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## Approaches to Governance for Scientific and Technological Advances in the Life Sciences Relevant to the Biological and Toxin Weapons Convention

**Submitted by the United States of America**

*Summary*

This paper considers approaches to governance of advances of science and technology of relevance to the Biological and Toxin Weapons Convention (BWC) to reduce the risks of misuse for biological weapons development. Managing these risks necessarily involves a suite of hard laws and informal measures, tailored to specific problem sets. The paper describes various governance tools, considerations in selecting appropriate tools, and the importance of agile governance approaches to both minimizing risks while realizing potential benefits of scientific advances. Finally, it highlights the role of the BWC intersessional program in sharing experiences and exploring harmonization of governance measures.

# I. Introduction

1. In the current cycle of intersessional discussions in MX2 on advances in science and technology and their implications for the Biological and Toxin Weapons Convention (BWC), the United States and other States Parties have urged taking a systematic approach by successively examining relevant advances, possible methods for assessing risks and benefits, and ways in which to manage risks and realize benefits. This paper explores a range of approaches to manage risks and the opportunities for States Parties to synchronize measures, ensure complementarity in approaches, and learn from one another's experiences. A systematic approach provides a foundation for consideration of specific measures to take during a review of advances in scientific and technological developments relevant to the Convention at the 2021 Review Conference.

2. In 2018, the States Parties identified a series of biotechnology developments with the potential for misuse in bioweapons development (i.e., "dual use" potential). States

Parties expressed views on both the bioweapons risks and peaceful benefits of technical capabilities including gene editing, gene synthesis, gene drives, and metabolic pathway engineering among others.[1] These tools are used in life science research for legitimate and beneficial applications in public health and medicine, agriculture and the environment, and other civil sectors. However, they also have the potential to change the landscape for biological weapons threats due to their accessibility, rapid development, and convergence with advances in other fields. States Parties also urged the creation of a more systematic and regular process through the BWC for providing advice on scientific and technical developments. The United States strongly supports establishing such a process and looks forward to working actively with other member states to develop a broadly acceptable approach.

3. Building on the 2018 analysis of relevant advances, the States Parties in 2019 reviewed science-based assessment tools that can help to analyze potential risks and benefits from these technological capabilities in order to focus attention and resources on the most likely or concerning threats. One framework, developed in 2007 by the U.S. National Science Advisory Board for Biosecurity (NSABB),[2] examines the nature of the potential threat by: whether countermeasures exist; the level of technical skill and sophistication required to use the technology; the scope of the potential threat; and the potential benefits of the particular technology. Building on this work, Dr. Jonathan B. Tucker, Senior Fellow at the Federation of American Scientists, created a tool in 2012[3] that includes technology assessment based on accessibility, ease of misuse, the magnitude of harm, and imminence of misuse followed by a governability analysis of the technology. More recently, a committee formed by the U.S. National Academy of Sciences (NAS) developed a framework for assessing risks posed by synthetic biology,[4] which centered on four major components: the usability of the technology; usability as a weapon; requirements of actors; and potential for mitigation.

4. The discussion of risk assessments of scientific advances highlighted that risks must be balanced with potential benefits. Many risk assessment frameworks acknowledge the importance of considering benefits, though it is difficult to obtain accurate benefits assessments with current tools. For example, the NSABB developed general considerations to assess the benefits of specific research experiments and Tucker recommended an explicit

[1] BWC/MSP/2018/MX.2/WP.2 — Technical Working Paper on Genome Editing and Other Scientific and Technological Developments of Relevance to the Convention — Submitted by Switzerland

BWC/MSP/2018/MX.2/WP.3 — Review of Developments in the Field of Science and Technology Related to the Convention — Genome editing — Submitted by Australia

BWC/MSP/2018/MX.2/WP.4 — Genome editing: addressing implications for the Biological and Toxin Weapons Convention — Submitted by the United Kingdom of Great Britain and Northern Ireland

BWC/MSP/2018/MX.2/WP.5 — Recent Advances in Gene Editing and Synthesis Technologies and their Implications — Submitted by the United States of America

BWC/MSP/2018/MX.2/WP.6 — Review of Developments in the Field of Science and Technology Related to the Convention — Genome Editing — Submitted by the Islamic Republic of Iran

BWC/MSP/2018/MX.2/WP.11 — Nuevos adelantos de la Ciencia y la Tecnología en la Esfera de la Biología, en particular la Edición de Genes y la Biología Sintética — Submitted by Cuba

BWC/MSP/2018/MX.2/WP.12 — Review of Developments in the field of Science and Technology related to the Convention — Submitted by the Bolivarian Republic of Venezuela on behalf of the Non-Aligned Movement and other States Parties to the Biological and Toxin Weapons Convention

[2] Proposed Framework for the Oversight of Dual-use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information, Appendix 4 pages 55-56 (https://osp.od.nih.gov/wp-content/uploads/Proposed-Oversight-Framework-for-Dual-Use-Research.pdf)

[3] Jonathan B. Tucker, ed., Innovation, Dual Use, and Security: Managing the Risks of Emerging Biological and Chemical Technologies (Cambridge: MIT Press, 2012).

[4] National Academies of Sciences, Engineering, and Medicine. 2018. Biodefense in the Age of Synthetic Biology. Washington, DC: The National Academies Press. (Figure 3-1, https://doi.org/10.17226/24890

cost-benefit analysis of specific governance measures. These discussions show that the benefits of scientific capabilities should be explicitly addressed when applying risk assessment tools, but the available approaches to accurately assess those benefits need further development and improvement. For instance, there is evidence in many cases that new technologies follow the typical technology "hype cycle"[5] and may not fulfil expectations. This disconnect between initial expectations and actual productivity of a given technology can lead to overestimations of both its benefits and risks, further complicating novel technology assessment. As applications of the scientific and technological advances in the life sciences evolve, it will be important to responsibly track innovations likely to be adopted so that their benefits can be maximized while minimizing their potential risks. Early efforts to evaluate the nature of bioeconomy benefits are already underway, both in the United States and elsewhere,[6,7] and often occur beyond the security sector, prioritizing economic consideration and strategic investments. Further work to develop appropriate tools with multi-sector input for more accurate assessments is important to minimize the risks while realizing the benefits of scientific advances.

# II. Approaches to Governance

## A. What is Governance?

5. In the context of advances in science and technology of relevance to the BWC, the concept of governance is often used to encompass a broad range of possible measures to reduce the risk that advances in the life sciences will be misused for biological weapons development. In other terms, governance deals with risk management for "dual use" science and technology. Importantly, governance is not limited to legal regulation.

## B. What Tools are Available for Governance?

6. There are a number of governance tools to reduce the risks of misuse of advances in life sciences, ranging from operational processes and policies, informal norms, and laws. While laws can only be passed by governments, other available tools can be developed or carried out by government entities as well as companies, civil society organizations, and communities of practice, either alone or in cooperation. There are several ways that governance tools can be characterized.

7. One possible characterization is "hard law" versus informal measures. "Hard law" refers to those measures that have binding legal effect, such as international agreements, like the Biological Weapons Convention, and national laws and regulations, including, for example, implementing legislation as mandated in Article IV of the BWC. Additionally, national regulations such as the United States Federal Select Agent Regulations[8] further strengthen the prohibition on the misuse of science and technology developments by overseeing the use and transfer of pathogens and toxins that could pose a safety or security threat.

8. Informal measures refer to those that are not legally binding, such as voluntary research moratoria, best practices, governmental procedural guidance, or codes of conduct. These measures act to reinforce the global norm that life scientists use their knowledge and

[5] A description of the expectations of a technology over time that begins with inflated expectations, followed by disillusionment, and ending with productivity (https://www.gartner.com/en/research/methodologies/gartner-hype-cycle)

[6] Safeguarding the Bioeconomy. National Academies of Sciences (2019 https://www.nap.edu/read/25525/chapter/1).

[7] Global Bioeconomy Summit 2018 (https://gbs2018.com/workshops/policy-measuring-and-monitoring/)

[8] The United States Federal Select Agent Regulations were implemented pursuant to a specific law: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

skills for peaceful purposes that benefit the public, dissuading unethical and illegal conduct and preventing the development of biological weapons. These informal measures can be developed by governments, like the voluntary guidelines for providers of synthetic double-stranded DNA,[9] by the practicing communities, like the American Society for Microbiology's Code of Ethics and Conduct,[10] or by both working together.

9. Another possible characterization is "top down" versus "bottom up." "Top down" measures typically involve measures enacted or imposed by governments in the form of laws, regulations, and/or policies. For example, the United States Government policies surrounding 'dual use research of concern' articulate oversight requirements for government-funded institutions that conduct or sponsor life sciences research.[11] In contrast, "bottom up" measures are often self-regulatory in character and can arise at a variety of levels — a few biological scientists in a specialized field, a group of research institutions, and/or a coalition of companies. These measures often involve practitioner stewardship and could include codes of conduct developed by professional societies, credentialing mechanisms supported by professional societies, or security programs developed by organizations. For instance, the International Genetically Engineered Machine (iGEM) Foundation that hosts annual world-wide synthetic biology competitions developed a Safety and Security Program which continuously evolves with advances and developments in the field.[12] Similarly, as an example of common international operational processes, the International Organization for Standardization (ISO) developed the *ISO 35001:2019 Biorisk Management for Laboratories and Other Related Organizations*.[13] Finally, forms of private international regulatory cooperation are emerging along with — or sometimes as a replacement for — inter-governmental cooperation, as pointed out in the 2019 International Risk Governance Center Workshop.[14] For example, the International Gene Synthesis Consortium brings together gene synthesis companies and facilitates adoption of industry-wide practices, like security screening of both sequences and customers, to promote beneficial applications while safeguarding biosecurity.[15]

10. Importantly, these various governance tools are not mutually exclusive, and it is often beneficial to apply a full suite of tools tailored to a specific problem set. For example, in ensuring pathogen safety and security, many governance tools can complement one another to employ context-appropriate measures: federal regulations and policies, institutional oversight and biosafety committees, laboratory standards and best-practices, and professional networks of biosafety and security practitioners.

## C. Deciding on Appropriate Measures for Governance

11. Managing the risk that advances in the life sciences could be misused necessarily involves a complex system of hard law and informal measures, tailored to address a particular set of issues. Determining a suite of governance measures for a particular technology will depend on a number of features. Factors that should be taken into account in selecting appropriate measures include:

- The risk involved compared to the likely benefits: Activities that pose a clear or probable high risk, but also clearly offer a potentially high reward may need a different suite of measures for effective regulation than high risk activities whose

[9] Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA (https://www.phe.gov/Preparedness/legal/guidance/syndna/Pages/default.aspx)

[10] https://asm.org/Articles/Ethics/COEs/ASM-Code-of-Ethics-and-Conduct

[11] Dual Use Research of Concern (DURC): https://www.phe.gov/s3/dualuse/Pages/default.aspx

[12] https://igem.org/Safety

[13] ISO 35001 Biorisk management for laboratories and other related organizations (https://www.iso.org/standard/71293.html) is a voluntary standard, approved by 164 ISO member bodies, that describes a process to identify, assess, control, and monitor the risks associated with hazardous biological materials to health, agriculture, and the environment.

[14] https://www.epfl.ch/research/domains/irgc/wp-content/uploads/2019/11/IRGC-2019.-Security-for-Emerging-Synthetic-Biology-and-Biotechnology-Threats-Workshop-report.pdf

[15] https://genesynthesisconsortium.org/

benefit is unknown or unclear. Additionally, initial perceptions of likely risks or benefits of an activity may differ among various entities and stakeholders, and can be better informed by both the weight of evidence and structured discussion between diverse groups.

- The type of risk: Risks associated with specific technical activities or specific materials could require different governance measures than risks linked to diffusion of skills or dissemination of knowledge. For example, the risks associated with synthesis of known pathogens are different compared to the risks in conducting "gain of function" experiments that inform how microorganisms become more infectious or deadly in order to develop defenses against them. Similarly, the effectiveness of certain governance measures may vary depending on the nature of a particular technology and its associated risk. In Tucker's framework, governability considerations include whether a technology is tangible or information-based, the maturity and convergence with other technologies, the rate of advance, and diffusion.
- Risk tolerance: In some cases, different communities, societies, and countries will have different attitudes toward acceptance of risks and of measures that might be implemented to manage risks. For example, research concerning a specific disease may have different perceived safety and security risks depending on whether that disease is endemic in that country. Additionally, there may be multiple views on how particular risks are perceived and prioritized. Reconciling these differing views, whether in national or international contexts, is inherently a political process or judgement, not a technical one. There is no one-size-fits-all solution and identifying appropriate measures for governance are necessarily context-dependent. However, decisions about risk tolerance can be informed by capability assessments, scientific and technical input, and public engagement.

12. In addition to these factors, different governance measures can be applied, and may be required, at various stages of scientific development, from the initial research stage to the product development stage. Each stage might have different appropriate measures because the risk changes as the research progresses. As noted in a 2018 workshop on Governance of Dual Use Research in the Life Sciences: Advancing Global Consensus on Research Oversight, a suite of distinct governance tools can be applied to different stages across the research life cycle.[16]

## D. Flexible Approaches to Governance

13. In addition to those steps that States Parties take in order to implement their obligations under the BWC, such as adoption of national implementing legislation, there are other important considerations that countries need to keep in mind as they consider their approaches to science and technology governance measures. As States Parties consider technological advances in the life sciences, it must be recognized that the rapid evolution of science and technology makes having complete technical knowledge and understanding improbable. Since knowledge is dynamic and changes as technologies progress through the hype cycle, risks considered very serious at the outset may turn out to be much less significant than initially thought. Conversely, new advances and other external factors may lead to new risks or to risks that are more significant than anticipated.

14. Furthermore, given the very complex relationship between the various measures being implemented and the imperfect knowledge of their likely effects, periodic reevaluation and, as appropriate, updates may be necessary, particularly as technologies and practices advance and as more information relevant to the evaluation of risks and benefits becomes available. For instance, measures that are effective when materials or knowledge

[16] National Academies of Sciences, Engineering, and Medicine. 2018. *Governance of Dual Use Research in the Life Sciences: Advancing Global Consensus on Research Oversight: Proceedings of a Workshop*. Washington, DC: The National Academies Press. (https://doi.org/10.17226/25154)

are not widely disseminated may become ineffective or counterproductive once equipment, materials, or knowledge diffuse widely. Other measures may turn out to be counterproductive or to have other unwanted consequences. For example, many countries take care that research institutions studying endemic or newly emerging pathogens are not over-burdened with regulations to a level that results in important public health work becoming disincentivized, while ensuring that research is conducted safely. Thus, in a rapidly evolving situation the applicable governance framework should be flexible, agile, and iterative.

15. Experience has demonstrated that once enacted, hard law measures can be difficult to change rapidly as circumstances evolve. Informal measures of various kinds are often easier to adapt. In either case, both types of measures benefit from continuous input from and engagement with the communities they affect. In the context of "top down" measures, dialogue with affected stakeholder communities helps ensure that governance measures remain effective and relevant. In the context of "bottom up" measures, engagement with governments can help to provide confidence to the governments that the measures are adequate minimize the potential for misuse.

16. In a rapidly evolving technical environment, it is hard to predict what measures will be most effective. As noted by an international workshop in 2018,[16] there is an opportunity to draw lessons from examples where various governance measures have been applied and impacted security or other aspects of scientific advances. Dissemination of information on such examples may allow the development of evidence-based strategies on the uptake and implementation of governance measures. One approach proposed by a group of largely non-governmental experts in April 2020[17] is to promote "experimentation" with new assumptions about the relationship among biology, security, and society, leading to the development, assessment, and iteration of governance hypotheses. The stated goal would be to move beyond approaches that are largely reactive and towards identifying proactive steps that could better protect economic vitality, academic freedom, and the health and security of states, people, and the environment. However, this goal comes with an obligation to be willing to adapt the measures if their underlying assumptions no longer seem to be appropriate.

## E. Governance Measures to Promote Benefits

17. In BWC discussions of science and technology, the concept of governance has largely been linked to restrictions intended to prevent misuse of such advances. It is important to note, however, that governance is also very relevant to efforts to achieve positive goals and outcomes. For example, governance measures are an important tool to facilitate cooperation in innovation and development in medicine, public health, agriculture, and other aspects of human well-being. Consequently, international discussions to explore governance measures that promote the realization of potential benefits of rapidly evolving technologies are ongoing in the work of the Organisation for Economic Co-operation and Development.[18]

18. In developing governance measures to reduce risks of misuse, care needs to be taken that those measures do not unreasonably stifle innovation. In addition to broad public benefits, the same scientific developments that change the threat landscape may also offer new opportunities and solutions for countering those same threats. The convergence of biology with other disciplines, like engineering or machine learning, is one example where innovative applications may lead to significant improvements in the capability to protect against biological threats, naturally or deliberately occurring. Furthermore, international discussions could include consideration of governance measures at the national and international level that could both manage the risks of advances in science and technology and strengthen efforts to develop and apply biotechnology for peaceful purposes. Given the

[17] Weiss Evans et al. Embrace experimentation in biosecurity governance, Science, 10 April 2020: 138-140 (https://science.sciencemag.org/content/368/6487/138)

[18] https://www.oecd.org/sti/emerging-tech/

natural tension between potential risks and benefits of scientific capabilities, explicit evidence-based benefit analysis could promote balanced discussions about governance options.

# III. Sharing Governance Measures in the BWC

19. The BWC Meetings of Experts are important venues for States Parties to exchange views and share experiences on various approaches to managing the risks — and protecting the benefits — that stem from advances in biological science and technology. The participation of non-governmental communities, either through presentations or side-events, is essential, since many of the advances are taking place in industry or academia. Such participation enables invaluable perspectives to be shared with government representatives. However, these exchanges can be improved by a more frequent, systematic process.

20. Furthermore, to be effective, approaches to governance must consider that scientific research is a global enterprise. International collaboration and sharing of information are standard practice and, often, scientific norms transcend national borders. The BWC meetings offer an exceptional forum for States Parties to provide general information on their national governance approaches, including implementing legislation, and on existing forums for harmonizing governance tools, such as the International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR)[19]. As appropriate, experts could also explore broadening existing international harmonization opportunities or considering new ones, including opportunities on a regional basis, to enable interested States Parties to compare notes, exchange best practices, and harmonize national approaches in order to minimize the risks associated with advances in biological science and technology while preserving the benefits. While there is no one-size-fits-all recipe for governance, there are opportunities to synchronize measures, ensure complementarity in approaches, and learn from one another's experiences. Such exchanges offer an additional benefit by increasing transparency among States Parties with the knowledge that national and international efforts are being undertaken by them to prevent the misuse of scientific advances and technologies for biological weapons programs. Given the global nature of scientific and technological developments and the rapid speed at which they progress, such harmonization is critical to ensuring advances in the life sciences are not misused. In advance of the Ninth Review Conference, there would be value in States Parties exploring possible practical steps that might be taken as part of or in addition to the intersessional process to further share and harmonize national governance approaches.

[19] https://iegbbr.org/