Introduction

1. The Biological and Toxin Weapons Convention (BWC) codifies the global norm against the use of biological and toxin weapons and commits States Parties to ensure that biology is only used for the benefit of humankind. The United States attaches great importance to compliance with the BWC by all States Parties. Maintaining and promoting confidence that States Parties are abiding by their commitments is essential to ensuring the stability and integrity of the treaty regime. Because the dual-use nature of biological materials, equipment, and technology makes it very difficult to verify compliance with the BWC, it is even more important to take practical steps to strengthen implementation, enhance transparency, build confidence in compliance, reduce doubts or concerns about States Parties’ actions or intentions, and to constructively address questions when they arise.

2. BWC States Parties have long recognized the need for such steps. The Second BWC Review Conference established a system of annual confidence-building measures (CBMs) and a multilateral consultative process as tools that could be used to address questions or concerns. Both mechanisms were further refined by the Third Review Conference. The Sixth Review Conference endorsed a move to an electronic CBM system and the publication of CBMs on a password-protected website. The Seventh Review Conference made the first substantive changes to the CBM forms in two decades, including streamlining some reporting requirements to encourage participation. Other refinements have been adopted by individual States Parties and have gradually spread; for example, more than one-third of all States Parties submitting CBMs now make their returns accessible to the general public. Despite this progress, the United States believes States Parties should consider further steps to strengthen both the confidence-building and consultative mechanisms.
3. Further steps to strengthen CBMs could provide for both easier access to, and analysis of, relevant information, as well as expanding participation. As the United States noted in a 2012 working paper, "not only should States Parties consider how to increase submission of CBM reports, but also how to make the data they contain more readily accessible and how to encourage States Parties to make constructive use of them. Without these steps, submission of CBMs – even on a universal basis – will be a hollow, ceremonial accomplishment, and do little to achieve the goals for which the CBMs were created."

4. To facilitate use of the consultative provisions of the Convention, a broader range of options and tools for consultation and cooperation under Article V could be developed to assist States Parties to resolve questions and concerns in a cooperative manner. The purpose of these tools would be to further operationalize the flexibility to States Parties inherent in Article V, and thereby make clear that a State Party could invoke Article V in order to clarify a concern through consultations without implying non-compliance with the BWC on the part of another State Party. A wide range of options should make it easier to select the approach most suitable to the circumstances, while not precluding States Parties from escalating a concern quickly if deemed necessary. These tools should facilitate the provision of information that addresses questions a State Party might have. These tools could assist in providing assurance of compliance to States Parties with questions and concerns.

5. With these goals in mind, the United States has identified a number of specific measures that could be considered and agreed to by the Eighth Review Conference or that could be further developed during the next intersessional process. The United States welcomes comments and suggestions on the ideas and recommendations proposed below.

**Consultation and Cooperation**

6. Article V of the BWC provides that "States Parties to this Convention undertake to consult one another and to cooperate in solving any problems which may arise in relation to the objective of, or in the application of the provisions of, the Convention…" and that such consultation and cooperation "may also be undertaken through appropriate international procedures within the framework of the United Nations and in accordance with its Charter." Subsequent Review Conferences have elaborated understandings and procedures designed to provide more detail than is provided in the Article, while preserving its flexibility to States Parties seeking clarification. While this flexibility should be maintained, a wider array of tools to facilitate bilateral and multilateral consultation could empower and encourage States Parties to engage more proactively in consultation and cooperation. Importantly, Article V of the Convention can and should be used not only for concerns about compliance, but also more broadly to resolve questions, clarify concerns, and/or address shared challenges. To facilitate and encourage more widespread use of Article V to address "any problems which may arise…," it can be strengthened in a number of ways. The United States proposes developing potential tools to facilitate consultations, either during the Eighth Review Conference itself or as tasks for the next intersessional period. These potential tools include:

(a) Developing more detailed options for bilateral consultations, including some basic procedures, with timelines, that could be invoked by a State Party when raising a concern. The Second and Third Review Conference documents set out specific procedures for multilateral consultative meetings and also envisaged bilateral engagements. These options for bilateral consultations could be adapted from the relevant provisions in

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1 BWC/MSP/2012/MX/WP.4
Article IX of the Chemical Weapons Convention (CWC); similar provisions are also found in the Comprehensive Nuclear-Test-Ban Treaty (CTBT). This would then provide a range of tools for States Parties seeking clarification, from an informal request for information, to a more formal procedure that, properly framed, would require a response by a certain period of time.

(b) Developing separate, informal procedures to ask questions about another State Party’s CBM submission bilaterally, or perhaps through the ISU. Because CBMs occasionally contain information that is unclear, inconsistent, or conflicts with other information, such questions should be welcomed as an opportunity to educate, and not be a rare occurrence. Seeking clarification of such issues would not carry any implication of suspicion of wrongdoing.

(c) Developing illustrative options or non-binding guidelines for suggested procedures to address concerns. These examples could increase the interest and willingness of States Parties to engage in such consultative procedures.

7. In addition to elaborating upon bilateral and multilateral options available to States Parties seeking to clarify concerns through consultations, the United States proposes that this Review Conference establish an understanding that, where bilateral or multilateral consultations are unsuccessful, a State Party could request the UN Secretary-General to use his or her ”good offices” to seek clarification, coupled with a call on all States Parties to cooperate with any such effort. Such an understanding would essentially serve as an “appeal” function, effectively escalating concern to a higher level if initial consultations are unsuccessful. It should serve to reassure States Parties that there are additional options available if their initial attempts to clarify a concern through consultations are unsuccessful.

Confidence-Building Measures

8. CBMs were established in 1986 as a politically binding commitment ”to strengthen the authority of the Convention and to enhance confidence in the implementation of its provisions.” Submission of annual CBMs is an effective way for States Parties to demonstrate their implementation of the BWC and enhances confidence among States Parties that others are fulfilling their treaty obligations. The CBMs are also one of the BWC’s few available tools to exchange information and facilitate discussions among States Parties. For these reasons, among others, we encourage all States Parties to fulfill their commitments by submitting yearly CBM reports.

9. There is cause for optimism regarding CBM participation. While the average yearly CBM participation rate is 36 per-cent, the rate for the years 2012 through 2016 is 41 per-cent – a full five percentage points higher than the overall rate. And by April 2016, the Implementation Support Unit (ISU) had already received a record-breaking 74 CBM returns. We applaud the increased participation in the CBMs and the increased commitment it demonstrates.

10. At the Eighth Review Conference, the United States seeks to enhance not only participation in BWC CBMs, but also their quality and utility to States Parties. With these objectives in mind, we suggest States Parties explore proposals that would:

(a) Reinforce the decision of the Sixth Review Conference to establish a CBM assistance network, coordinated by the Implementation Support Unit (ISU), to provide expert advice and assistance for States Parties upon request, and urge States Parties in a

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2  BWC/CONF.II/13/II (Second Review Conference Final Declaration)
position to do so to offer and to coordinate assistance, training, translations, and workshops in support of tasks such as compiling and submitting CBMs;

(b) Provide for the further development and ongoing operation and maintenance of the CBM electronic platform, following through on the decision of the Sixth Review Conference. Completing the transition to a fully electronic CBM system would simplify both reporting and analysis, and make the data more useful; and

(c) Further technical refinement of the type and range of information requested in select CBM forms with a view to generating more useful information. For example:

(i) Revising CBM Form A, part 2 (i), which calls for information on national biodefense research programs, to clarify that the request for information includes both military and civilian programs. At present, roughly one-third of the States Parties declaring national biodefense research programs report civilian biodefense research. For the remaining two-thirds of States Parties, it is not clear whether they have construed the request for information to apply only to military programs, or whether they do not have biodefense research programs conducted by civilians aimed at protecting the civilian population.

(ii) Expanding CBM Form E on national implementation measures to provide more information, for example, by adding a request for short descriptions of implementation measures. The current requests consist of a handful of yes/no questions with boxes to be checked, and do not provide sufficient information to make informed judgements regarding the status of BWC implementation by States Parties. Such national implementation measures are fundamental steps to upholding and strengthening the norm against the misuse of biological materials, and critical to guarding against the acquisition and use of biological weapons by both State and non-State actors.

Recommendations

Consultation and Cooperation

11. The Review Conference should agree on an informal procedure, conducted bilaterally or through the ISU, by which any State Party could seek to clarify details of another State Party’s CBM submission.

12. In addition to the procedures already understood to be available to States Parties, as well as the informal procedure specified above, States Parties should also consider incorporating language into the Final Document of the Eighth Review Conference establishing a specific bilateral consultation process that may be used by States Parties. The United States proposes that States Parties include a timeline, taking into account the relevant provisions of the CWC (which provides for the requested State Party to respond to a bilateral request from another State Party or to a request conveyed by the Executive Council within ten days), or the CTBT, which provides for the requested State Party to respond to a bilateral request from another State Party or to a request conveyed by the Executive Council within 48 hours. (Please see footnotes for references to original text; proposed new text appears in bold font.)

(a) The Conference notes the importance of Article V and reaffirms the obligation of States Parties to consult and cooperate with one another in solving any problems which might arise in relation to the objective of, or in the application of the provisions of, the Convention. The Conference reaffirms that: (a) this article provides an appropriate framework for States Parties to consult and cooperate with one another to resolve any problem and to make any request for clarification, which may have arisen in
relation to the objective of, or in the application of, the provisions of the Convention; (b) any State Party which identifies such a problem should, as a rule, use this framework to address and resolve it; (c) States Parties should provide a specific, timely response to any compliance concern alleging a breach of their obligations under the Convention.¹

(b) The Conference affirms that States Parties should make every effort to clarify and resolve, through exchange of information and consultations, any matter which may cause doubt about compliance with this Convention, or which gives rise to concerns about a related matter which may be considered ambiguous. The Conference also reaffirms that the consultation procedures agreed at the Second and Third Review Conferences remain valid to be used by States Parties for consultation and cooperation pursuant to this Article. The Conference reaffirms that such consultation and cooperation may also be undertaken bilaterally and multilaterally, or through other appropriate international procedures within the framework of the United Nations and in accordance with its Charter.²

(c) The Conference decides that any State Party, when seeking to clarify and resolve, through exchange of information and consultations, from another State Party of any matter which the requesting State Party considers to cause doubt or concern about compliance with the Convention, may invoke the following timelines: an initial response to be provided as soon as possible, but in any case not later than X days after the request; and provision of information sufficient to answer the doubt or concern raised, along with an explanation of how the information provided resolves the matter, not later than Y days after receipt of the request.

(d) The Conference reaffirms the right of any two or more States Parties to arrange by mutual consent appropriate procedures to clarify and resolve any matter which may cause doubt about compliance or gives rise to a concern about a related matter which may be considered ambiguous. States Parties decided to develop illustrative options or non-binding guidelines for States Parties to draw upon in seeking clarification, in order to facilitate the process.

(e) The Conference agrees on an informal procedure, conducted bilaterally or through the ISU, by which any State Party could seek to clarify details of another State Party’s CBM submission.

(f) The Conference stresses the need for all States Parties to deal effectively with compliance issues. In this connection, the States Parties agreed to provide a specific, timely response to any compliance concern alleging a breach of their obligations under the Convention. Such responses should be submitted in accordance with the procedures agreed upon by the Second Review Conference and further developed by the Third Review Conference. The Conference reiterates its request that information on such efforts be provided to the Review Conferences.³

13. States Parties should agree to note the potential role of the UN Secretary-General in clarification. Following is suggested language:

The Conference notes that, where bilateral or multilateral consultations are unsuccessful in addressing a concern, a State Party may request the UN Secretary-

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³ This text is a proposed update to part II, paragraph 18 of the Seventh Review Conference Final Document (BWC/CONF.VII/7)
⁴ This text is a proposed update to part II, paragraph 19 of the Seventh Review Conference Final Document (BWC/CONF.VII/7)
⁵ Verbatim text: part II, paragraph 21 of the Seventh Review Conference Final Document (BWC/CONF.VII/7)
General to use his or her good offices to clarify a concern through further consultations, and calls upon all States Parties to cooperate with any such effort.

Confidence-Building Measures

14. With a view to enhancing utility and actual use of CBMs by States Parties, we suggest consideration of two examples for technical refinement of select CBM forms:

(a) Revising CBM Form A, part 2 (i) to clarify that the request for information includes both military and civilian biodefense research and development programs.

(b) Revising CBM Form E to include a request for short descriptions of national implementation measures.

15. We suggest States Parties consider the following elements for possible incorporation in the Final Document of the Eighth Review Conference. (Please see footnotes for references to original text; proposed new text appears in bold font.)

(a) The Conference recognizes the continuing need to increase the number of States Parties participating in the CBMs and calls upon all States Parties to participate annually. The Conference notes that since the Seventh Review Conference, there has been an encouraging increase in the percentage of States Parties submitting their CBMs; however, fewer than half of all States Parties submit reports. The Conference emphasizes the importance of all States Parties meeting this important political commitment, which was established in order to reduce the occurrence of doubts and ambiguities.  

(b) The Conference recognizes the technical difficulties experienced by some States Parties in completing full and timely CBM submissions. The Conference urges those States Parties in a position to do so to provide technical assistance and support, through training or workshops for instance, to those States Parties requesting it to assist them to complete their annual CBM submissions; reaffirms the decision of the Sixth Review Conference directing the ISU to centralize requests and offers of assistance regarding the submission of CBMs; and encourages States Parties to participate in this CBM assistance network.  

(c) The Conference notes the desirability of making the CBMs more user-friendly and stresses the need to ensure they provide relevant and appropriate information to States Parties. Recalling the decision of the Sixth Review Conference to develop an electronic format for CBMs, the Conference emphasizes the importance of completing this task, and decides to provide resources to support the further development and ongoing operation and maintenance of the CBM electronic platform.  

(d) The Conference recalls that the Third Review Conference agreed, "that the exchange of information and data, using the revised forms, be sent to the United Nations Department for Disarmament Affairs no later than 15 April on an annual basis." The Conference reaffirms that the data submitted in the framework of the annual exchange of information should be provided to the Implementation Support Unit within the United Nations Office for Disarmament Affairs and promptly made available electronically by it to all States Parties according to the updated modalities and forms in Annex I. The Conference

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6 This text is a proposed update to part II, paragraph 23 of the Seventh Review Conference Final Document (BWC/CONF.VII/7)

7 This text is a proposed update to part II, paragraph 24 of the Seventh Review Conference Final Document (BWC/CONF.VII/7)

8 This text is a proposed update to part II, paragraph 25 of the Seventh Review Conference Final Document (BWC/CONF.VII/7)
recalls that information supplied by a State Party must not be further circulated or made available without the express permission of that State Party. The Conference notes the fact that certain States Parties made the information they provide publicly available.9
Possibilities for strengthening the international community’s ability to investigate alleged use

Submitted by the United States of America

Why is the ability to investigate alleged use important?

1. Biological weapons are different in important ways from most other types of weapons. Pathogenic materials, once disseminated into the air, water, or food supply, are not readily recognized. Their effects are delayed, with symptoms typically occurring days or even weeks after exposure, and those symptoms may not clearly indicate that those exposed were victims of an attack. This potential uncertainty over whether or not a biological weapons attack has taken place has important implications for the operation of the Convention, particularly for the provision of assistance.

2. Article VI of the BWC provides that:

   “Any State Party to this Convention which finds that any other State Party is acting in breach of obligations deriving from the provisions of the Convention may lodge a complaint with the Security Council of the United Nations. Such a complaint should include all possible evidence confirming its validity, as well as a request for its consideration by the Security Council.”

3. Article VII states that:

   “Each State Party to this Convention undertakes to provide or support assistance, in accordance with the United Nations Charter, to any Party to the Convention which so requests, if the Security Council decides that such Party has been exposed to danger as a result of violation of the Convention.” (Emphasis added)

4. A State Party might suspect that it was the victim of a biological weapons attack, and need assistance, but lack clear evidence. While paragraph 2 of Article VI foresees that the Security Council might call for an investigation in response to such a complaint, there is no requirement for such an investigation, and no common understanding concerning the amount of evidence that would be required to galvanize Security Council action. Thus
uncertainty about whether biological weapons have been used could prevent the assistance obligation of Article VII from being triggered.

The United Nations Secretary-General’s Mechanism for investigations of alleged use

5. In the 1980’s, acting pursuant to a series of General Assembly resolutions, the Secretary-General of the United Nations established a mechanism (often referred to as the Secretary-General’s Mechanism) to investigate claims of chemical or biological weapons use, which has been used to investigate allegations on numerous occasions. Most notably, the mechanism unambiguously confirmed use of chemical weapons on multiple occasions during the Iran-Iraq war, and again in Syria in 2013. The Secretary-General’s Mechanism is the only recognized international tool for investigation of alleged biological weapons use.

6. The Secretary-General’s Mechanism has both strengths and weaknesses. An important virtue is that it can be activated relatively easily: typically, the Secretary-General receives a request for an investigation from a member state, evaluates it, and determines how to proceed. There is no requirement to obtain agreement from the United Nations Security Council or any executive body, which could potentially delay an investigation. This virtue is also a key limitation: absent Security Council action, States are not legally obligated to cooperate with an investigation. Some early investigations were stymied when states refused to permit entry onto their territories; in other cases, there have been significant delays in granting access, making the task of confirming or refuting an allegation much more challenging.

7. Allegations of use have been rare: while this is unquestionably positive, it means that maintaining a standing capability for such investigations is challenging. For a biological weapons investigation, the Secretary-General’s Mechanism would rely heavily on experts and laboratories nominated by UN member states, and on cooperative arrangements the United Nations has entered into with the World Health Organization.

8. Many BWC States Parties have been actively engaged in efforts to support the Secretary-General’s Mechanism through training for nominated experts, workshops, voluntary financial contributions, and other steps. Some States Parties however, have registered concerns about the mechanism, either asserting that Article VI, paragraph 2 of the BWC should be interpreted to mean that any investigation into an allegation concerning a BWC State Party should require action by the United Nations Security Council, or expressing a more general sentiment that BWC States Parties should have a mechanism of their own, rather than relying on other institutions. The former view is inconsistent with past agreements by States Parties, most notably at the Third Review Conference, while the latter seems inconsistent with the text of the BWC itself: both Article VI and Article VII explicitly provide a role for the United Nations and clearly envision a close relationship between the United Nations and the BWC. The infrequency of biological weapons use allegations also suggests that, as a practical matter, it would be unwise to seek to resource and maintain two competing mechanisms – and as long as the BWC continues to lag well behind the United Nations in membership, there can be no serious question of “replacing” the Secretary-General’s Mechanism with a BWC-specific mechanism.

Strengthening the international community’s ability to investigate biological weapons use

9. If the ability to rapidly and effectively investigate allegations of use is important to effective implementation of the Biological Weapons Convention, yet the principal tool for
such investigations resides with the United Nations, what action could the Eighth Review Conference take to strengthen this key capability? Several steps could be considered:

(a) Support for implementation of the International Health Regulations (IHR) and Global Health Security Agenda (GHSA): The Joint External Evaluation Tool—International Health Regulations (2005) (JEE) was published by the World Health Organization in 2016 to assess country capacity to prevent, detect and respond to public health emergencies, regardless of origin. Under the indicator of “Linking Public Health and Security Authorities,” which encompasses the priorities set out in GHSA Action Package Respond-2, countries are given the following target: “In the event of a biological event of suspected or confirmed deliberate origin, a country will be able to conduct a rapid, multi-sectoral response, including the capacity to link public health and law enforcement, and to provide and/or request effective and timely international assistance, including to investigate alleged use events.” The Review Conference could note that building national capabilities to conduct effective joint criminal and epidemiological investigations of suspicious outbreaks will help ensure that international investigations, if required, will be sought at an early stage, and with better underlying information and evidence. Achieving this goal will also build a larger cadre of experts around the world with the experience and skills needed to conduct such an investigation. It is noteworthy that the JEE specifically indicates that States Parties to the IHR should work in collaboration with relevant regional and international entities, including the FAO, INTERPOL, OIE, WHO, the BWC and the Secretary-General’s Mechanism to develop and implement systems to identify, investigate and respond to suspected deliberate biological use events;

(b) Clarify the relationship between the BWC and the Secretary-General’s Mechanism: The Review Conference could articulate a clearer understanding of how the Secretary-General’s Mechanism relates to and reinforces the Convention. In particular, the Review Conference could recognize that the Mechanism could play an important role in implementing provisions of the Convention related to Articles V, VI, and VII. It could be initiated in several ways, all of which are fully consistent with the provisions of the BWC: first, a BWC State Party, or a consultative meeting convened in accordance with the decisions of the Second and Third Review Conferences, could ask the Secretary-General to investigate an allegation pursuant to Article V of the Convention as a means of clarifying a situation involving suspected use: in other words, in such cases, the Secretary-General’s Mechanism constitutes an “appropriate international procedure within the framework of the United Nations.” Second, a State Party could request an investigation in an effort to assemble all possible evidence” before submitting a complaint to the United Nations Security Council. Third, the Security Council itself could mandate an investigation, as provided for under Article VI, paragraph 2;

(c) Support efforts to ensure the operational readiness of the Secretary-General’s Mechanism: the Review Conference could affirm the importance of maintaining a credible international investigative capability, and urge the United Nations Secretary-General to ensure the operational readiness of the Secretary-General’s Mechanism; States Parties could be encouraged by the Review Conference to support the Secretary-General in

1 BWC Article V provides that “consultation and cooperation pursuant to this article may also be undertaken through appropriate international procedures within the framework of the United Nations and in accordance with its Charter.” The Third Review Conference agreed in its review of Article V that “the consultative meeting, or any State Party, may request specialized assistance in solving any problems which may arise through, inter alia, appropriate international procedures within the framework of the United Nations and in accordance with its Charter,” and that in such cases, States Parties will “cooperate in appropriate international procedures within the framework of the United Nations and in accordance with its Charter.”
these efforts. They could also be called upon to update their nominations of experts and laboratories and ensure their availability; and

(d) **Commit in advance to cooperate with an investigation**: Historically, delays by a United Nations Member State in accepting an investigation have been a key factor limiting their success. At the Third Review Conference, BWC States Parties agreed “to cooperate fully with the United Nations Secretary-General in carrying out such [alleged use] investigations.” At the Eighth Review Conference, BWC States Parties could collectively reaffirm their commitment to cooperate with international investigations of alleged biological weapons use, and affirm that this includes their willingness to provide access to an investigation team, consistent with safety and domestic legal constraints.
INTRODUCTION

1. The United States signed the Biological and Toxin Weapons Convention (BWC) on April 10, 1972, and ratified the Convention on March 26, 1975. The United States is in full compliance with all of its obligations under the BWC.

2. The United States is committed to reducing the risks of acquisition or use of biological agents as weapons by either States or non-state actors and to minimizing the consequences of such events should they occur. The United States’ approach, described in the 2009 National Strategy for Countering Biological Threats,1 encompasses improving global access to the life sciences to combat infectious disease regardless of its cause; establishing and reinforcing norms of safe and responsible conduct within the life sciences; improving capacity to prevent, detect, and respond to outbreaks as they occur; and instituting a suite of coordinated activities that collectively help to influence, identify, inhibit, and interdict those who seek to misuse the life sciences.

3. The key elements of U.S. compliance set forth below are intended to underscore multi-faceted domestic measures and are not an exhaustive list of all national-level compliance tools. Further, many measures are mutually reinforcing, fulfill more than one purpose, and touch on more than one BWC article. For example, import and export licensing procedures help guard against misuse of the life sciences and contribute to fulfillment of Article III and IV obligations, but they also promote the fullest possible exchange of equipment, materials, and knowledge for peaceful purposes, in accordance with Article X, by minimizing the risk of diversion for prohibited purposes.

4. As part of being in compliance, effective implementation of the BWC is an ongoing responsibility, rather than a task met by passing a law or issuing a regulation. A State Party must continue to invest adequate resources to implement and enforce laws, regulations, and other measures once adopted. The United States takes a robust and multi-faceted approach to implementing its obligations under the BWC. Implementing legislation and regulations comprise part of the national architecture, but such measures are complemented by an array of mutually reinforcing tools, including policy and other guidance documents, outreach and education, investment, and assistance to achieve the aims of the Convention. Laws and regulations that prohibit and punish violations are necessary, but so are the guidance, policies, and awareness-raising initiatives that prevent violations or other risky behaviors.

5. Moreover, changes in technology, industry, and the nature of the biological weapons threat require States Parties to regularly review laws, regulations, policies, and guidance to ensure they remain relevant and effective. Although the United States considers its approach

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comprehensive, we continue to look for ways to better address the biological weapons threat and improve national implementation of the BWC. Advisory committees, federal and non-governmental studies, mandated review cycles, and other resources and processes are critical components of this process.

6. This paper presents an article-by-article analysis of the United States’ compliance with its obligations under the BWC. Where appropriate, each article below contains one section outlining the fundamental aspects of U.S. compliance, with a principal focus on relevant domestic laws, regulations, and policy documents; and one section addressing how the United States implements each article, highlighting concrete examples of how the United States executes and enforces compliance at the national level. All items in bold text are listed in the appendix at the end of the document.

**ARTICLE I**

**COMPLIANCE**

7. The United States fully complies with its Article I obligations requiring BWC States Parties, “never in any circumstances to develop, produce, stockpile or otherwise acquire or retain: 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; and weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.”

**IMPLEMENTATION**

8. Pursuant to Section 403 of the *Arms Control and Disarmament Act of 1961*, as amended, the Executive Branch of the United States is required to annually assess and report to Congress on, among other things, U.S. adherence to obligations undertaken in arms control, nonproliferation, and disarmament agreements and related commitments.

9. Through its deep-seated legal traditions, commitment to the rule of law, and belief in the importance of arms control agreements to enhance international security, the United States fully complies with its BWC obligations. As a reflection of the seriousness with which the United States views these obligations, it has established legal and institutional procedures to ensure U.S. compliance. Individual agencies within the Executive Branch have established policies and procedures to ensure that plans and programs under those agencies’ purview remain consistent

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2 E.g., the National Science Advisory Board for Biosecurity established by the U.S. Government in 2006 to provide advice, guidance, and leadership regarding biosecurity oversight of dual use research to all Federal departments and agencies with an interest in life sciences research.

3 E.g., the biennial review and republication of the list of select agents and toxins and the revision of the list as necessary by the Department of Agriculture and the Department of Health and Human Services.
with U.S. international obligations. For example, U.S. Department of Defense (DoD) Compliance Review Groups oversee and manage DoD compliance with arms control, nonproliferation and disarmament agreements, and related commitments. Within the Department of Homeland Security’s (DHS’s) Compliance Assurance Program Office, the Treaty Compliance Team reviews DHS-sponsored activities involving biological agents and related surrogates or simulants for compliance with the BWC. Further, the DHS Deputy Secretary chairs a committee that reviews DHS-sponsored activities in appropriate cases, including when such activities may raise potential treaty compliance or perception concerns, and ensures that all DHS programs comply with treaty requirements. Finally, Congress performs oversight functions through committee hearings and budget allocations.

**ARTICLE II**

**COMPLIANCE**

10. The United States fully complies with its Article II obligations. The U.S. offensive biological weapons program was dismantled following President Richard M. Nixon’s 1969 statement renouncing the use of biological weapons and the issuance of National Security Decision Memorandum 35. President Nixon’s statement included the following:

> ...the United States of America will renounce the use of any form of deadly biological weapons that either kill or incapacitate. Our bacteriological programs in the future will be confined to research in biological defense, on techniques of immunization, and on measures of controlling and preventing the spread of disease.

In 1970, the U.S. ban on biological weapons was extended to cover toxins, regardless of their means of production. The dismantlement process was completed prior to entry into force of the Convention on March 26, 1975.

**IMPLEMENTATION**

11. The White House in December 1975 directed the heads of all Executive Departments and Agencies to certify that all activities of those departments and agencies which retain any biological agents and toxins were conducted only for justifiable peaceful purposes; that the total quantities of materials held were committed or reserved solely to those activities; and that any

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6 Office of the White House Press Secretary (Key Biscayne, FL), Statement on Toxins, February 14, 1970, in FRUS, document 189. www.state.gov/r/pa/ho/frus/nixon/e2/83627.htm
weapons, equipment, or means of delivery designed to use biological agents or toxins for hostile purposes or in armed conflict had been destroyed or diverted to peaceful purposes. In March 1976, the certifications were forwarded to the Department of State (DOS) to be retained as part of the permanent record of U.S. compliance with the BWC.

12. The United States reported on past offensive and defensive biological research and development programs dating back to 1941 on Form F of its 1997 Confidence-Building Measure (CBM) submission. There have been no updates to Form F since 1997.

**ARTICLE III**

**COMPLIANCE**

13. The United States fully complies with its Article III obligations through a comprehensive set of legislative, regulatory, and administrative measures to regulate transfers relevant to Article III. These measures include lists of materials and technologies requiring authorization to export, “catch all” controls on unlisted items, and civil and criminal penalties for violations. Further, the U.S. export licensing system evaluates the potential dual-use applications of items; relevant information on the recipient; stated end-use and end-use assurances; and risks of unauthorized misuse, diversion, or retransfer. The guidelines provided in the legislation and regulations described below are designed to limit the risks of proliferation of biological weapons by States and non-state actors.

14. The Export Administration Act of 1979 (EAA), as amended, directs the establishment of “a list of goods and technology that would directly and substantially assist a foreign government or group in acquiring the capability to develop, produce, stockpile, or deliver chemical or biological weapons, the licensing of which would be effective in barring acquisition or enhancement of such capability.” The Export Administration Regulations (EAR) implement the EAA and contain the Commerce Control List required by the EAA. Violations of the EAA, the EAR, or an order, license, or authorization issued thereunder can incur administrative penalties (including civil monetary penalties, denial of export privileges, and exclusion from practice), criminal fines, and imprisonment.

15. The Arms Export Control Act of 1976 (AECA) authorizes the President to “control the import and the export of defense articles and defense services” and to “designate those items which shall be considered as defense articles and defense services for the purposes of this section and to promulgate regulations for the import and export of such articles and services.” The International Traffic in Arms Regulations implement the AECA and contain the United States Munitions List (USML) required by the AECA. Category XIV of the USML covers “Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment.” Violations of the AECA can incur civil monetary penalties and criminal penalties of fines and imprisonment.
16. The **Biological Weapons Anti-Terrorism Act of 1989** (BWATA), as amended, prohibits transfers of “any biological agent, toxin, or delivery system for use as a weapon, or knowingly [assisting] a foreign state or any organization to do so.” The **Intelligence Reform and Terrorism Prevention Act of 2004** prohibits the import, export, direct or indirect transfers, and receipt of the variola virus, except under the authority of the Secretary of Health and Human Services. The **USA PATRIOT**\(^8\) **Act of 2001** prohibits “restricted persons”\(^9\) from transporting select agents in interstate or foreign commerce, possessing select agents in or affecting commerce, or receiving any select agent or toxin\(^10\) that has been shipped or transported in interstate or foreign commerce.

**IMPLEMENTATION**

17. In implementing Article III, the United States rigorously enforces the laws and regulations described above and conducts regular outreach to all stakeholders, including industry and academia. Each year, the Department of Commerce/Bureau of Industry and Security (DOC/BIS) hosts a three-day Update Conference for exporters to learn first-hand from U.S. Government officials about current issues and trends in export control policies, regulations, and practices. It also hosts smaller export control seminars throughout the year and across the country\(^11\) and posts free online trainings in a variety of formats.\(^12\) These resources are aimed at U.S. exporters, but international firms and foreign governments also use them, as they can be useful to understand U.S. requirements related to re-exports, in-country transfers, and other issues.

18. A 2009 presidentially directed\(^13\) review of the U.S. export control system determined that the export control system was overly complicated and redundant and diminished the focus on the most critical national security priorities. As a result, the Administration launched the Export Control Reform Initiative to enhance U.S. national security and strengthen the United States’ ability to counter threats such as the proliferation of weapons of mass destruction. The Administration is implementing the Initiative in three phases. In Phases I and II, definitions, regulations, and policies for export controls will be reconciled and simplified. Phase III will

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\(^8\) Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism  
\(^10\) A select agent or toxin is one that has the potential to pose a severe threat to public health and safety, to animal health or animal products, or to plant health or plant products. They are listed in 7 CFR §331.3 (plants), 9 CFR §121.3 and §121.4 (animals), and 42 CFR §73.3 and §73.4 (public health).  
\(^12\) [http://www.bis.doc.gov/index.php/compliance-a-training/export-administration-regulations-training/online-training-room](http://www.bis.doc.gov/index.php/compliance-a-training/export-administration-regulations-training/online-training-room)  
create a single control list, a single licensing agency, a unified information technology system, and an enforcement coordination center.\textsuperscript{14}

19. Either the DOC or DOS reviews each license application, keeping in mind both accuracy and timeliness. For example, between 2010 and 2014, DOC/BIS received an average of nearly 25,000 applications per year for tangible items, software, and technology, and 1 percent or fewer of these applications were denied. DOC/BIS’s average processing time per application has fallen to a low of 23 days, 67 days below the required completion time of 90 days per the EAR and Executive Order 12981.\textsuperscript{15,16}

20. The DOC and DOS also conduct targeted end-use checks before and after approving licenses and after shipments have been made. These checks serve to increase confidence and cooperation; expedite future requests; facilitate transfer of more advanced technology; prevent diversions; protect end-users from untrustworthy intermediaries; foster communication among the U.S. Government, recipient country, and industry; establish an expectation of due diligence by exporters and importers; and educate industry on laws and regulations.

21. The usefulness and necessity of such checks to maintaining the integrity of the export control program are proven by the high occurrence of unfavorable findings. Of the 3,609 end-use checks completed by the DOS’s Blue Lantern End-Use Monitoring Program from 2011-2015, 21 percent were deemed unfavorable, meaning that the findings of fact were not consistent with information in the license application. The most common causes of unfavorable determinations in 2015, accounting for 85 percent of such determinations, were the discovery of derogatory information concerning the end user, refusal to cooperate, unauthorized retransfer or re-export, and the involvement of a foreign party in the transaction that is not listed on the license or application.

**ARTICLE IV**

**COMPLIANCE**

22. The United States fully complies with its Article IV obligations through laws, regulations, and other measures designed to prohibit and prevent the development, production, stockpiling, acquisition, or retention of items specified in Article I. Mr. Christopher Park, Director, Biological Policy Staff, DOS, is the U.S. Designated National Authority for implementation of the Convention.

23. In addition to prohibiting transfers of biological agents, toxins, or delivery systems, the BWATA, as amended, prohibits knowingly developing, producing, stockpiling, acquiring,

\textsuperscript{14} http://2016.export.gov/ecr/
retaining, or possessing any biological agent, toxin, or delivery system for use as a weapon, or knowingly assisting a foreign state or any organization, including terrorist organizations, to do so. Similarly, the Intelligence Reform and Terrorism Prevention Act of 2004 prohibits the use, production, engineering, synthesis, acquisition, or possession of variola virus, except under the authority of the Secretary of Health and Human Services. The USA PATRIOT Act also prohibits possession by any individual of a “biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose.” The USA PATRIOT Act further prohibits placing a biological agent or toxin for use as a weapon on a mass transportation vehicle and setting fire to a biological agent or toxin near a mass transportation facility.

24. A 1999 statute (Public Law 106–54) prohibits teaching or demonstrating the making or use of a weapon of mass destruction, or distributing information pertaining to the manufacture or use of a weapon of mass destruction, with the intent that the teaching, demonstration, or information would be used for a federal crime of violence. The USA PATRIOT Improvement and Reauthorization Act of 2005 prohibits transportation of biological materials within U.S. jurisdiction with the intent to commit a crime. The Violent Crime Control and Law Enforcement Act of 1994 prohibits the use of weapons of mass destruction, including threatening, attempting, or conspiring to use weapons of mass destruction.

25. The Antiterrorism and Effective Death Penalty Act of 1996 directed the creation of a list of biological agents with the potential to pose a severe threat to public health and safety and the creation of the Select Agent Regulations to ensure proper biosafety and biosecurity measures for those agents. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agriculture Bioterrorism Protection Act of 2002 give the Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) the authority to implement the Federal Select Agent Program (FSAP). The USDA, through the Animal and Plant Health Inspection Service, regulates select agents and toxins of concern to plant health or plant products and to animal health or animal products. The HHS, through the Centers for Disease Control and Prevention (CDC), regulates select agents and toxins of concern to public health and safety.

26. The FSAP and associated regulations contribute to U.S. compliance with Article IV by helping to secure especially dangerous pathogens and prevent their unauthorized possession, loss, theft, misuse, diversion, or release. Entities seeking to work with a select agent or toxin must register with the applicable department (HHS or USDA, depending on the agent or toxin). The Select Agent Regulations also cover biocontainment; biosafety; biosafety and security training; and facility, personnel, and shipment security requirements for an entity required to register to possess, use, or transfer select agents and toxins, including specific requirements for
Tier 1 select agents and toxins. The USA PATRIOT Act prohibits a “restricted person” from shipping or possessing a select agent or toxin. The Department of Transportation prescribes technical regulations for shipping hazardous materials, including select agents and toxins.

27. Enhancing a national biosafety and biosecurity system that protects scientists, healthcare workers, and the public from exposure to harmful pathogens is a critical part of the United States’ efforts to conduct state-of-the-art life sciences research and to make new lifesaving treatments, vaccines, and diagnostics widely available. Over the past two years, the United States has conducted a comprehensive review of its biosafety and biosecurity enterprise. Experts from within and outside of the Federal Government reviewed the current system, discussed recent incidents, identified best practices for the future, and urged implementation of a set of recommendations published on October 29, 2015.

28. The recommendations highlight several key principles for the national biosafety and biosecurity system, including: transparency, swift incident reporting and accountability to the public, and material stewardship that includes strong inventory management and control measures. These principles emphasize a commitment to protecting Americans and the global community, and ensuring a system designed to prevent dangerous actors from accessing or misusing sensitive biological material. In addition, while the focus of the recommendations is aimed at facilities that possess, use, or transfer the most dangerous agents, these principles should also be applied to work that is conducted with any biological agent that could pose a serious threat to public health or agriculture.

29. In addition, in 2014, thousands of facilities across the United States underwent intensive internal assessments as part of a “Safety Stand-Down.” This effort resulted in a review of laboratory biosafety and biosecurity best practices and protocols, as well as plans for more consistent inventory monitoring. By continuing to review inventories, laboratory safety procedures, and security best practices, facilities can help achieve a laboratory culture of responsible conduct. Therefore, the U.S. Government continues to strongly encourage the application, at non-Federal as well as Federal facilities, of core principles, best practices, and the recommendations released on October 29, 2015.18

30. The U.S. Government maintains national policy that prescribes processes and procedures for the U.S. Government and U.S. Government-funded research, including classified life sciences research. Agencies that fund, direct, or execute classified life sciences research are required to implement processes to ensure activities comply with applicable law, standards, regulations, policies and international legal obligations.

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17 Tier 1 select agents and toxins are those “biological agents and toxins [that] present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety” (www.selectagents.gov/faq-general).
18 https://www.whitehouse.gov/blog/2015/10/29/national-biosafety-and-biosecurity-system-united-states
31. The U.S. Government has issued two policies for oversight of life sciences dual-use research of concern (DURC) to “preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.” The 2012 United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern\(^{19}\) requires U.S. federal departments and agencies that fund life sciences research to identify and manage the risks associated with certain types of DURC, while the 2014 United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern\(^{20}\) complements the 2012 policy by establishing institutional review processes and oversight requirements for institutions receiving federal funding for life sciences research. Together, the two policies support U.S. compliance with Article IV by engaging life sciences research institutions and federal funding agencies in shared responsibility to address the risk that knowledge, information, products, or technologies generated by DURC could be used for harm.

32. The U.S. Government advocates and conducts regular reviews of advances in science and technology to ensure its policies are sufficient to address potential risks. In October 2014, the U.S. Government announced a pause in new funding for gain-of-function (GOF) research on influenza, Middle East Respiratory Syndrome (MERS), or Severe Acute Respiratory Syndrome (SARS) viruses until completion of a deliberative process to review the risks and benefits of such research.\(^{21}\) As part of the process, the National Science Advisory Board for Biosecurity was charged to advise the U.S. Government on risk and benefit assessments for GOF research. Its recommendations on a conceptual approach to the evaluation of proposed GOF research were provided to the U.S. Government in May 2016.

IMPLEMENTATION

33. Awareness-raising initiatives are designed to maximize compliance with laws, regulations, and national policies. Examples include online FSAP resources for training and compliance assistance and guidance,\(^{22}\) resources on implementation of the 2014 policy on institutional oversight of dual-use research of concern,\(^{23}\) and additional guidance such as *Biosafety in Microbiological and Biomedical Laboratories (BMBL),*\(^{24}\) *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules,*\(^{25}\) and *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA.*\(^{26}\)

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22 [http://www.selectagents.gov/resources.html](http://www.selectagents.gov/resources.html)
26 [http://www.phe.gov/Preparedness/legal/guidance/syndna/Pages/default.aspx](http://www.phe.gov/Preparedness/legal/guidance/syndna/Pages/default.aspx)
34. The U.S. Government also hosts workshops and other public events related to FSAP and the DURC policies. For example, the 2\textsuperscript{nd} and 3\textsuperscript{rd} USDA Agricultural Research Service International Biosafety and Biocontainment Symposia in 2013 and 2015 included sessions on the Select Agent Regulations, personnel reliability programs, building a culture of responsibility, bioterrorism awareness, biorisk management, global health security, and other topics related to biosafety and biosecurity.\textsuperscript{27, 28} The U.S. Government also sponsored international participants to attend the Symposia. In 2015 the U.S. Government hosted a public Stakeholder Engagement Workshop, attended by nearly 200 domestic and international stakeholders, to improve communication about the 2014 institutional DURC policy.\textsuperscript{29}

35. Investigation and prosecution of violations of BWC-related criminal statutes demonstrate U.S. implementation of its Article IV obligations. The Federal Bureau of Investigation (FBI) maintains capabilities to investigate allegations of activities prohibited by BWC-related criminal statutes, and the Department of Justice prosecutes violations of BWC-related criminal statutes. Below are examples of recent prosecutions of violations and attempts to violate statutes that demonstrate investigatory capabilities and successful enforcement of the criminal statutes.

- Cheng Le was sentenced on March 8, 2016, to 192 months’ imprisonment stemming from his efforts to obtain and then sell ricin for use as a weapon. Le attempted to purchase ricin through the dark web and revealed his intent to resell the ricin to at least one secondary buyer.
- Jesse Korff was sentenced on February 18, 2015, to 110 months’ imprisonment for developing, stockpiling, and transferring ricin and abrin, attempting to export the toxins, and conspiracy to kill or injure persons in a foreign country. Korff made biological toxins for use as weapons and was selling them over the internet, knowing the buyers intended to use them to kill other people.
- Jeff Boyd Levenderis was convicted on June 4, 2014, of possessing ricin for use as a weapon, of possessing ricin of an unauthorized type or quantity without justification, and of two counts of making false statements to agents of the Federal Bureau of Investigation. Levenderis was sentenced to six years’ imprisonment.
- James Everett Dutschke pleaded guilty on January 23, 2014, to developing and possessing ricin for use as a weapon and mailing ricin-laced letters to the President of the United States, a U.S. Senator, and a Mississippi Justice Court judge. Dutschke was sentenced to 300 months’ imprisonment and 5 years of supervised release.
- Ray H. Adams and Samuel J. Crump were convicted on January 17, 2014, of possessing and conspiring to possess ricin for use as a weapon and later each sentenced to ten years’ imprisonment and five years’ supervised release.

\textsuperscript{27} http://arssymposium.absa.org/past-symposia/2013-program/
\textsuperscript{28} http://arssymposium.absa.org/past-symposia/2015-program/
\textsuperscript{29} http://www.phe.gov/about/OPP/DURCworkshop/Pages/default.aspx
• Shannon Guess Richardson pleaded guilty on December 10, 2013, to possession of a toxin for use as a weapon and was sentenced to 216 months’ imprisonment and ordered to pay $367,222.29 in restitution.


ARTICLE V

COMPLIANCE

37. The United States fully complies with its Article V obligations and believes that maintaining and promoting confidence that States Parties are abiding by their commitments is essential to ensuring the stability and integrity of the Convention. This obligation is a useful tool for fulfilling States Parties’ mutual responsibilities of building a shared confidence in compliance with the BWC. Rather than stigmatizing the entities or activities about which questions are raised, regular cooperative bilateral and multilateral consultations can improve communications among States Parties and increase transparency.

38. In the interest of promoting transparency and confidence, the United States submitted working papers to BWC meetings on its Select Agent Regulations, its policies on oversight of life sciences dual-use research of concern, and its policies on high-containment laboratories and, at the 2015 Meeting of Experts, provided a representative from the DoD to respond publicly to questions about shipments of incompletely inactivated Bacillus anthracis from a biodefense facility and follow-on corrective actions.

IMPLEMENTATION

39. The United States supports a broad range of efforts to strengthen implementation and enhance transparency and assurance of compliance with the BWC.

40. First, the United States submits annual confidence-building measures (CBMs) as agreed by the Second Review Conference in 1986 to “prevent or reduce the occurrence of ambiguities, doubts, and suspicions” and makes them publicly available through the ISU website. The United

States considers annual CBM participation an effective way for States Parties to demonstrate their implementation of the BWC and to enhance confidence among States Parties that others are fulfilling their obligations. Submission of annual CBM returns is a politically binding commitment and, accordingly, the United States has submitted a CBM every year since 1987.

41. Second, the United States supports efforts to enhance transparency of biological defense programs using CBMs and other tools and takes efforts to be responsive to others’ concerns. For example, in 1997 the United States participated in consultations with Cuba regarding questions of U.S. compliance. More recently, in 2016 the United States and the Russian Federation engaged on matters of U.S. compliance and implementation of the BWC. These consultations can provide a constructive framework to address both broad implementation challenges that affect many States Parties and specific questions and concerns in a cooperative manner.

42. Finally, affirming the value the United States places on voluntary initiatives that demonstrate transparency and build confidence in compliance, the United States has partnered with Canada, Chile, Ghana, and Mexico on a BWC Implementation Review project. The purpose of the exercise is to strengthen national implementation and promote transparency among the participating countries. The concept for the project involves exchanging reports on measures to implement the Convention and holding meetings of experts in each capital to discuss the implementation measures in the reports.

ARTICLE VI

COMPLIANCE

43. The United States fully complies with its Article VI obligations. The United States has not lodged a complaint with the United Nations (UN) Security Council (UNSC) but has taken steps to demonstrate its intent to support and cooperate with an investigation by the UN Secretary General’s Mechanism (UNSGM) on U.S. territory.

IMPLEMENTATION

44. One example of implementation of Article VI obligations is the strong U.S. commitment to facilitating investigations of alleged use of biological weapons. In particular, at the Third Review Conference, BWC States Parties agreed “to cooperate fully with the United Nations Secretary General in carrying out such [alleged use] investigations.” In support of this agreement and in recognition that the only realistic tool for an investigation of alleged biological weapons use is the UNSGM, the United States committed to cooperating with an investigation in a letter to the UN Secretary General dated April 4, 1991. In the letter, the United States pledged “to cooperate fully with you in your investigation of such reports [of possible use of chemical, biological, and toxin weapons in violation of international law], consistent with safety and domestic legal constraints. Such cooperation would include receiving a team of qualified experts on U.S. territory should you have occasion to request such an investigation.”
The United States also contributed to developing the capabilities of the UNSGM by holding a workshop in 2016 in cooperation with the UN Office for Disarmament Affairs (UNODA). Participants at the workshop exchanged ideas to build a strategy for helping UNODA improve its capability to conduct investigations of alleged biological weapons use.

**ARTICLE VII**

**COMPLIANCE**

46. The United States is prepared to comply with Article VII should it be invoked. Specifically, the United States has capabilities to provide and to support international assistance, including technical, public health, and medical assistance, to a requesting State Party deemed to have been exposed to danger as a result of violation of the Convention.

47. Additionally, the United States complies with Article VII by supporting efforts to strengthen the UNSGM to investigate allegations of biological weapons use. The UNSGM has significance for Article VII, in addition to the relevance to Article VI discussed above. For instance, if a State Party believes it has been exposed to danger as a result of a violation of the Convention, but lacks the technical capabilities or capacities to produce the evidence needed to present its case to the UNSC, then the UNSGM could assist this effort.

**IMPLEMENTATION**

48. U.S. efforts to strengthen implementation of Article VII have focused on ensuring an efficient, effective response to an outbreak at the earliest possible point and on ensuring that transition to formal activation of Article VII provisions is seamless and complementary to any ongoing public health or animal health response.

49. Specifically, the U.S. Government maintains capabilities within multiple Departments and Agencies, including HHS, CDC, and the U.S. Agency for International Development’s Office of U.S. Foreign Disaster Assistance, among others, to support international assistance. The U.S. Government also maintains relationships with private sector and non-governmental organizations to request their assistance to supplement and otherwise amplify these capacities, if needed.

50. Recognizing that key capabilities must be in place within both sending and receiving countries in order for international assistance to be effective, the United States supports implementation of the International Health Regulations (2005), which oblige nations to develop capacity to respond to public health emergencies of international concern, and the Global Health Security Agenda, which facilitates building the capacity of nations to respond to human and animal infectious disease events. The United States also recognizes the integral role of international agreements, initiatives, and organizations committed to enhancing preparedness.
and response efforts for humanitarian disasters and public health emergencies, including the G7 Global Partnership Against the Spread of Weapons and Materials of Mass Destruction.

51. Though the UNSGM has investigated and confirmed cases of chemical weapons use, it has never been used to investigate an allegation of biological weapons use. The capability should be developed and maintained so that, like domestic response capabilities, it is ready and able to carry out its mission should the UN Secretary General decide it is needed. The United States is working with UNODA and other concerned States and international organizations to strengthen the capability and capacity of the UNSGM. The United States has participated in workshops to develop the network of laboratories that would be available to test samples and in April 2016 hosted a workshop with policy, technical, and field experts to develop a collaborative strategy for contributing to a basic operational capacity within two years.

ARTICLE VIII

52. The United States fully complies with its obligations under the 1925 Geneva Protocol. The United States signed the Protocol on June 17, 1925, and deposited its instrument of ratification on April 10, 1975. At that time, there was no ban on the possession or stockpiling of chemical weapons. The U.S. reservation to the Protocol, which applied only to “the use in war of asphyxiating, poisonous or other gases, and of all analogous liquids, materials, or devices,” was intended to deter the use of chemical weapons against the United States or its allies.

53. On May 13, 1991, during the Chemical Weapons Convention negotiations, President George H.W. Bush announced that “[t]o demonstrate the United States commitment to banning chemical weapons, we are formally forswearing the use of chemical weapons for any reason, including retaliation, against any state, effective when the Convention enters into force.” This pronouncement and our obligations as a State Party to the Chemical Weapons Convention prohibit all activities that were reserved under the Protocol and such legal obligations apply, despite existence of the reservation.

ARTICLE IX


ARTICLE X

55. The United States fully complies with its Article X obligations. Through Article X activities, the United States envisions building two international norms. First, participation in the “exchange of equipment, materials and scientific and technological information” should be encouraged to improve biosecurity and work actively against the proliferation of biological

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weapons. Second, “the further development and application of scientific discoveries…for disease prevention and other peaceful purposes” are essential to working actively toward improved quality of life for all. Specifics on U.S. activities under Article X can be found in the Article X paper submitted by the United States to the Implementation Support Unit in advance of the Eighth Review Conference.
APPENDIX: SUMMARY OF LAWS, REGULATIONS, POLICIES, AND OTHER DOCUMENTS

LAWS (IN CHRONOLOGICAL ORDER)

- **Arms Control and Disarmament Act of 1961**
  - Requires the President to submit reports to Congress on the status of U.S. policy and actions with respect to arms control, nonproliferation, and disarmament

- **Arms Export Control Act of 1976**
  - Authorizes the President to control the export of defense articles and services

- **Export Administration Act of 1979**
  - Authorizes the Department of Commerce to regulate the export or re-export of U.S.-origin dual-use goods, software, and technology

- **Biological Weapons Anti-Terrorism Act of 1989**
  - http://thomas.loc.gov/cgi-bin/query/z?c101:S.993.ENR:
  - Prohibits knowingly developing, producing, stockpiling, transferring, acquiring, retaining, or possessing any biological agent, toxin, or delivery system for use as a weapon, or knowingly assisting a foreign state or any organization, including terrorist organizations, to do so

- **Violent Crime Control and Law Enforcement Act of 1994**
  - https://www.gpo.gov/fdsys/pkg/BILLS-103hr3355enr/pdf/BILLS-103hr3355enr.pdf
  - Prohibits the use of weapons of mass destruction, including threatening, attempting, or conspiring to use weapons of mass destruction

- **Antiterrorism and Effective Death Penalty Act of 1996**
  - Directed the creation of a list of biological agents with the potential to pose a severe threat to public health and safety and the regulation of biosafety and biosecurity measures for those agents

- **USA PATRIOT Act of 2001**
- Establishes penalties for the unauthorized possession or transfer of biological select agents and toxins, and restricts the persons who can have access to listed biological select agents and toxins

- **Public Health Security and Bioterrorism Preparedness and Response Act of 2002**
  - Authorizes the regulation of the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety

- **Agriculture Bioterrorism Protection Act of 2002**
  - Authorizes the regulation of the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products

- **Intelligence Reform and Terrorism Prevention Act of 2004**
  - Prohibits knowingly producing, engineering, synthesizing, acquiring, transferring directly or indirectly, receiving, possessing, importing, exporting, or using, or possessing and threatening to use, variola virus, except under the authority of the Secretary of Health and Human Services

- **USA PATRIOT Improvement and Reauthorization Act of 2005**
  - Prohibits transportation of biological materials within U.S. jurisdiction with the intent to commit a crime

**REGULATIONS (IN ALPHABETICAL ORDER)**

- **Export Administration Regulations**
  - Implement authorities in the Export Administration Act of 1979, as amended

- **International Traffic in Arms Regulations**
  - http://www.ecfr.gov/cgi-bin/text-idx?SID=7f87f58daca8205a719c8aa090640178&mc=true&tpl=/ecfrbrowse/Title22/22CISubchapM.tpl
  - Implement authorities in the Arms Export Control Act of 1976

- **Select Agent Regulations**
Implement relevant sections of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Bioterrorism Protection Act of 2002

**POLICIES (IN ALPHABETICAL ORDER)**

- **Executive Order 12981**
  - [Details](https://www.gpo.gov/fdsys/pkg/FR-1995-12-08/pdf/95-30106.pdf) procedures for export license application submitted under the Export Administration Regulations

- **National Security Decision Memorandum 35**
  - [Details](https://history.state.gov/historicaldocuments/frus1969-76ve02/d165) Renounced the use of biological weapons by the United States

- **National Strategy for Countering Biological Threats**
  - [Guides](http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf) U.S. Government efforts to prevent bioterrorism incidents by reducing the risk that misuse of the life sciences will result in the use of biological agents to cause harm and complements existing preparations to advance U.S. abilities to respond to public health crises of natural, accidental, or deliberate origin

- **United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern**
  - [Addresses](http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf) institutional oversight of DURC, which includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented

- **United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern**
  - [Details](http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf)
Establishes regular review of U.S. Government-funded or -conducted research with certain high-consequence pathogens and toxins for its potential to be Dual Use Research of Concern (DURC) in order to mitigate risks as appropriate and collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC.

**GUIDANCE (IN ALPHABETICAL ORDER)**

- **Biosafety in Microbiological and Biomedical Laboratories (BMBL)**
  - Details the code of practice for biosafety and biocontainment in the United States

- **NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules**
  - Details safety practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules

- **Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA**
  - Aims to reduce the risk that synthetic DNA will be deliberately misused to create dangerous organisms

  - Developed to facilitate the use of resources and maximize communication and interaction among law enforcement and public health in an effort to minimize potential barriers during a response to a biological threat
U.S. Remarks at the 7th Annual International Symposium “Biosecurity and Biosafety: Future Trends and Solutions”

Round Table 5: International Conventions: The contribution to Biosecurity

Milan, Italy
March 24, 2017

Opportunities to Strengthen the BWC

Let me begin by reflecting on U.S. views on the outcomes of the recent Biological and Toxin Weapons Convention (BWC) Review Conference that took place this past November.

While the United States regrets that the BWC Review Conference fell short of reaching agreement on a substantive program of work for the inter-sessional process, I believe it is important to emphasize the United States does not doubt the strength of the Convention, nor does it believe the international arms control and nonproliferation regime was diminished by the outcome.

In fact, the United States recognizes the widespread support by delegations at the Review Conference for a more active and productive BWC intersessional work plan and will continue to work in this direction. We also strongly support other activities that can strengthen the Convention, even in the absence of a formal BWC intersessional work plan.

So what is the course of action following the Review Conference?

Like many other delegations, the United States put forward a number of proposals in advance of the Review Conference, which provided a way forward to strengthen efforts to enhance safety and security in the biological field and implementation of the Convention. One such proposal was highlighted in the U.S. working paper submitted to the BWC Review Conference (RevCon) and entitled, “Strengthening Confidence-Building and Consultative Mechanisms Under the Biological Weapons Convention.”

Considering the great importance the United States attaches to compliance with the BWC by all States Parties, this working paper highlights our believe that

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strengthening and promoting greater use of the consultative mechanisms and tools under Article V is an important step for resolving questions or clarifying concerns about confidence-building measures and compliance with the Convention. The goal is to offer a range of options to States Parties and to destigmatize engagement under Article V. Over the years, the United States has supported efforts to enhance transparency of biological programs using CBMs and other voluntary transparency measures and has taken efforts to be responsive to the concerns of other States Parties. As highlighted in the United States compliance statement to the 2016 BWC Review Conference, in 1997 the United States participated in consultations with Cuba regarding questions of U.S. compliance. And more recently, in 2016, the United States and the Russian Federation have engaged on matters of U.S. compliance and implementation of the BWC. Based on our experience, such consultations can provide a constructive framework to address both broad implementation challenges that affect many States Parties and specific questions and concerns in a cooperative manner.

Representing a bureau that has the lead in compiling a congressionally mandated report assessing U.S. and other nations’ adherence to obligations undertaken in arms control, non-proliferation and disarmament agreements and related commitments, and as the main drafter of the BWC section, the United States will undertake significant efforts to engage States Parties, as appropriate, on findings in the report relating to BWC compliance matters in 2017.

**Possibilities for strengthening the UNSGM**

In terms of other contributions to strengthen the BWC, the United States is strongly committed to strengthening the international community’s ability to investigate any use of biological weapons. It’s clearly a good thing that BW use has been alleged so rarely, but maintaining a standing capability for such investigations is challenging. In another U.S. BWC RevCon working paper titled: “Possibilities for strengthening the international community’s ability to investigate alleged use,” the United States discusses the importance of being able to rapidly and effectively investigate allegations of use.

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2 [http://www.unog.ch/80256ee600585943.nsf/htmlPages/57a6e253edfb1111c1257f39003ca243?OpenDocument&ExpandSection=4#Section4](http://www.unog.ch/80256ee600585943.nsf/htmlPages/57a6e253edfb1111c1257f39003ca243?OpenDocument&ExpandSection=4#Section4) (U.S. Compliance with the BWC)

In this paper, the United States offered several steps for consideration. I will focus my remarks here on efforts needed to ensure the operational readiness of the UN Secretary General’s Mechanism (UNSGM). In 2016, the United States contributed to developing the capabilities of the UNSGM by holding a workshop in cooperation with the UN Office for Disarmament Affairs (UNODA). Participants at the workshop exchanged ideas to build a strategy for helping UNODA improve its capability to conduct investigations of alleged biological weapons use. Since the Amerithrax investigation of 2001, the United States government continues to make significant investments in scientific activities (such as microbial forensics) and thus has an interest in understanding how scientific conclusions will be accepted as a source of truth and validity. In 2017, the United States will set out to review ways we can propose to strengthen the capability to investigate biological weapons attack. While we work on specific steps internally, we hope to work with other States Parties on the “action plan for a robust analytical laboratory system” developed by the Friends of the Mechanism. In particular, we are interested in developing a plan for promoting the credibility, consistency, and reliability of laboratory results in support of UNSGM investigations. We also believe there may be a need for further workshops on the role of microbial forensic methods in investigating biological weapons and options for ensuring the credibility and reliability of results.

Conclusion

To leave you with some final thoughts, in our view, the future of the BWC itself is still sound and, as noted in Ambassador Robert Wood’s closing statement at the Conference; there is still a chance for States Parties to agree on a meaningful program of work at the end of this year. Nevertheless, we believe that collaborative work among States Parties, to strengthen biosecurity, confidence building and consultative mechanisms, and the UNSGM, among other areas, can and should continue, with or without a formal BWC intersessional work plan.