

Working Group on the Strengthening of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

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Identifying, examining and developing specific and effective measures, including possible legally-binding measures, and making recommendations to strengthen and institutionalize the Convention in all its aspects within the mandate of the Working Group

Measures to Strengthen National Implementation of the Biological Weapons Convention: Information, Expectations, and International Cooperation

Submitted by the United States of America

I. Effective national implementation is key to the success of the Convention

1. The ability of the Biological and Toxin Weapons Convention (BWC) to stand as a bulwark against biological weapons is dependent on effective national implementation by its States Parties to turn the commitments of the BWC into effective national action. The development of potential new institutional measures to strengthen the Convention could provide new ways to assist States Parties in adopting and enhancing such measures.

2. National action is required to effectively implement many provisions of the Convention. Article IV, in particular, provides that:

Each State Party to the Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.

3. States Parties have consistently recognized the important role of national implementation in combating the threat of misuse of biological material, technology, and knowledge – including by terrorists. It should be expected then that a State Party’s national implementation measures will evolve over time to adapt to evolving threats, identified gaps, and its own unique national circumstances and experiences. For example, the evolution of U.S. national implementation measures reflects our own national experiences with bioterrorism, such as the 2001 anthrax mailings, and our efforts to further prevent bioterrorism.

4. One example is the establishment and regulation of safety and security measures to prevent unauthorized access to biological agents and toxins. In the United States, the Federal Select Agent Program regulates the possession, use, and transfer of biological select agents or toxins (BSATs) that have the potential to pose a severe threat to public, animal, or plant



health, or to animal or plant products.¹ Currently, 68 BSATs are regulated; the list is reviewed at least every two years. The program also develops, implements, and enforces the select agent regulations; provides oversight of possession of BSATs; conducts inspections and approves registrations for facilities that handle BSATs; approves individual access to BSATs; receives reports of theft, loss, or release of BSATs and takes appropriate enforcement actions; serves as a resource on the select agent regulations; and collaborates with international partners to assist in the development and implementation of their own oversight programs. While domestic laws and regulations that prohibit and penalize violations are necessary, these must be supported by the guidance, policies, and awareness-raising initiatives that help to prevent violations or other risky behaviors in the first place.

5. While recognizing that each State Party has unique national circumstances and experiences, States Parties have reached consensus on a number of common understandings about national implementation that should inform expert discussions during the Working Group on the Strengthening of the Convention. Strengthening national implementation calls for action in three critical areas: better information to understand the status of implementation, clearer expectations to guide national action, and international cooperation to assist in developing measures and building capacity for effective implementation.

II. Information on national implementation measures – a fundamental requirement

6. Credible action to strengthen implementation requires sufficient information about what implementation measures States Parties already have in place. States Parties have repeatedly noted the value of sharing of up-to-date information on their legislative, administrative, and other national implementation measures. The availability of specific, current information can improve understanding and cooperation; help to identify gaps and needs; showcase best practices and new approaches; and, importantly, allow States Parties to assess progress in strengthening national implementation over time.

7. There are a variety of ways in which the need for such information may be met. For instance, in 2016, as part of an implementation review exercise, Canada, Chile, Ghana, Mexico, and the United States developed a detailed reporting format to share information on each of their national implementation measures, which could serve as a potential model.²

8. Additionally, compiling such information in a way that is searchable and supports comparison and analysis could help States Parties to better assess the overall level of implementation of the Convention by its States Parties. The United States has provided support to the UN Institute for Disarmament Research to develop a comprehensive, user-friendly, and widely accessible online database with information related to national implementation measures, and we are working with other States Parties, such as Kenya, on national implementation assistance they have identified for their country.³ Better information, including information about gaps, can help to guide international cooperation and assistance, and so strengthen the Convention.

III. Building on existing understandings to clarify expectations for effective implementation

9. Ensuring that biological weapons are not used *by anyone at any time*—including by terrorists—is a fundamental responsibility of BWC States Parties. Indeed, the preamble of the Convention expresses the determination “to exclude completely the feasibility of bacteriological (biological) agents and toxins being used as weapons.”

¹ [Federal Select Agent Program Overview](#)

² BWC/CONF.VIII/WP.22

³ BWC/MSP/2020/MX.3/WP.2

10. State Parties have recognized that effective national implementation measures are of fundamental importance, and that such measures must be managed, coordinated, enforced, and regularly reviewed to ensure their effectiveness concurrent with advances in the biological sciences and associated fields. Article IV's requirement to "prohibit" is straightforward. But States Parties are also enjoined to "prevent" the acquisition and use of biological weapons, and this is a more complex matter. Past BWC Review Conferences and Meetings of States Parties have consequently developed an extensive catalogue of measures that have been accepted as playing an important role in national implementation, while emphasizing the importance of taking into account specific national circumstances. Although by no means an exhaustive list, these recognized measures can be summarized as, *inter alia*, the following:

- Legislative, regulatory, and administrative measures, including judicial and criminal penalties for prohibited activities;
- Measures to control access to and use of pathogens and materials to prevent misuse;
- Biosafety and biosecurity management, including appropriate oversight of certain research;
- Outreach, education, and training for relevant professionals;
- Regular review and updating of existing measures.

11. Building on past work, the Working Group should identify key elements in these five areas that could comprise an agreed framework for effective national implementation.

IV. International cooperation and assistance for national implementation

12. States Parties have repeatedly encouraged information sharing and international cooperation and assistance related to strengthening national implementation. While States Parties have different legal systems and contexts, exchanges of information, training, and assistance can promote and facilitate effective implementation. For instance, the Sixth Review Conference urged "States Parties with relevant experience in legal and administrative measures for the implementation of the provisions of the Convention, to provide assistance on request to other States Parties" and "also encouraged such initiatives on a regional basis." This is one area where many States Parties are already cooperating that is directly relevant to the BWC.

13. The member countries of the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (GP) have identified strengthening biosecurity as a key priority for collective programming efforts with partner countries. Between 2017-2022, twenty GP member countries, including the United States, implemented or funded 311 projects, valued at more than \$1.6 billion (with dozens of partner countries worldwide).⁴ GP members are also providing support to the UN Office for Disarmament Affairs for the Implementation Support Unit to work together with African States Parties in their efforts to strengthen national implementation and promote universalization of the BWC.⁵

14. As one specific example of the kinds of international cooperation and assistance that can help strengthen national implementation of the BWC, the United States has worked together with the Philippines through an iterative process to help develop draft legislation and a list of biological agents to be regulated; in the process of being finalized, this approach was informed by national implementation efforts taken by other States Parties. In November

⁴ BWC/CONF.IX/WP.51

⁵ [Supporting Universalization and Effective Implementation of the Biological Weapons Convention in Africa](#)

2019, the United States facilitated a subject matter expert exchange to support a Philippines CBRN National Team-hosted “write-shop” in which participants discussed and integrated into the drafting process biosecurity operational and regulatory best practices. Through this partnership both the United States and the Philippines are advancing implementation of our BWC obligations.

V. Role of International Cooperation and Assistance to Promote BWC National Implementation

15. Cooperation, assistance, and capacity building to strengthen national implementation of the BWC could be an especially useful area for a potential international cooperation and assistance mechanism within the BWC. The Working Group should recommend measures to promote and facilitate further international cooperation, assistance, and exchange of best practices in national implementation. These might include:

- Support for States Parties seeking to conduct a comprehensive needs assessment and produce a national implementation plan;
- Capacity-building assistance guided by such plans to strengthen national implementation;
- Workshops and other meetings in which experts can exchange best practices in specific areas of implementation;
- Support for participation in voluntary implementation review exercises;
- Identifying resources to support States Parties’ efforts to enhance biorisk management; and
- Identification of key elements for a potential future National Implementation Framework.

Annex

Common Understandings on National Implementation

Legislative, regulatory, and administrative measures, including judicial and criminal penalties:

- The Second, Third and Fourth Review Conferences noted "the importance of... legislative, administrative and other measures designed to enhance domestic compliance with the Convention... and believed that such measures which States might undertake in accordance with their constitutional processes would strengthen the effectiveness of the Convention."
- The First Review Conference invited "States Parties which have found it necessary to enact specific legislation or take other regulatory measures relevant to this Article [IV] to make available the appropriate texts to the United Nations Centre for Disarmament [now the Office for Disarmament Affairs], for the purposes of consultation."
- The Sixth, Seventh and Eighth Review Conferences called upon "States Parties to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and other measures, including penal legislation, designed to ... enhance domestic implementation of the Convention and ensure the prohibition and prevention of the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery as specified in Article I of the Convention."
- The 2003 MSP agreed on the value of States Parties taking steps "to review, and where necessary, enact or update national legal, including regulatory and penal, measures which ensure effective implementation of the prohibitions of the Convention, and which enhance effective security of pathogens and toxins."
- The 2007 Meeting of States Parties "recognized the value of ensuring that national implementation measures:
 - i. penalize and prevent activities that breach any of the prohibitions of the Convention, and are sufficient for prosecuting prohibited activities;
 - ii. prohibit assisting, encouraging or inducing others to breach any of the prohibitions of the Convention;
 - iii. are not limited to enacting relevant laws, but also strengthen their national capacities, including the development of necessary human and technological resources;
 - iv. include an effective system of export/import controls, adapted to national circumstances and regulatory systems;
 - v. avoid hampering the economic and technological development of States Parties, or international cooperation in the field of peaceful uses of biological science and technology."

Measures to control access to and use of pathogens and materials to prevent misuse:

- The Second, Third and Fourth Review Conferences noted "the importance of legislation regarding the physical protection of laboratories and facilities to prevent unauthorised access to and removal of microbial or other biological agents, or toxins."
- The Sixth Review Conference called "for appropriate measures by all States Parties to ensure that biological agents and toxins relevant to the Convention are protected and

safeguarded, including through measures to control access to and handling of such agents and toxins."

- The 2003 MSP agreed on the value of "comprehensive and concrete national measures to secure pathogen collections and the control of their use for peaceful purposes. There was a general recognition of the value of biosecurity measures and procedures, which will ensure that such dangerous materials are not accessible to persons who might or could misuse them for purposes contrary to the Convention."
- The Sixth, Seventh and Eighth Review Conferences called for "appropriate measures, including effective national export controls, by all States Parties to implement this Article, in order to ensure that direct and indirect transfers relevant to the Convention, to any recipient whatsoever, are authorized only when the intended use is for purposes not prohibited under the Convention."

Biosafety and biosecurity management:

- The Third Review Conference stressed that "States parties should take all necessary safety precautions to protect populations and the environment in relation to activities not prohibited by the Convention."
- The Sixth, Seventh and Eighth Review Conferences called "upon States Parties to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and other measures, including penal legislation, designed to... ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins."
- The Seventh and Eighth Review Conferences noted "the value of national implementation measures, as appropriate, in accordance with the constitutional process of each State Party, to... implement voluntary management standards on biosafety and biosecurity."
- At the 2008 MSP "Recognising that biosafety and biosecurity measures contribute to preventing the development, acquisition or use of biological and toxin weapons and are an appropriate means of implementing the Convention, States Parties agreed on the value of:
 - i. National authorities defining and implementing biosafety and biosecurity concepts in accordance with relevant national laws, regulations and policies, consistent with the provisions of the Convention and taking advantage of relevant guidance and standards, such as those produced by the FAO, OIE and WHO;
 - ii. National governments taking the leading role, including by nominating a lead agency (or focal point), specifying mandates for participating departments or agencies, ensuring effective enforcement and regular review of relevant measures, and integrating such measures into relevant existing arrangements at the national, regional and international level;
 - iii. National governments, supported by other relevant organisations as appropriate, using tools such as: accreditation, certification, audit or licensing for facilities, organizations or individuals; requirements for staff members to have appropriate training in biosafety and biosecurity; mechanisms to check qualifications, expertise and training of individuals; national criteria for relevant activities; and national lists of relevant agents, equipment and other resources.
 - iv. Ensuring measures adopted are practical, sustainable, enforceable, are readily understood and are developed in concert with national stakeholders², avoid unduly restricting the pursuit of the biological sciences for peaceful purposes, are adapted for local needs, and appropriate for the agents being handled and the work being undertaken, including through applying appropriate risk assessment and risk management strategies."

- The 2013 Meeting of States Parties “noted the value of, in accordance with national laws and regulations:
 - i. Promoting regulation, at the national level, of possession, use and transfer of potentially dangerous biological agents and toxins;
 - ii. Promoting oversight of pathogens, at the national level, by harmonizing and updating applicable biosafety and biosecurity standards and guidelines, and clarifying and updating biocontainment requirements.”

Outreach, education, and training for relevant professionals:

- The Second, Third, Fourth and Sixth Review Conferences urged "the inclusion in medical, scientific and military educational materials and programmes of information on the Convention and the 1925 Geneva Protocol."
- The Sixth Review Conference encouraged "States Parties to take necessary measures to promote awareness amongst relevant professionals of the need to report activities conducted within their territory or under their jurisdiction or under their control that could constitute a violation of the Convention or related national criminal law" and recognized "the importance of codes of conduct and self-regulatory mechanisms in raising awareness, and called upon States Parties to support and encourage their development, promulgation and adoption."
- The Sixth, Seventh and Eighth Review Conferences urged "States Parties to 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, in order to raise awareness of the risks, as well as of the obligations of States Parties under the Convention."
- The Seventh and Eighth Review Conferences noted "the value of national implementation measures...to... 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" and noted "the value of national implementation measures...to... encourage the promotion of a culture of responsibility amongst relevant national professionals and the voluntary development, adoption and promulgation of codes of conduct."
- The 2008 Meeting of States Parties addressed numerous aspects of outreach, education, and awareness-raising. In particular, States Parties:
 - i. “recognized the importance of ensuring that those working in the biological sciences are aware of their obligations under the Convention and relevant national legislation and guidelines, have a clear understanding of the content, purpose and foreseeable social, environmental, health and security consequences of their activities, and are encouraged to take an active role in addressing the threats posed by the potential misuse of biological agents and toxins as weapons, including for bioterrorism”;
 - ii. agreed on the value of including a number of specific elements in education and awareness programmes;
 - iii. Agreed that codes of conduct “can complement national legislative, regulatory and oversight frameworks and help guide science so that it is not misused for prohibited purposes” and recognised “the need to further develop strategies to encourage national stakeholders to voluntarily develop, adopt and promulgate codes of conduct in line with the common understandings reached by the 2005 Meeting of States Parties and taking into account discussions at the 2008 Meeting of Experts.”

National capacity building and International cooperation on national implementation:

- The 2003 Meeting of States Parties agreed on "the positive effect of cooperation between States Parties with differing legal and constitutional arrangements. States Parties in a position to do so may wish to provide legal and technical assistance to others who request it in framing and/or expanding their own legislation and controls in the areas of national implementation and biosecurity."
 - The 2007 Meeting of States Parties "agreed on the value of ensuring effective enforcement of their legislative and regulatory measures, including through building capacity to collect evidence, to develop early-warning systems, to coordinate between relevant agencies, to train law enforcement personnel, and to provide enforcement agencies with the necessary scientific and technological support. Recognising that implementing the Convention is a continuing process, the States Parties agreed on the importance of regular national reviews of the adopted measures, including by ensuring the continued relevance of their national measures in light of scientific and technological developments; by updating lists of agents and equipment relevant to safety, security and transfer regimes; and by implementing additional measures as required."
 - The 2008 MSP further agreed on the value of "International cooperation on biosafety and biosecurity at the bilateral, regional and international levels, in particular to overcome difficulties encountered by some States Parties where additional resources, improved infrastructure, additional technical expertise, appropriate equipment and increased financial resources are necessary to build capacity" and "encouraged those States Parties in a position to do so to provide assistance, upon request, to other States Parties to enact and improve national legislation to implement biosafety and biosecurity; to strengthen laboratory infrastructure, technology, security and management; to conduct courses and provide training; and to help incorporate biosafety and biosecurity in existing efforts to address emerging or re-emerging diseases. States Parties noted that where relevant assistance is currently available bilaterally and regionally, as well as through international organisations, those seeking assistance are encouraged, as appropriate, to make use of existing offers to the fullest extent possible."
 - At the 2014 and 2015 Meetings, "States Parties noted the importance of regional and sub-regional cooperation the sharing of experiences and identifying additional ways and means to strengthen national implementation" and "the value of exchanging best practice with relevant regional and sub-regional organizations and using them, as appropriate and in accordance with their mandates, to promote networking, collaboration and coordination, and capacity-building as well as to support national and local training and human capacity-building."
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