

# 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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Agenda item 6

**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**

## U.S. Approach to the Working Group on the Strengthening of the Biological Weapons Convention

### Submitted by the United States of America

*“Working with partners and allies, we will strengthen the Biological Weapons Convention to deter state biological warfare capabilities; prevent terrorist acquisition or use of biological weapons; and reinforce international norms against biological weapons’ development and use.”*

President Joseph R. Biden, October 2022.

1. At the Ninth BWC Review Conference, U.S. Under Secretary of State Bonnie Jenkins posed the fundamental question - “How do we strengthen implementation of the Convention and enhance mutual assurance of compliance?” The Biological and Toxin Weapons Convention (BWC) was signed and entered-into-force five decades ago. We must now address the challenges posed by the biological landscape of the 21st century. We need to examine how technology has changed and what the bioweapons threats of today and tomorrow look like.
2. At the Ninth Review Conference, the United States strongly supported the establishment of an intersessional, expert Working Group with a view to examining and recommending a set of measures for meaningfully strengthening the implementation of the Convention. Reaching consensus on a framework of such measures would provide a substantive basis for consideration by States Parties of any further action, including the possible negotiation of a supplementary agreement.
3. The success of this Working Group is important to the future of the BWC. Success, however, requires the Working Group to identify effective measures, including possibly legally-binding measures, to strengthen and institutionalize the Convention in all its aspects. To develop such effective measures, we all must recognize that the verification challenge for biological weapons is unique in comparison to other classes of weapons of mass destruction (WMD) and warrants a different approach to addressing verification.
4. In this regard, the United States considers it essential that the Working Group distinguish between verification measures and transparency measures. This is not an issue of semantics, rather it is necessary to establish a shared understanding of the specific purposes of these two types of measures. The purpose of any verification measures would be to provide specific information to support a determination, with a significant level of confidence, of



whether activities of a State Party are compliant with the Convention. As noted by the Second BWC Review Conference, the purpose of transparency measures is to prevent or reduce the occurrence of ambiguities, doubts and suspicions and to improve international cooperation in the field of peaceful biological activities. For example, the current BWC confidence-building measures (CBMs) do not constitute verification; instead, they promote transparency.

5. In addition to the threat posed by State-based BW programs, the United States considers it critical that the Working Group also consider and address the bioterrorism threat posed by non-state actors. Promoting and assisting effective national implementation of the Convention is essential to countering bioterrorism and other misuses of biology.

## **I. Promoting Transparency of National Activities**

6. Transparency measures should be one of the key recommendations identified in the report of the Working Group for strengthening implementation of the Convention. The national information provided under such measures can help to prevent or reduce the occurrence of ambiguities, doubts and suspicions and to improve international cooperation in the field of peaceful biological activities.

7. The Working Group should consider recommending measures to achieve consistent implementation of the CBMs and whether, and how, to transform some or all of the current CBM topics into annual, legally-binding declaration requirements. Since many countries currently do not submit annual CBMs or do so only intermittently, transparency measures would be much more effective and beneficial if they were legally mandatory for all States Parties. The current CBM topics are as follows:

- Exchange of information on Biosafety Level 4 (BSL-4) laboratories or highest level of containment;
- Exchange of information on specific national biological defense research and development programs;
- Exchange of information on unusual outbreaks of disease and similar occurrences caused by toxins;
- Encouragement of publications of results and promotion of use of knowledge;
- Declaration of legislation, regulations, and other measures;
- Declaration of past activities in offensive and/or defensive biological research and development programs;
- Licensed vaccine production (for the protection of humans) facilities.

8. Since the current CBMs were conceived over three decades ago, the Working Group should consider what measures do, or would, prevent or reduce the occurrence of ambiguities, doubts and suspicions and thereby build confidence that State Parties are in compliance with the Convention. Such measures should not entail any requirement to disclose national security information or confidential commercial/business information and not impose any undue national implementation burden on States Parties.

## **II. Developing a Verification Toolbox**

9. Biological weapons pose unique challenges for arms control verification and compliance, warranting a different, more tailored approach. These unique challenges derive from the very nature of such weapons and the worldwide spread of biotechnology.

10. Unlike nuclear and chemical weapons, the potential threat posed by biological organisms and toxins has its origin in nature, not human invention. The use of pathogens and toxins as weapons dates back many hundreds of years before the discovery of bacteria or viruses. In the 20th century, early military biological weapons programs harvested pathogens and toxins directly from nature and turned them into weapons. The advent and advance of

modern biology carried with it the potential to develop increasingly sophisticated biological weapons and effective delivery mechanisms. Today, dual-use equipment -- widely available and small in scale - could produce the quantity of agent required for a localized attack or, if a contagious agent was employed, causing a regional epidemic or global pandemic.

11. Further, unlike nuclear and chemical weapons, humanity has responded globally to the natural threat of disease with peaceful public health facilities, research institutes, pharmaceutical facilities, laboratories, and biotechnology centers - all directed at protecting humanity through research, development and production of prophylactic treatments, vaccines, medicines, and other therapies. To combat natural disease threats, these types of facilities often work with dangerous pathogens/toxins and with dual-use technology and equipment intended for peaceful purposes but capable of being exploited for purposes prohibited by the Biological Weapons Convention.

12. In sum, the broad geographic scope, vast scale, complexity, and dual-use character of the global biological landscape impose serious limitations on the ability of any multilateral regime to verify on a routine basis the very wide range of relevant biological facilities and activities. The central challenge for the Working Group is to develop a realistic approach to verification and compliance which fully takes into account the obligations of the Convention and the inherent limitations of the unique dual-use landscape. The obligations of Article I of the Convention prohibit activities based on their purpose. Thus, whether an activity is prohibited depends in large part on the actor's intent. Because biological organisms and toxins, research and development, equipment, and technology can be used for good as well as harm, BW programs and related activities are difficult to detect - posing serious verification challenges.

13. This central reality has direct implications for the utility of routine facility inspections - a common aspect of other WMD arms control regimes. In the context of on-site verification, the United States has concluded that any regime that would periodically inspect biological facilities -- either identified in annual CBM submissions or selected through some other criteria -- would not provide the information needed to verify a State Party's compliance with the Convention. Specifically:

- The number of relevant facilities is vast and growing. There are tens of thousands of facilities worldwide containing dual-use equipment, microbiological production capabilities, dangerous pathogens or toxins, and/or other relevant biological capabilities - which will only continue to increase as biological science and technology advance worldwide;
- Any future BWC implementing organization would only be able to conduct a very limited number of such routine inspections each year;
- For those few facilities inspected, the inherent, dual-use nature of biological activities would pose serious challenges to accurately assessing compliance;
- The verification effectiveness of a routine inspection regime could be easily negated if a State Party simply did not declare facilities engaged in offensive biological weapons activities. Such illicit activities could be conducted in a relatively small and non-descript space, not readily susceptible to external detection.

14. For all these reasons, the United States recommends that the Working Group conduct a process for considering what effective verification measures could be identified in the event a State Party has specific compliance concerns and credible supporting evidence with respect to the activities of another State Party. These additional measures for addressing compliance concerns could constitute a "toolbox" approach to verification specifically intended to address alleged BW programs and other activities prohibited by the Convention, including the use of biological weapons. Approaches that could be considered as part of this toolbox are as follows.

### **Investigation of Alleged Use of Biological Weapons**

15. The Working Group should support consideration by States Parties of measures, to include possible legally-binding measures, to facilitate rapid, credible investigations of alleged use of biological weapons. In this regard, as part of its consideration of how and whether to establish a future BWC implementing organization, the Working Group should explore what technical and logistical capabilities would be needed to conduct such investigations. Further, by facilitating such an investigation, it would also strengthen implementation of Article VII by enhancing the ability to obtain evidence that a State Party has “been exposed to a danger as a result of violation of the Convention” -- the threshold requirement for Article VII. In this regard, given the critical importance of addressing BW use, the Working Group should consider how to authorize and structure support to any such UN investigation when requested by the UN Secretary-General.

### **Concerns about Biological Activities at Facilities**

16. The Working Group should recommend consideration of additional measures for addressing compliance concerns regarding activities at facilities. The BWC prohibits the development, production, stockpiling, or otherwise acquiring or retaining biological weapons - illicit activities which could be pursued at such facilities. However, the biological weapons context faces significant and unique challenges. Such measures must carefully balance appropriate investigatory access with the need for States Parties to protect sensitive national security and confidential commercial/business information. Moreover, it is important to effectively deter and address unfounded, abusive investigation requests.

17. Other arms control agreements contain provisions for addressing concerns about noncompliant activities at facilities. These include detailed procedures for when treaty implementing organizations can conduct an on-site inspection at a facility in response to a specific concern lodged by a State Party. Some agreements also provide for clarification procedures for States Parties, under the auspices of the implementing organization, to address concerns about the noncompliance of another State Party. For purposes of the Working Group, the United States would support a recommendation for further consideration of procedures for addressing compliance concerns regarding activities at facilities. However, given the technical complexities, difficulties in determining intent, and political sensitivities, the type, modalities, and other details of any such procedure would need to be subsequently considered by States Parties.

18. Finally, the Working Group should recommend consideration of the capability to provide upon request on-site technical assistance and technical evaluation to States Parties in implementing the provisions of the Convention. The experience of the Organization for the Prohibition of Chemical Weapons (OPCW) underscores the importance of such technical assistance in implementing the provisions of the Convention.

## **III. Countering Bioterrorism through Effective National Implementation**

19. Preventing the misuse of biology, most critically bioterrorism, should be of central concern to all States Parties. Article IV of the Convention obligates States Parties to take necessary measures to “prohibit and prevent” development and acquisition of biological weapons. To counter any such threats, the Working Group should recommend consideration, with respect to dangerous microorganisms, viruses, and toxins, of national measures to: (1) prevent unauthorized access and misuse, (2) ensure the physical security of laboratories, (3) regulate and control possession and transfer of materials, and (4) ensure oversight and responsible conduct of research.

20. Consistent with UN Security Council Resolution 1540 and Article III of the Convention, the Working Group should also recommend that States Parties enhance national efforts to regulate, through export controls and other measures, transfers to other countries

related to dual-use equipment and dangerous pathogens and toxins as well as other biological materials.

21. The recommendations of the Working Group should note the important connection and synergy between international cooperation and assistance and achieving effective national implementation of UN Security Council Resolution 1540 and Articles III and IV of the Convention.

22. Finally, the United States also recognizes the potential value of voluntary on-site visits offered by a State Party to promote expert exchange partnerships, conduct peer-review of its national implementation measures, and enhance confidence in effective implementation of Articles III and IV.

#### **IV. Enhancing International Cooperation and Assistance**

23. With respect to any future implementing organization, the Working Group should consider how best to structure a mechanism for international cooperation and assistance (ICA) with the following objectives:

- Assisting States Parties in fulfilling their national implementation obligations;
- Enhancing international cooperation and assistance;
- Promoting assistance, response, and preparedness, including under Article VII;
- Promoting the peaceful uses of biology consistent with Article X.

24. With reference to paragraph 18, Part II, of the Report of the Ninth BWC Review Conference, any ICA mechanism established by States Parties could be incorporated into the ICA activities of any future implementation body, if one is established. The United States has actively supported the establishment of an ICA mechanism and, in this regard, co-sponsored an official working paper to the second meeting of the Working Group (BWC/WG/2/WP.3/Rev.1).

#### **V. Institutionalizing Implementation**

25. The OPCW and the International Atomic Energy Agency (IAEA) underscore the fundamental role of an international organization for effective treaty implementation and provide models for the Working Group to consider for institutionalizing implementation of the BWC. To perform the functions outlined above, the Working Group should explore options for institutional structures for promoting the object and purpose of the Convention.

26. Consideration should also be given to the possible establishment of a certified network of national laboratories. Given the overlap between the BWC and the Chemical Weapons Convention regarding toxins, such a network could potentially be formed in partnership with the OPCW.

27. Finally, the United States fully supports the near-term establishment of a scientific and technology review mechanism in accordance with paragraph 19, Part II, of the Final Report of the Ninth Review Conference. Such an S&T mechanism could be incorporated into any future implementing organization.

#### **VI. Achieving the Promise of the Ninth Review Conference**

28. The United States fully supports the mandate and efforts of the intersessional Working Group on the Strengthening of the Convention. The Review Conference directed the Working Group “to complete its work as soon as possible, preferably before the end of 2025.”

29. The year 2025 will be the 100th anniversary of the signing of the 1925 Geneva Protocol and the 50th anniversary of the entry-into-force of the Biological Weapons

Convention. These impending anniversaries are a reminder of our solemn responsibility as States Parties to work towards a world free of biological weapons.

30. As tasked by the Ninth Review Conference, we are committed to working with interested States Parties to successfully establish a mechanism for enhancing cooperation and assistance as well as a mechanism for scientific and technology review by 2025.

31. The United States is further committed to finalizing a report of the Working Group by the end of 2025 which sets out recommendations on measures to support a way forward to strengthen the Biological Weapons Convention and the international norm against the possession and use of biological weapons.

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