WAHIS).¹⁸ WAHIS also serves as an early-warning system for epidemiological events that occur on the territory of OIE Member States. Besides WAHIS, the OIE administers the Performance of Veterinary Services (PVS) Pathway, a capacity building platform that provides national veterinary services with a comprehensive understanding of their strengths and weaknesses using a globally consistent methodology based on international standards.¹⁹

The International Plant Protection Convention (IPPC) adopted in 1951 and administered by the Food and Agriculture Organization of the United Nations (FAO) aims to secure coordinated, effective action to prevent and control the introduction and spread of pests of plants and plant products.²⁰ The Convention is recognised by the World Trade Organization's (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) as the only international standard setting body for plant health. While the IPPC's primary focus is on plants and plant products moving in international trade, the Convention also covers research materials, biological control organisms, germplasm banks, containment facilities, food aid, emergency aid and anything else that can act as a vector for the spread of plant pests – for example, containers, packaging materials, soil, vehicles, vessels and machinery.²¹

FAO also administers the internationally adopted food standards set in *Codex Alimentarius*.²² In 2010, FAO established an Emergency Prevention System for Food Safety (EMPRES Food Safety) to serve as a key international system to assist in the prevention and management of

¹⁶ World Organisation for Animal Health (OIE), *Terrestrial Animal Health Code* (Paris: World Animal Health Organisation, 2019), <https://www.oie.int/en/standard-setting/terrestrial-code/access-online/> (accessed 24 October 2019).

¹⁷ World Organisation for Animal Health (OIE), *Aquatic Animal Health Code* (Paris: World Animal Health Organisation, 2019), <https://www.oie.int/en/standard-setting/aquatic-code/access-online/> (accessed 24 October 2019).

¹⁸ World Organisation for Animal Health (OIE), *World Animal Health Information System*, 2019, <https://www.oie.int/animal-health-in-the-world/the-world-animal-health-information-system/the-world-animal-health-information-system/> (accessed 24 October 2019).

¹⁹ World Organisation for Animal Health (OIE), *Performance of Veterinary Services (PVS) Pathway*, 2019, <https://www.oie.int/solidarity/pvs-pathway/> (accessed 24 October 2019).

²⁰ United Nations Food and Agricultural Organization (FAO), International Plant Protection Convention (1951), 2019, <https://www.ippc.int/en/structure/> (accessed 24 October 2019).

²¹ United Nations Food and Agricultural Organization (FAO), International Plant Protection Convention (1951), 2019, <https://www.ippc.int/en/structure/> (accessed 24 October 2019).

²² United Nations Food and Agricultural Organization (FAO), *Codex Alimentarius* (1963), 2019, <http://www.fao.org/fao-who-codexalimentarius/about-codex/en/> (accessed 24 October 2019).

global food safety emergencies.²³ The EMPRES system allows authorities to better appreciate and understand major food safety risks and to refocus prevention efforts. It also allows early detection of adverse food safety events and prompt and effective response. FAO collaborates with WHO and OIE in a number of activities aimed at prevention and management of food safety emergencies.

To advance the development of an integrated approach to health security, the Global Health Security Agenda (GHSa), a global collaborative, multi-sectoral and multi-stakeholder initiative was launched in 2014. GHSa is a political driver that leverages and complements the strengths and resources of global partners to build and improve country capacity and leadership in the prevention and early detection of, and effective response to, infectious disease threats.²⁴ GHSa is structured around 11 Action Packages in the areas of prevention, detection, and response to biological risks. It is worth noting that two of the GHSa Action Packages that are currently being implemented (Prevent 3, Biosafety and Biosecurity and Respond 2, Linking Public Health with Law and Multisectoral Rapid Response) address biosecurity issues, as well.²⁵

Biodiversity Preservation

Biodiversity plays a critical role in ensuring the health of natural ecosystems. Its preservation is therefore indispensable to the implementation of a ‘one health’ approach for realising health security. The Convention on Biological Diversity which entered into force in 1993 seeks to ensure (1) the conservation of biological diversity; (2) the sustainable use of the components of biological diversity; and (3) the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.²⁶ To this end, the Convention contains provisions for the identification and monitoring of biological species that may require urgent conservation (Art. 7), promotion of awareness of the measures required for the conservation of biological diversity, including through formal education (Art. 13), and development of appropriate procedures and arrangements for environmental impact assessment for any projects that are likely to have significant adverse effects on biological diversity (Art. 14). The Convention further acknowledges the adverse effects that living modified organisms (LMOs) may have on the conservation and sustainable use of biological diversity, as well as the need for an additional protocol setting out appropriate procedures for the safe handling, transport, and use of LMOs (Art. 19).

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity which entered into force in 2003 aims to ensure the safe handling, transport, and use of living

²³ United Nations Food and Agricultural Organization (FAO), *Emergency Prevention System for Food Safety (EMPRES Food Safety)*, 2019, <http://www.fao.org/food/food-safety-quality/empres-food-safety/en/> (accessed 24 October 2019).

²⁴ Global Health Security Agenda, 2019, <https://www.ghsagenda.org/> (accessed 24 October 2019).

²⁵ Global Health Security Agenda, *Action Packages*, 2019, <https://www.ghsagenda.org/packages> (accessed 24 October 2019).

²⁶ Convention on Biological Diversity (1993), 2019, <https://www.cbd.int/intro/default.shtml> (accessed 24 October 2019).

modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health (Cartagena Protocol 2003).²⁷ The Protocol establishes an advance informed agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory (Art. 7). It also contains provisions for risk assessment (Art. 15) and risk management (Art. 16), as well as for emergency measures in case of an unintentional transboundary movement of a living modified organism (Art. 17). In order to assist States with the implementation of the Cartagena Protocol, a technical document titled *Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the Context of Risk Assessment* was published in 2016²⁸ and a *Training Manual on the Detection and Identification of Living Modified Organisms in the Context of the Cartagena Protocol on Biosafety* is currently being developed.²⁹ The Protocol also establishes a Biosafety Clearing-House to facilitate the exchange of information on living modified organisms and to assist countries in the implementation of the Protocol. The Biosafety Clearing-House gives global access to a variety of relevant scientific, technical, environmental, legal and capacity building information.³⁰

To strengthen the provisions of the Cartagena Protocol on Biosafety with regard to LMOs, a supplementary protocol, the *Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress* which introduces international rules and procedures in the field of liability and redress relating to living modified organisms has been adopted.³¹ The Supplementary Protocol entered into force in 2018.

Article 25 of the Convention on Biological Diversity establishes an open-ended intergovernmental scientific advisory body known as the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) to provide the Conference of the Parties (COP) with timely advice relating to the implementation of the Convention.³² In 2014, the Conference of the Parties, noting the conclusions of the SBSTTA with regard to the issue of synthetic biology, decided to establish an Ad Hoc Technical Expert Group on Synthetic

²⁷ Cartagena Protocol on Biosafety to the Convention on Biological Diversity (2003), 2019, <http://bch.cbd.int/protocol> (accessed 24 October 2019).

²⁸ Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety, *Guidance on risk assessment of living modified organisms and monitoring in the context of risk assessment*, UNEP/CBD/BS/COP-MOP/8/8/Add.1, 14 September 2016, http://bch.cbd.int/protocol/cpb_technicalseries.shtml#bst4 (accessed 24 October 2019).

²⁹ Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety, *Draft training manual on detection and identification of living modified organisms*, CBD/CP/MOP/9/8/Add.1, 13 September 2018, <https://www.cbd.int/doc/c/53d0/e838/574441c6ca03e5e68340abdd/cp-mop-09-08-add1-en.pdf> (accessed 24 October 2019).

³⁰ Convention on Biological Diversity, *Biosafety clearing-house*, 2019, <https://bch.cbd.int/> (accessed 24 October 2019).

³¹ Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (2018), 2019, <http://bch.cbd.int/protocol/supplementary/> (accessed 24 October 2019).

³² Convention on Biological Diversity, Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), 2019, <https://www.cbd.int/sbstta/> (accessed 24 October 2019).

Biology.³³ The mandate of this Ad Hoc Technical Expert Group includes among other things the following objectives:

- *Identify if other national, regional and/or international instruments adequately regulate the organisms, components or products derived from synthetic biology techniques in so far as they impact on the objectives of the Convention and its Protocols;*
- *Identify the potential benefits and risks of organisms, components and products arising from synthetic biology techniques to the conservation and sustainable use of biodiversity and related human health and socioeconomic impacts relevant to the mandate of the Convention and its Protocols; Building on the work on risk assessment and risk management undertaken by the Cartagena Protocol, compile information on best practices on risk assessment and monitoring regimes currently used by Parties to the Convention and other Governments, including transboundary movement, to inform those who do not have national risk assessment or monitoring regimes, or are in the process of reviewing their current risk assessment or monitoring regimes and to help those Parties and other Governments to regulate organisms, components and products from synthetic biology techniques appropriately;*
- *Identify if the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology relevant to the objectives of the Convention on Biological Diversity and its Protocols, in particular threats of significant reduction or loss of biological diversity.*

Among the substantive issues that were considered by the Ad Hoc Technical Expert Group on Synthetic Biology during its meeting in June 2019 were:

- *New technological developments in synthetic biology;*
- *Synthetic biology applications that are in early stages of research and development, vis-à-vis the three objectives of the Convention;*
- *Synthetic biology organisms that may fall outside the definition of living modified organisms as per the Cartagena Protocol;*
- *The state of knowledge on the potential environmental impacts of applications of synthetic biology, including those applications that involve organisms containing engineered gene drives;*
- *Options for regular horizon scanning, monitoring and assessing of developments.*³⁴

³³ Conference of the Parties to the Convention on Biological Diversity, Decision XII/24: *New and emerging issues: synthetic biology*, UNEP/CBD/COP/DEC/XII/24, 17 October 2014, <https://www.cbd.int/doc/decisions/cop-12/cop-12-dec-24-en.pdf> (accessed 24 October 2019).

³⁴ Convention on Biological Diversity, *Report of the Ad-Hoc Expert Group on Synthetic Biology*, CBD/SYNBIO/AHTEG/2019/1/3, 7 June 2019, <https://www.cbd.int/doc/c/b2bb/cf58/b09729bb00be6abf72325a1a/synbio-ahteg-2019-01-03-en.pdf> (accessed 24 October 2019).

During its Twenty-Second Meeting held in July 2018, the SBSTTA recommended the establishment of an Ad Hoc Technical Expert Group on Risk Assessment for the identification and prioritization of specific issues regarding risk assessment of living modified organisms.³⁵ This recommendation was adopted by the Conference of the Parties to the CBD serving as the Meeting of the Parties to the Cartagena Protocol (COP-MOP) on Biosafety in November 2018.³⁶ The Ad Hoc Technical Expert Group on Risk Assessment is expected also to complement the work of the Ad Hoc Technical Expert Group on Synthetic Biology.

In addition to the Cartagena Protocol on Biosafety, in 2010 the Parties to the CBD adopted the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity* (CBD 2019d).³⁷ The Nagoya Protocol which entered into force in 2014 provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

Safe Handling of Biological Materials

Safe and responsible procedures and practices for handling, shipping, transfer, and transport of biological agents and toxins are required for preventing laboratory acquired infections and ensuring that such materials are not accidentally released in the environment. The International Organisation for Standardisation (ISO) is currently developing an ISO Management System Standard titled ISO 35001 on Biorisk Management for Laboratories and other Related Organisations.³⁸ ISO 35001 is intended as a performance-based standard which can be used for improving the overall biorisk performance of laboratories and research facilities.³⁹ It is expected to be published in late 2019.

The 2004 *Laboratory Biosafety Manual (3rd Edition)* of the World Health Organisation builds upon the two earlier versions of the document (1983 and 1993) in seeking to ‘encourage countries to accept and implement basic concepts in biological safety and to develop national

³⁵ Convention on Biological Diversity, Subsidiary Body on Scientific, Technical, and Technological Advice, Recommendation 22/2: *Risk assessment and risk management of living modified organisms*, CBD/SBSTTA/REC/22/2, 7 July 2018, <https://www.cbd.int/doc/recommendations/sbstta-22/sbstta-22-rec-02-en.pdf> (accessed 24 October 2019).

³⁶ Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety, Decision 9/13: *Risk assessment and risk management (Articles 15 and 16)*, CBD/CP/MOP/DEC/9/13, 30 November 2018, <https://www.cbd.int/doc/decisions/cp-mop-09/cp-mop-09-dec-13-en.pdf> (accessed 24 October 2019).

³⁷ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity (2014), 2019 <https://www.cbd.int/abs/about/default.shtml> (accessed 24 October 2019).

³⁸ International Organization for Standardization, ISO 35001 – Biorisk management for laboratories and other related organizations, 2019, <https://www.iso.org/obp/ui/#iso:std:iso:35001:ed-1:v1:en> (accessed 25 October 2019).

³⁹ Patty Olinger, ‘ISO 35001: Biorisk management for laboratories and other related organizations’, paper presented at USDA ARS 5th International Biosafety and Biocontainment Symposium, Baltimore, MD, 12 February 2019, <https://arssymposium.absa.org/wp-content/uploads/2019/02/1025-SIMS-Olinger.pdf> (accessed 25 October 2019).

codes of practice for the safe handling of pathogenic microorganisms in laboratories within their geographical borders'.⁴⁰ It covers risk assessment and safe use of recombinant DNA technology, as well as guidelines for the commissioning and certification of laboratories. The *Manual* emphasises the key role of 'continuous, on-the-job training' and outlines a set of critical elements for an effective biosafety training programme. It also introduces biosecurity concepts – the protection of microbiological assets from theft, loss or diversion, which could lead to the inappropriate use of these agents to cause public health harm – which are reviewed in detail in subsection 3.2. In order to assist in assessments of microbiological laboratory safety and security status of biomedical laboratories, the *Manual* features a safety checklist.

Similarly to the World Health Organisation, the OIE has produced relevant guiding documents intended for veterinary laboratories. The *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* aims to provide internationally agreed diagnostic laboratory methods and requirements for the production and control of relevant vaccines and other biological products and thus contribute to preventing and controlling animal diseases, including zoonoses.⁴¹ The *Manual* provides guidance concerning, *inter alia* the management of veterinary diagnostic laboratories; collection, submission, and storage of diagnostic specimens; transport of specimens of animal origin; biosafety and biosecurity: standard for managing biological risk in the veterinary laboratory and animal facilities.

The *Manual of Diagnostic Tests for Aquatic Animals* aims to 'provide a standardised approach to the diagnosis of the diseases listed in the Aquatic Code, to facilitate health certification for trade in aquatic animals and aquatic animal products'.⁴² The *Manual* is a key and unique document describing the methods that should be applied to the OIE-listed diseases in aquatic animal health laboratories all over the world, thus increasing efficiency and promoting improvements in aquatic animal health world-wide.

The transport, shipment, and transfer of biological agents and toxins are subject to international control. The World Health Organisation technical *Guidance on Regulations for the Transport of Infectious Substances 2019-2020* provides information for identifying, classifying, marking, labelling, packaging, documenting and refrigerating infectious substances for transportation and ensuring their safe delivery.⁴³ The *Guidance* also provides a

⁴⁰ World Health Organization, *Laboratory biosafety manual*, 3rd edition (Geneva: World health Organization, 2004), https://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/ (accessed 25 October 2019).

⁴¹ World Organisation for Animal Health (OIE), *Manual of diagnostic tests and vaccines for terrestrial animals*, 8th edition (Paris: World Animal Health Organisation, 2018), <https://www.oie.int/en/standard-setting/terrestrial-manual/> (accessed 25 October 2019).

⁴² World Organisation for Animal Health (OIE), *Manual of diagnostic tests for aquatic animals* (Paris: World Organisation for Animal Health, 2019), <https://www.oie.int/en/standard-setting/aquatic-manual/access-online/> (accessed 25 October 2019).

⁴³ World Health Organization, *Guidance on regulations for the transport of infectious substances 2019-2020* (Geneva: World Health Organization, 2019), https://www.who.int/ihr/publications/guidance_infectious_substances/en/ (accessed 25 October 2019).

detailed overview of the United Nations System for the Transport of Dangerous Goods by air, water, road, including railway, and post.⁴⁴

3.2 International Biosecurity Instruments

International biosecurity instruments seek to prevent the deliberate misuse of life science knowledge, materials, and technologies in ways that can cause harm to humans, animals, or plants. These instruments focus on upholding the international norm against biological weapons and promoting the use of the life sciences for peaceful, prophylactic, and protective purposes.

The Protocol for the Prohibition of the Use of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare (Geneva Protocol) was concluded in 1925 under the auspices of the League of Nations. The Protocol reaffirmed the provisions of the Hague Conventions (1899 and 1907) with respect to the Laws and Customs of War on Land for the prohibition of deploying poison weapons and bacteriological methods of warfare during an armed conflict.⁴⁵

The Biological and Toxin Weapons Convention (BTWC) entered into force in 1975 to become the first international legally-binding instrument that outlaws an entire class of weapons of mass destruction (WMD). Article I of the Convention defines a general purpose criterion for the prohibition of biological weapons:

Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:

- (1) microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;*
- (2) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.⁴⁶*

The Convention further contains provisions for the prohibition of assisting in the development or acquisition of biological weapons (Article III) and for promoting ‘the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes’ (Article X).

⁴⁴ United Nations Economic Commission for Europe (UNECE), Dangerous goods, 2019, <http://www.unece.org/?id=3305> (accessed 25 October 2019).

⁴⁵ Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare (1925), 2019, <https://ihl-databases.icrc.org/applic/ihl/ihl.nsf/INTRO/280> (accessed 25 October 2019).

⁴⁶ Biological and Toxin Weapons Convention (1975), 2019, [https://www.unog.ch/80256EE600585943/\(httpPages\)/77CF2516DDC5DCF5C1257E520032EF67?OpenDocument](https://www.unog.ch/80256EE600585943/(httpPages)/77CF2516DDC5DCF5C1257E520032EF67?OpenDocument) (accessed 25 October 2019).

The BTWC does not possess a formalised system for verification of compliance. The Second Review Conference in 1986 agreed to the exchange of Confidence-Building Measures (CBMs) “in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions and in order to improve international cooperation in the field of peaceful biological activities”. The CBMs consist of six measures as follows:

- 1) **CBM A:** *Part 1: Exchange of data on research centres and laboratories;*
Part 2: Exchange of information on national biological defence research and development programmes.
- 2) **CBM B:** *Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins.*
- 3) **CBM C:** *Encouragement of publication of results and promotion of use of knowledge.*
- 4) **CBM E:** *Declaration of legislation, regulations and other measures.*
- 5) **CBM F:** *Declaration of past activities in offensive and/or defensive biological research and development programmes.*
- 6) **CBM G:** *Declaration of vaccine production facilities.*⁴⁷

Article IV of the Convention requires that States Parties shall, in accordance with their constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition or retention of biological weapons. The Eighth Review Conference held in 2016 when considering Article IV called upon States Parties to adopt legislative, administrative, judicial and other measures to ‘ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorised access to and removal of such agents or toxins.’ The Conference also noted the value of national implementation measures to:

- (a) *implement voluntary management standards on biosafety and biosecurity;*
- (b) *encourage the consideration of development of appropriate arrangements to promote awareness among relevant professionals in the private and public sectors and throughout relevant scientific and administrative activities;*
- (c) *promote amongst those working in the biological sciences awareness of the obligations of States Parties under the Convention, as well as relevant national legislation and guidelines;*
- (d) *promote the development of training and education programmes for those granted access to biological agents and toxins relevant to the Convention and for those with the knowledge or capacity to modify such agents and toxins;*
- (e) *encourage the promotion of a culture of responsibility amongst relevant national professionals and the voluntary development, adoption and promulgation of codes of conduct;*
- (f) *strengthen methods and capacities for surveillance and detection of outbreaks of disease at the national, regional and international levels, noting that the International*

⁴⁷ Biological and Toxin Weapons Convention, Confidence-Building Measures (CBMs), 2019, [https://www.unog.ch/80256EE600585943/\(httpPages\)/5E2E8E6499843CCBC1257E52003ADED4?OpenDocument](https://www.unog.ch/80256EE600585943/(httpPages)/5E2E8E6499843CCBC1257E52003ADED4?OpenDocument) (accessed 25 October 2019). The CBM forms officially do not feature item D.

*Health Regulations (2005) are important for building capacity to prevent, protect against, control and respond to the international spread of disease; and (g) prevent anyone from developing, producing, stockpiling, or otherwise acquiring or retaining, transporting or transferring and using under any circumstances, biological agents and toxins, equipment, or their means of delivery for non-peaceful purposes.*⁴⁸

It is therefore evident that BTWC States Parties consider the full and effective implementation of the international biosafety instruments an important pre-condition for preventing the deliberate misuse of life science knowledge, materials, and technologies. Equally, BTWC States Parties recognise the importance of ensuring that those engaged in the life sciences are aware of the scope and purpose of the Convention and of their responsibilities to contribute to its full and effective implementation.

The Chemical Weapons Convention (CWC) which entered into force in 1997 prohibits the development, stockpiling, acquisition, retention, and use of chemical weapons. CWC is similar in structure to the BTWC and both Conventions address and prohibit toxins.⁴⁹

Two functional areas of overlap between the BTWC and CWC include the review of developments in science and technology and stakeholder engagement through outreach and education. The Scientific Advisory Board (SAB) that was established in 1997 is a subsidiary body within the framework of the Organisation for the Prohibition of Chemical Weapons (OPCW) tasked with the provision of specialised advice on science and technology with relevance to the Convention.⁵⁰ In 2011, the SAB set up a Temporary Working Group (TWG) on Convergence of Biology and Chemistry. The TWG drew upon a pool of wide-ranging expertise featuring industrial and academic scientists, defence laboratory scientists, toxicologists, analytical chemists and chemical engineers (including those with experience in biomediated processes). The Final Report of the TWG issued in 2014, specifically considered the item “On bringing together expertise on the BWC and CWC in order to discuss areas of common interest and share relevant knowledge”.⁵¹

The Advisory Board on Education and Outreach (ABEO) was established as a result of a decision of the Twentieth Session of the Conference of the States Parties to the CWC in

⁴⁸ Eighth 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.VIII/4, 711 January 2017, Geneva, Switzerland.

[https://www.unog.ch/80256ee600585943.nsf/\(httpPages\)/57a6e253edfb1111c1257f39003ca243?OpenDocument&ExpandSection=3#_Section3](https://www.unog.ch/80256ee600585943.nsf/(httpPages)/57a6e253edfb1111c1257f39003ca243?OpenDocument&ExpandSection=3#_Section3) (accessed 25 October 2019).

⁴⁹ Chemical Weapons Convention (1997), 2019 <https://www.opcw.org/chemical-weapons-convention/genesis-and-historical-development/> (accessed 25 October 2019).

⁵⁰ Organisation for the Prohibition of Chemical Weapons, Scientific Advisory Board (SAB), 2019, <https://www.opcw.org/about-us/subsidiary-bodies/scientific-advisory-board> (accessed 25 October 2019).

⁵¹ Scientific Advisory Board, *Convergence of chemistry and biology: report of the Scientific Advisory Board's Temporary Working Group*, SAB/REP/1/14, The Hague: Organisation for the Prohibition of Chemical Weapons, 2014, https://www.opcw.org/fileadmin/OPCW/SAB/en/TWG_Scientific_Advisory_Group_Final_Report.pdf (accessed 25 October 2019).

December 2015.⁵² Its principal task is to “provide advice on the development of strategies and key messages for education and outreach activities that support the implementation of the Convention”. The OPCW has also published The Hague Ethical Guidelines which are intended to serve as elements for ethical codes and discussion points for ethical issues related to the practice of chemistry under the CWC.⁵³

The United Nations Security Council Resolution (UNSCR) 1540 which was adopted unanimously under *Chapter VII: Action with Respect to Threats to the Peace, Breaches of the Peace, and Acts of Aggression* of the Charter of the United Nations in 2004 addresses the non-proliferation of weapons of mass destruction and more specifically, the risk that non-State actors “may acquire, develop, traffic in or use nuclear, chemical and biological weapons and their means of delivery”. UNSCR 1540 requires

[...] that all States shall take and enforce effective measures to establish domestic controls to prevent the proliferation of nuclear, chemical, or biological weapons and their means of delivery, including by establishing appropriate controls over related materials and to this end shall:

- (a) Develop and maintain appropriate effective measures to account for and secure such items in production, use, storage or transport;*
- (b) Develop and maintain appropriate effective physical protection measures;*
- (c) Develop and maintain appropriate effective border controls and law enforcement efforts to detect, deter, prevent and combat, including through international cooperation when necessary, the illicit trafficking and brokering in such items in accordance with their national legal authorities and legislation and consistent with international law;*
- (d) Establish, develop, review and maintain appropriate effective national export and trans-shipment controls over such items, including appropriate laws and regulations to control export, transit, trans-shipment and re-export and controls on providing funds and services related to such export and trans-shipment such as financing, and transporting that would contribute to proliferation, as well as establishing end-user controls; and establishing and enforcing appropriate criminal or civil penalties for violations of such export control laws and regulations.⁵⁴*

In order to ensure that international exports do not contribute to the development of biological weapons, both the BTWC and UN Security Council Resolution 1540 require States to implement domestic controls on the transfer, including the countering of illicit trafficking of biological materials and equipment that may assist state or non-state actors in acquiring

⁵² Chemical Weapons Convention, Conference of the States Parties, *Decision: Establishment of an Advisory Board on Education and Outreach*. C-20/DEC.9. 3 December 2015, The Hague, https://www.opcw.org/fileadmin/OPCW/CSP/C-20/en/c20dec09_e.pdf (accessed 25 October 2019).

⁵³ Organisation for the Prohibition of Chemical Weapons, *The Hague Ethical Guidelines* (2015), 2019, <https://www.opcw.org/hague-ethical-guidelines> (accessed 25 October 2019).

⁵⁴ United Nations Security Council, Resolution 1540 (2004), S/RES/1540 (2004), 28 April 2004, [http://www.un.org/en/ga/search/view_doc.asp?symbol=S/RES/1540\(2004\)](http://www.un.org/en/ga/search/view_doc.asp?symbol=S/RES/1540(2004)) (accessed 25 October 2019).

biological weapons. The Australia Group is an informal forum of 42 States working on the harmonisation of export controls.⁵⁵ To this end, the Australia Group has developed three Common Control Lists with relevance to the prevention of biological and toxin weapons:

- *Control List of Dual-use Biological Equipment and Related Technology and Software* (May 2017);
- *List of Human and Animal Pathogens and Toxins for Export Control* (July 2017);
- *List of Plant Pathogens for Export Control* (June 2012).

All three biological weapons-related control lists are described in detail in the *Australia Group Common Control List Handbook, Volume II: Biological Weapons-Related Common Control Lists*.⁵⁶

Another international initiative that seeks to strengthen customs control is the Green Customs Initiative, a partnership of international organisations which cooperate to prevent the illegal trade in environmentally-sensitive commodities, and facilitate the legal trade in such commodities.⁵⁷ The aim of the Green Customs Initiative is to enhance the capacity of customs and other relevant enforcement personnel to monitor, detect and prevent illegal trade in environmentally-sensitive commodities, such as ozone depleting substances (ODS), toxic chemical products including toxins, hazardous wastes, endangered species and living-modified organisms. The Green Customs Initiative operates in partnership with INTERPOL, OPCW, the UN Office on Drugs and Crime (UNODC), and the World Customs Organization, among others.

In the event of a suspected deliberate release of bacteriological (biological) or toxin weapons, any affected state, regardless of whether they are a State Party to the BTWC may request that the UN Secretary General Mechanism for Investigation of Alleged Use of Chemical and Biological Weapons (UNSGM) is triggered. The UNSGM grants the UN Secretary General the authority to carry out an investigation including a dispatching a fact-finding team to the site/s of the alleged incident/s and to report to all UN Member States. The primary purpose of the Mechanism is to ascertain in an objective and scientific manner whether a violation of the 1925 Geneva Protocol has taken place.⁵⁸

Both the World Health Organisation and the World Organisation for Animal Health have developed policy guidance documents that address the need for countering the deliberate misuse of the life sciences.

⁵⁵ Australia Group, 2019, <https://australiagroup.net/en/> (accessed 25 October 2019).

⁵⁶ Australia Group, *Volume II: biological weapons-related common control lists*, 4 February 2018, <https://australiagroup.net/en/controllists.html> (accessed 25 October 2019).

⁵⁷ Green Customs Initiative, 2019, <http://www.greencustoms.org/> (accessed 25 October 2019).

⁵⁸ United Nations Office for Disarmament Affairs, Secretary-General's Mechanism for Investigation of Alleged Use of Chemical and Biological Weapons, 2019, <https://www.un.org/disarmament/wmd/secretary-general-mechanism/> (accessed 25 October 2019).

In 2006, the World Health Organisation published a document titled *Biorisk Management: Laboratory Biosecurity Guidance*, which provides detailed guidance on laboratory biosecurity and addresses its basic principles and best practices for preventing the loss, theft, and misuse of biological agents and toxins. According to the *Guidance* document, laboratory biosecurity measures should be based on a comprehensive programme of accountability for valuable biological materials (VBM) that includes:

1. Regularly updated inventories with storage locations;
2. Identification and selection of personnel with access;
3. Plans of use of VBM;
4. Clearance and approval processes;
5. Documentation of internal and external transfers within and between facilities; and
6. Inactivation and/or disposal of the material.⁵⁹

In addition, institutional laboratory biosecurity protocols should include how to handle breaches or near-breaches in laboratory biosecurity. The *Guidance* further outlines an integrated biorisk management approach underpinned by three key components:

1. Reducing the risk of unintentional exposure to pathogens and toxins or their accidental release (biosafety), and reducing the risk of unauthorized access, loss, theft, misuse, diversion or intentional release of VBM to tolerable, acceptable levels (laboratory biosecurity);
2. Providing assurance, internally and externally (facility, local area, government, global community, etc.), that suitable measures have been adopted and effectively implemented;
3. Providing a framework for continuous awareness-raising for biosafety, laboratory biosecurity and ethical code of conduct, and training within the facility.⁶⁰

In 2010, the World Health Organisation published a document titled *Responsible Life Sciences Research for Global Health Security: A Guidance Document* which “aims at strengthening the culture of scientific integrity and excellence characterised by openness, honesty, accountability and responsibility: such a culture is the best protection against accidents and deliberate misuse, and the best guarantee of scientific progress and development”.⁶¹ The *Guidance* is intended to help researchers and institutions:

⁵⁹ World Health Organization, *Biorisk management: laboratory biosecurity guidance* (Geneva: World Health Organization, 2006), https://www.who.int/ihr/publications/WHO_CDS_EPR_2006_6/en/ (accessed 25 October 2019).

⁶⁰ World Health Organization, *Biorisk management: laboratory biosecurity guidance* (Geneva: World Health Organization, 2006), https://www.who.int/ihr/publications/WHO_CDS_EPR_2006_6/en/ (accessed 25 October 2019).

⁶¹ World Health Organization, *Responsible life sciences research for global health security: a guidance document* (Geneva: World Health Organization, 2010), http://www.who.int/csr/resources/publications/HSE_GAR_BDP_2010_2/en/ (accessed 25 October 2019).

1. *[Develop] a better understanding of the potential risks associated with accidents and the deliberate misuse of life sciences research;*
2. *Learn about practical measures that will enable them to manage some of the risks posed by life sciences research;*
3. *Assess their needs and capacities using a self-assessment tool to review existing structures and mechanisms and identify potential needs.*⁶²

The OIE *Biological Threat Reduction Strategy: Strengthening Global Biological Security* that was published in 2015 seeks to develop a sustainable and effective protection against threats from deliberate and accidental releases of animal pathogens by strengthening existing systems for surveillance, early on-farm detection, and rapid response and fostering scientific networks for promoting biosafety and biosecurity.⁶³ To facilitate the achievement of these objectives, the OIE has developed *Guidelines for Investigation of Suspicious Biological Events* and *Guidelines for Responsible Conduct in Veterinary Research*. The *Guidelines for Investigation of Suspicious Biological Events* are intended to aid Veterinary Services to prepare for the investigation of suspicious biological events in relation to animal health, regardless of their origin, taking into account the additional challenges related to joint investigations.⁶⁴ The *Guidelines for Responsible Conduct in Veterinary Research* seek to raise awareness about the dual-use potential of research in veterinary settings, supporting veterinary professionals, researchers and other stakeholders to effectively identify, assess and manage dual-use implications.⁶⁵

A model for an integrated approach for preventing the deliberate use of biological agents and addressing the unique biological security and safety challenges around the world is the Biological Security Working Group of the Global Partnership against the Spread of Weapons and Materials of Mass Destruction. The Global Partnership is an international forum of 31 States that was launched in 2002 to counter CBRN terrorism and proliferation. Its Biological Security Working Group works in conjunction with the Global Health Security Agenda focusing on five inter-related areas of activity which underscore the vital importance of strengthening the web of prevention for ensuring effective biosafety and biosecurity worldwide. These areas include:

- *Secure and account for materials that represent biological proliferation risks.*

⁶² World Health Organization, *Responsible life sciences research for global health security: a guidance document* (Geneva: World Health Organization, 2010), http://www.who.int/csr/resources/publications/HSE_GAR_BDP_2010_2/en/ (accessed 25 October 2019).

⁶³ World Organisation for Animal Health (OIE), *Biological threat reduction strategy: strengthening global biological security*, Paris, October 2015, <https://www.oie.int/scientific-expertise/biological-threat-reduction/> (accessed 25 October 2019).

⁶⁴ World Organisation for Animal Health (OIE), *Guidelines for investigation of suspicious biological events* (Paris: World Organisation for Animal Health, 2018), https://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Guidelines_Investigation_Suspicious_Biological_Events.pdf (accessed 25 October 2019).

⁶⁵ World Organisation for Animal Health (OIE), *Guidelines for responsible conduct in veterinary research* (Paris: World Organisation for Animal Health, 2019), https://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/BTR/A_GUIDELINES_VETERINARY_RESEARCH.pdf (accessed 25 October 2019).

- *Develop and maintain appropriate and effective measures to prevent, prepare for, detect and disrupt the deliberate misuse of biological agents.*
- *Strengthen national and international capabilities to rapidly identify, confirm/assess and respond to biological attacks.*
- *Reinforce and strengthen the BTWC and other biological disarmament and non-proliferation obligations, principles, practices and instruments.*
- *Reduce biological proliferation risks through the advancement and promotion of safe and responsible conduct.*⁶⁶

4. Conclusions

As noted in the conclusion of 1997 JAMA paper:

*In considering biological control regimes for the future, it is instructive to look back over the developments in both security and environmental controls.*⁶⁷

Addressing the complex spectre of biological risks in the twenty-first century that ranges from naturally occurring disease outbreaks, laboratory-acquired infections, and negligence to the deliberate release of pathogens and toxins against humans, animals, or plants requires the full and effective implementation of both international biosafety and biosecurity instruments. The web of prevention can serve as a conceptual framework for developing an understanding of the mutually reinforcing relationship of these two sets of instruments and devising integrated policy strategies for promoting compliance with their provisions. Consideration should be given to the following steps and measures for strengthening the web of prevention:

1. Universalisation of international legally binding instruments. Table 1 provides information on the status of ratification of the international Conventions and Protocols that have been examined in the preceding section. By participating actively in relevant international agreements, States develop an appreciation of the complementary role of these agreements and are more likely to take effective steps for their national implementation.

2. Enhancing the interaction between the existing international mechanisms for multilateral negotiations with relevance to biosafety and biosecurity. It is important that the outcomes achieved in one area of biological risk management are fed in a timely manner into the proceedings of other international agreements, in order to ensure cross-fertilisation and effective data sharing. For instance, those working in the field of disarmament need to be kept up-to-date with international policy developments in the field of environmental protection and health, and vice versa.

3. Creating platforms for promoting effective action in support of the web of prevention for biological risk management. Biological risk management is complex and multifaceted,

⁶⁶ Global Partnership against the Spread of Weapons and Materials of Mass Destruction, Biological Security Working Group, 2019, <https://www.gpwm.com/bswg> (accessed 25 October 2019).

⁶⁷ Pearson, 'The complementary role of environmental and security biological control regimes in the 21st century', p.372.

and hence it is important that the existing processes for international multilateral negotiations are supplemented with opportunities for a broad stakeholder engagement. Semi-formal or informal forums and platforms can bring together both government and civil society representatives, including industry and academia, in order to foster the development of innovative solutions and facilitate the transfer of best practices and lessons learned. As such, they can play an instrumental role in informing States' efforts to promote common understanding and effective action on strengthening the norms of biosafety and biosecurity worldwide.

4. Developing integrated approaches for the national implementation of all elements of the web of prevention for biological risk management. International law defines the legal responsibilities of States in their conduct with each other, and their treatment of individuals within State boundaries.⁶⁸ With regard to biological risk management, States are expected to take all necessary steps to ensure that all elements of the web of prevention are effectively implemented nationally within the territories under their jurisdiction. The implementation of integrated approaches and initiatives that are underpinned by cross-sectorial collaboration at national level is to be encouraged, in order to ensure that all those engaged in the life sciences whether in government, academia, industry, or as individuals are aware of their responsibility to cause no harm.⁶⁹

Table 1: Membership in International Legally Binding Agreements / International Organisations with Relevance to Biological Risk Management (as of October 2019)

International Agreement/Organisation	Number of States Parties
United Nations – UN Secretary General’s Mechanism and UNSC Resolution 1540 https://www.un.org/en/sections/member-states/growth-united-nations-membership-1945-present/index.html	193 and 2 observers (Holy See and Palestine)

⁶⁸ United Nations, *Uphold International Law*, 2019, <https://www.un.org/en/sections/what-we-do/uphold-international-law/> (accessed 5 November 2019).

⁶⁹ Examples of integrated national approaches for biological risk management include: Portugal, *Biopreparedness field training exercises: national and international capacity-building*, BWC/MSP/2017/WP.11, Meeting of the States Parties, 1 December 2017, <https://undocs.org/BWC/MSP/2017/WP.11>; United Kingdom, *Strengthening national implementation: The UK Biological Security Strategy*, BWC/MSP/2018/MX.3/WP.4, Meeting of Experts on Strengthening National Implementation, 31 July 2018, <https://undocs.org/en/bwc/msp/2018/mx.3/wp.4>; United States of America, *Strengthening national implementation: The United States National Biodefense Strategy*, BWC/MSP/2019/MX.3/WP.1, Meeting of Experts on Strengthening National Implementation, 11 July 2019, <https://undocs.org/bwc/msp/2019/mx.3/wp.1>; Mexico, *Institutional actions for the implementation of the BWC in Mexico*, presentation delivered during the 2019 BWC Meeting of Experts on Review of Developments in the Field of Science and Technology Related to the Convention, 31 July 2019, [https://www.onug.ch/unog/website/disarmament.nsf/\(httpPages\)/99E884C517B29FCEC12583C1003FB1D3?OpenDocument](https://www.onug.ch/unog/website/disarmament.nsf/(httpPages)/99E884C517B29FCEC12583C1003FB1D3?OpenDocument) (all accessed 4 November 2019).

1925 Geneva Protocol https://ihl-databases.icrc.org/ihl/INTRO/280?OpenDocument	142
Biological and Toxin Weapons Convention https://www.unog.ch/	183
Chemical Weapons Convention https://www.opcw.org/media-centre/opcw-numbers	193
World Health Organisation https://www.who.int/countries/en/	194
World Organisation for Animal Health http://www.oie.int/about-us/our-members/member-countries/	182
Food and Agriculture Organisation http://www.fao.org/about/en/	194
International Plant Protection Convention https://www.ippc.int/en/structure/	183 including the EU
Codex Alimentarius http://www.fao.org/fao-who-codexalimentarius/about-codex/members/en/	189 including the EU
Convention on Biological Diversity https://www.cbd.int/information/parties.shtml	196 including the EU
Cartagena Protocol on Biosafety http://bch.cbd.int/protocol	172 including the EU
Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress http://bch.cbd.int/protocol/supplementary/	45 including the EU
Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml	119 including the EU