

Ninth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

21 November 2022

English only

Geneva, 28 November to 16 December 2022

Item 12 of the provisional agenda

Follow-up to the recommendations and decisions of the Eighth Review Conference and the question of future review of the Convention

Confidence-Building Measures 30 years later – a good time for renewed consideration?

Submitted by the United States of America

I. Summary

1. Established in 1986 and expanded in 1991 by Third Review Conference, the Confidence-Building Measures (CBMs) for the Biological and Toxin Weapons Convention (BWC) have been in place for over 30 years. This working paper reviews their original purpose and identifies some major changes over the last three decades that have implications for the content, quality, and usability of the CBM forms. The United States continues to support strengthening mechanisms to improve confidence in compliance of the BWC and proposes areas to revisit the CBMs in light of dramatic developments since 1991. These areas could benefit from a more deliberate review process, such as by the temporary expert working group proposed by Canada and The Netherlands.

II. The Purpose of Confidence-Building Measures

2. Maintaining and promoting confidence that States Parties are complying with their obligations under the BWC is essential to ensuring the stability and integrity of the Convention. Due to the inherently dual-use nature of some biological materials, equipment, and technology, it is important to continue to take practical steps to strengthen national implementation, enhance transparency, build confidence in compliance, reduce doubts or concerns about States Parties' actions or intentions, and to constructively address legitimate questions when they arise.

3. The Second Review Conference established a system of annual Confidence-Building Measures as one tool for States Parties to achieve these objectives. Specifically, States Parties established the CBMs in 1986 "to strengthen the authority of the Convention and to enhance confidence in the implementation of its provisions" and agreed to implement them "on the basis of mutual co-operation...in order to prevent or reduce the occurrence of ambiguities, doubts, suspicions, and in order to improve international co-operation in the field of peaceful bacteriological (biological) activities."¹

4. The Third Review Conference updated the CBM forms and guidelines, which continue to be the basis for the information contained in CBM reports today. While the Sixth Review Conference endorsed moving to an electronic CBM system and the Seventh Review

¹ [BWC/CONF.II/13/II](#), Second Review Conference Final Document, Article V.



Conference adopted minor amendments to the forms as well as removed one CBM form, the CBMs remain largely unchanged since the Third Review Conference in 1991.

III. Changes since the establishment of BWC Confidence-Building Measures

5. While the CBMs have remained mostly the same over the last 30 years, much has undeniably changed. The Ninth Review Conference brings an opportunity for States Parties to revisit the challenge of enhancing assurances of compliance, including establishing a more deliberate review process for building confidence in compliance. One relevant area for future discussion could be updating the annual CBM forms. The developments since 1991 are significant, including *inter alia*: a growing global biotechnology enterprise, increased non-state actor interest and capability to pursue biological weapons, and the worst pandemic in a century. Some of these have implications that warrant renewed consideration of the CBMs by States Parties as provided in the following illustrative examples:

A. Worst pandemic in over a century: COVID-19

6. In 1991, naturally occurring infectious diseases were already recognized to cross borders, disrupt societies, and challenge global stability. The COVID-19 pandemic demonstrated our shared vulnerability to biological threats, led to an unprecedented level of international scientific cooperation, and exposed areas for every country to improve in protecting against infectious diseases. The impacts felt around the world from COVID-19, which has so far resulted in millions of deaths and trillions of dollars of economic losses globally, once again demonstrate the potential far-reaching consequences of infectious disease outbreaks. Beyond COVID-19, the global community is concurrently fighting outbreaks of monkeypox, polio, Ebola, and highly pathogenic avian influenza, among other infectious diseases. While these outbreaks were not the result of biological weapons, States Parties' preparedness for and responses to them may offer insights into international scientific exchanges envisioned in the provisions of the BWC. For instance, as noted in a recent State Party's working paper, "the pandemic opens up a window of opportunity to strengthen international preventative security networks that are conducive both to the goals of the BTWC and to strengthening international resilience against future pandemics."²

7. International scientific cooperation assists States Parties with pandemic preparedness and outbreak response, but States Parties did not turn to the information in the CBMs, either in Form B or elsewhere, to combat the COVID-19 pandemic. The original purpose of Form D of the CBMs was for States Parties to "exchange information on active promotion of contacts between scientists engaged in biological research directly related to the Convention, including exchanges for joint research on a mutual agreed basis."³ The Seventh Review Conference decided to delete Form D. States Parties have instead been encouraged "to provide at least biannually appropriate information on how they implement this Article [Article X] to the Implementation Support Unit" - a much broader range of information.⁴ Given the lessons that might be learned from the COVID-19 pandemic, particularly in the area of international scientific collaboration, States Parties may wish to revisit ways to facilitate and promote cooperation in areas such as pandemic preparedness, laboratory biosafety and biosecurity, or outbreak response, including through improvements to the existing Article X reports.

² [BWC/MSP/2020/MX.1/WP.5](#).

³ [BWC/CONF.IX/PC/3](#).

⁴ [BWC/CONF.VII/7](#) Seventh Review Conference Final Document.

B. Nature of the biological weapons threat: Rise of bioterrorism, small-scale, and lone actors

8. In 1991, many States Parties focused on the traditional signatures that once characterized a nation state's biological weapons program such as large-scale production enterprises, connection with military programs, or battlefield applications. Over the last three decades, in addition to enduring concerns regarding state biological weapons programs, the international community has seen threats arise from a different set of perpetrators, procurement methods, and applications. For example, the United States experienced anthrax attacks by a lone actor that targeted politicians and news media, Japan experienced attempted anthrax attacks by a religious cult, and terrorist groups have and continue to signal intent to acquire and use biological and toxin weapons. The task of preventing diversion to biological weapons programs is more challenging now than it was in 1991, in light of a number of changes such as: the increased interest in and capability of non-state actors to pursue biological and toxin weapons; the technical possibility of small-scale, low-cost weapons programs aided by the intersect of emerging technologies; and the growing availability of dual-use equipment. Importantly, this changing threat landscape means that a broader array of government ministries may have a role in preventing the proliferation of biological weapons, including, for example, agricultural, environmental, and trade ministries, among others. Over recent years, several working papers from States Parties remark on the expanding roles for multiple government agencies and increasing complexity for national implementation of the BWC.^{5,6,7}

9. States Parties use Form E of the CBMs to provide information regarding national implementation measures, including domestic legislation and regulations. The underlying rationale for Form E was to provide confidence that States Parties were enacting national measures to implement the BWC and to share national measures so that other States Parties can learn from them and/or adapt them to their own national contexts. Taking into account the evolving nature of the biological weapons threat and the broadening role of measures beyond national legislation, States Parties may wish to consider how to make Form E most useful.

C. Spread of a global biotechnology enterprise: Vaccines

10. Thirty years ago, vaccine production was largely performed in nationally based governmental or privately run facilities producing bulk quantities of attenuated or inactivated virus. Today, vaccine production and distribution is no longer limited to national governments nor to nationally based entities. Rather, groups ranging from multi-national pharmaceutical companies to niche biotechnology start-ups and non-governmental foundations, like CEPI,⁸ now work across national borders to innovate and create new vaccines. Furthermore, newer vaccine production technologies can have significant safety and security benefits as they do not rely on live pathogens for vaccine production. These

⁵ BWC/MSP/2020/WP.8 notes "...with the recent dramatic developments in biotechnology, the respective roles of government agencies, the relevant industries, and academia have become more critical for the national implementation of the BWC."

⁶ BWC/MSP/2020/MX.3/WP.3, regarding the National Biorisk Management Committee in Iraq, notes "The communication and coordination between the relevant authorities and the overlapping of roles, responsibilities, and procedures taken by the various institutions constitute another challenge that affects implementation of the procedures in the long term."

⁷ BWC/MSP/2020/MX.3/WP.2 notes "Information about which States Parties may have challenges and in what areas – which could help prioritize specific assistance efforts in response to requests, to promote national implementation where it is needed most – remains difficult to ascertain."

⁸ <https://cepi.net/>.

developments have been the subject of working papers from States Parties over the past several years.^{9,10,11}

11. Form G of the CBMs collects information about vaccine production facilities, both governmental and non-governmental, within its territory or under its jurisdiction or control anywhere, licensed by the State Party for the protection of humans “to further increase the transparency of biological research and development related to the Convention and to broaden scientific and technical knowledge as agreed in Article X.”¹² One rationale for Form G of the CBMs in 1991 was concern that vaccine manufacturing sites represent a latent government capability for biological weapons production. It has also been suggested that States Parties may find value in (1) knowing which vaccines other States Parties prioritize for protecting their own populations and (2) having awareness about available vaccine types and capabilities in other States Parties. Given the global expansion of national and private vaccine production and emerging platforms that reduce the need for large quantities of live or attenuated pathogens, States Parties may wish to revisit whether Form G addresses the intended purpose.

IV. Confidence-Building in the 21st Century

12. States Parties have long expressed a desire to improve the submission rate, quality of information, and the usability of BWC CBMs. The United States continues to support technical refinement of the type and range of information included with a view to generate more directly useful information for States Parties¹³, including:

- Clarifying that the request for information on national biodefense research programs (Form A) includes both military and civilian programs;
- Expanding the level and detail of description provided on national implementation measures (Form E); and
- Including user-friendly explanatory descriptions to the CBM cover sheet (Form 0).

13. Further, the United States continues to support processes to increase the usefulness of BWC CBMs¹⁴, including:

- Developing informal procedures to ask questions about another State Party’s CBM submission that would not carry any implication of suspicion of wrongdoing;
- Supporting a CBM assistance network, including assistance, training, and workshops to assist States Parties’ in completing CBMs as well as supporting translations; and
- Maintaining and improving the CBM electronic platform to simplify both reporting and analysis of States Parties’ CBMs.

14. Beyond these immediate measures, the United States welcomes an in-depth dialogue among States Parties’ experts and analysis of changes over the past three decades that may have implications for the CBMs and other measures to further build confidence and enhance transparency as well as international cooperation and assistance. While this working paper provides illustrative examples, there are likely other areas that warrant study and, thus, States Parties may wish to consider the following general questions:

15. How could the CBM forms and process be made more user-friendly?

⁹ [BWC/MSP/2017/WP.6](#) notes that “pharmaceutical companies are increasingly outsourcing vaccine production processes in whole or in part to contract manufacturers.”

¹⁰ [BWC/MSP/2019/MX.3/WP.4](#) notes that “multinational companies may have their manufacturing operations in a different country from the holders of the marketing authorisations.”

¹¹ [BWC/MSP/2020/MX.2/WP.9](#) notes “The unprecedented level of collaboration in the multinational pharmaceutical industry...led to multiple vaccines authorized for use by numerous countries...less than a year after detection of the novel [SARS-CoV-2] virus.”

¹² [BWC/CONF.III/22/Add.3](#) Third Review Conference Final Document Annex (page 22).

¹³ [BWC/MSP/2018/MX.3/WP.3](#).

¹⁴ [BWC/CONF.VIII/PC/WP.6/Rev.1](#).

- (a) What assistance or processes would improve both participation in and the quality of the content of BWC CBMs?
- (b) How could the information provided in CBMs be made directly useful to States Parties seeking to (a) improve their national implementation or (b) resolve doubts?
- (c) What other information would States Parties find useful to reduce the occurrence of suspicions or to improve international cooperation?
- (d) Is such information amenable to the BWC CBM format or is there another way to approach it?

16. A comprehensive review and analysis of the questions and concerns outlined above certainly warrant more discussion. Toward that end, the United States believes the temporary expert working group proposed by Canada and The Netherlands¹⁵ would provide a suitable forum to consider these issues and provide meaningful recommendations.

¹⁵ [BWC/CONF.IX/WP.2.](#)