
**Meeting 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**

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Item 7 of the provisional agenda

**Standing agenda item: strengthening
national implementation**

National Implementation

Submitted by the United States of America

I. Background

1. The Seventh Review Conference (RevCon) established a standing agenda item on “strengthened national implementation” with five sub-items. National implementation measures have been addressed in previous intersessional meetings in 2003 and 2007. These meetings were successful in developing a number of common understandings about what steps are necessary to effectively implement the Biological and Toxin Weapons Convention (BTWC), while recognizing the need to bear in mind the particular circumstances of an individual State Party.

2. Nevertheless, strengthening national implementation and improving transparency about whether and how States Parties are implementing the Convention remain high priorities, and much work remains to be done. The level of implementation among States Parties is highly variable, and (despite valuable contributions of both the UNSCR 1540 Committee and VERTIC) it remains difficult to clearly understand the status of implementation in many States Parties.

II. Strengthening National Implementation

3. The United States has identified several key areas within the scope of this Standing Agenda Item that merit particular attention—areas where greater agreement among States Parties and concerted efforts could substantially advance international security and the object and purpose of the Convention.

1. Further develop common understandings on the elements required for full implementation of Articles III and IV

4. Beginning with the Fourth Conference of States Parties in 1996, BWC States Parties have consistently recognized the threat posed by non-state actors and the important role of BTWC Article IV in combating this threat. States Parties have agreed that effective national implementation measures are of fundamental importance, and that such measures must be managed, coordinated, enforced, and regularly reviewed to ensure their effectiveness. States Parties have also recognized that such measures should:

- (a) Penalize and prohibit activities that breach any of the prohibitions of the Convention;
- (b) Prohibit assisting, encouraging, or inducing others to carry out such activities;
- (c) Include not only legal measures, but efforts to strengthen relevant national capacities, including those relevant to investigation and prosecution;
- (d) Include effective import and export control systems;
- (e) Address the physical protection of laboratories to prevent unauthorized access to and removal of microbial or other biological agents or toxins, not only through legal and regulatory measures, but through effective enforcement and the use of a range of tools including:
 - (i) accreditation, certification, and auditing or licensing procedures for facilities, organizations, and individuals;
 - (ii) requirements for appropriate training in biosafety and biosecurity;
 - (iii) mechanisms to check qualifications, expertise, and training of individuals;
 - (iv) national criteria for relevant activities; and
 - (v) national lists of relevant agents, equipment, and other resources;
- (f) Be practical, sustainable, and enforceable, appropriate to the context and the risks involved, and developed in concert with national stakeholders;
- (g) Include regular review and updating of lists of agents and equipment relevant to safety, security, and transfer regimes.

5. RevCons have also invited States Parties to consider, to the extent feasible, extraterritorial application of such measures to their nationals, as well as ways and means to ensure that individuals or subnational groups are effectively prohibited from acquiring biological agents for other than peaceful purposes.

6. National measures should also encompass the full range of biological weapons, consistent with the terms of Article I and the understandings reached by past Rev Cons (e.g., that anti-animal and anti-crop agents and synthetic analogs of toxins are encompassed by Article I).

7. It is also noteworthy that, as far back as the Second RevCon, States Parties have consistently recognized the importance of outreach to and engagement with the scientific community as a necessary complement to formal legislative and regulatory action.

8. States Parties should seek to further develop these understandings - specifically, what they imply, how they are best achieved, and what tools, resources, or information would assist States Parties in implementing them. It would also be appropriate to consider

whether any additional understandings would be useful in advancing the goal of effective international implementation of the Convention.

2. Improve Understanding of the Status of Implementation—And Act on It

9. Greater clarity in our shared understandings of what it means to implement the Convention is important in itself; but in today's interdependent world, the security of every BTWC State Party depends in part on the actions of others. It is thus essential that BTWC States Parties enhance their collective understanding of the state of implementation around the world. Constructive proposals have been advanced in this area in recent years, ranging from a BTWC implementation/legislation database to the Canadian/Swiss idea of an "accountability framework" and the French proposal for bilateral "peer review." These ideas appear to have merit, and might even work well in concert. It must remain clear, however, that the purpose of such efforts is not punitive; rather, they are a means of reassuring States Parties that everyone's security needs are being met by their treaty partners, and of identifying gaps and needs, and developing means to redress them. Implementation assistance is a challenging task without clear information on the status of implementation. States Parties should, therefore, agree on means to increase the availability of such information, invite those in need of such assistance to make their needs known, and encourage others to provide such assistance.

3. Take Practical Steps to Strengthen Biosafety and Biosecurity Worldwide

10. Work with dangerous pathogens is being undertaken around the world for a wide range of important, peaceful purposes. The number of high-containment laboratories continues to grow at a rapid pace. These are, in most senses, extremely positive developments – but they are not without risk. For example, every facility working with a given pathogen poses some small risk of inadvertent release – so the greater the number of facilities, the greater the total risk. Such facilities can also be highly resource-intensive, making sustainability a challenge. Finally, the rapid increase in high-containment facilities means that there is a need for wider availability of high-quality training, for risk-assessment tools, and for the development of facility-specific, risk-appropriate standard operating procedures. Regulatory mechanisms are appropriate but by themselves inadequate to address this situation. States Parties should, therefore, emphasize the importance of regulatory or other approaches that require adherence to widely recognized standards of biosafety and security (or biorisk management, as the two together are sometimes referred to); in addition, States Parties should seek to identify the major areas of need for such laboratories (e.g., training materials, reference standards, other tools) and explore collaborative approaches, such as internationally available curricula and training resources.

11. National biosecurity measures include much more than simply preventing theft of biomaterial from a laboratory, however. They include maintaining continuous awareness of threats (coercion, manipulation, illicit solicitation) and conducting activities to prevent biosecurity incidents from both external threats as well as internal threats. These efforts might include:

(a) A pre-suitability check to verify records (accuracy of education, publications, military history, etc.) and determine past issues that may be of concern (criminal history, violent behavior, medical health, etc.);

(b) Maintaining a personnel reliability program to conduct on-going reliability assessments of laboratory staff to ensure staff is suitable to work with pathogens;

(c) Promoting awareness of potential suspicious activities (missing biological material or equipment, odd hours working in laboratory, unsolicited request for technical information, etc.) and a non-attribution reporting mechanism for staff;

(d) Training laboratory staff on violence prevention (termination process training, annual evaluation of workplace stress/concerns, conflict resolution programs, etc.);

(e) Highlighting the benefits of providing a robust employee health and wellness program.

12. Active outreach and engagement between the scientific and security communities could greatly assist the mitigation of the aforementioned biosecurity risks, thereby protecting research endeavors.

4. Promote Action at the Regional and Sub-Regional Levels

13. All of the above areas could benefit from concerted discussion, cooperation, and action at the regional and sub-regional levels, where groups of countries may explore commonalities, areas of need, and solutions. The regional workshops and meetings held during the run-up to the Seventh RevCon illustrated the usefulness of such approaches. States Parties should therefore encourage and promote regional and sub-regional coordination on the issues raised above.

III. Recommendations

14. The 2012 Meeting of States Parties should:

(a) Call upon all States Parties to further elaborate the existing understandings of the core elements required for the full implementation of Articles III and IV.

(b) Urge States Parties to improve understanding of the status of implementation and identify obstacles to achieving comprehensive national implementation.

(c) Urge States Parties to collaborate to offer assistance or training in support of legislative and other implementation measures (including training programs, increased awareness of requirements, and drafting, implementing, and enforcing laws and regulations), particularly at the regional and sub-regional levels.

(d) Call upon States Parties to establish a regular review of progress on national implementation measures.

(e) Urge States Parties to take regulatory or other steps to ensure that laboratories adhere to widely recognized standards of biosafety and biosecurity; including by providing necessary support.

(f) Welcome regional and sub-regional initiatives to address these issues.
