
**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**

7 December 2010
English Only

2010 Meeting

Geneva, 6–10 December 2010

Item 9 of the agenda

**Arrangements for the Seventh Review Conference
and its Preparatory Committee in 2011**

**United States initiatives building on the 2007-2010 BWC
work program**

Submitted by the United States of America

I. Overview

1. The work undertaken by States Parties to the Biological Weapons Convention since the Sixth Review Conference has strengthened both the Convention and international security. The combination of formal meetings engaging the participation of numerous communities and regional and bilateral initiatives on topics relevant to the intersessional Work Program have kept the BWC current and vital, providing the umbrella for diverse activities that work together to counter biological threats.

2. In this last intersessional meeting of the Work Program before the Seventh Review Conference, it is useful to review activities and progress in the areas of the agreed Work Program. The Work Program has been successful not only in bringing together the international community to advance dialogue and cooperation on specific topics but on stimulating action at the national, regional and international level to improve security and enhancing global cooperation. This paper highlights some of the actions the United States has taken in support of Work Program topics outside of the formal BWC meeting process.

<i>BWC Work Program,</i>	
2007 - National Implementation	Enhancing national implementation, including enforcement of national legislation, strengthening of national institutions and coordination among national law enforcement institutions. (2) Regional and sub-regional cooperation on implementation of the Convention.
2008 - Biosafety and Biosecurity	National, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins. (2) Oversight, education, awareness raising, and adoption and/or development of codes of conduct with the aim of preventing misuse in the context of advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention.
2009 - Assistance in infectious disease surveillance	Enhancing international cooperation, assistance and exchange in biological sciences and technology for peaceful purposes, discussed, and promoted common understanding and effective action on promoting capacity building in the fields of disease surveillance, detection, diagnosis, and containment of infectious diseases: (1) for States Parties in need of assistance, identifying requirements and requests for capacity enhancement; and (2) from States Parties in a position to do so, and international organizations, opportunities for providing assistance related to these fields.
2010 - Alleged Use	The provision of assistance and coordination with relevant organizations upon request by any State Party in the case of alleged use of biological or toxin weapons, including improving national capabilities for disease surveillance, detection and diagnosis and public health systems.

II. 2007 – National implementation measures

3. The U.S. has crafted and continues to review and update national measures to implement BWC obligations while ensuring a robust, safe and responsible scientific enterprise and international cooperation. At the core of our national framework is the Biological Weapons Anti-terrorism Act of 1989, which comprehensively prohibits the production and use of biological weapons. Consistent with our BWC obligations, the U.S. adopted laws requiring national measures to secure and account for highly-infectious pathogens and prevent exports from being diverted to the production of biological weapons. These two laws are implemented through national regulations; the Select Agent Regulations (SAR) and the Export Administration Regulations (EAR) respectively. To further assist national implementation, the U.S. has also published guidelines on emerging topics, such as the screening of commercial orders of synthetic DNA and the handling of research involving recombinant DNA.

4. Given the rapid advances in the life sciences and the ever-changing nature of the threat of misuse, the U.S. conducts ongoing review of policies, practices, laws and regulations to ensure that the most appropriate measures are in place. For example, to ensure the necessary safeguards and security measures for biological agents and toxins that pose a severe threat to animal health, plant health, animal products, or plant products, and strengthen the regulatory authorities of the responsible federal agencies the U.S. Government has enacted a series of laws, reviews and updates the SAR on a regular basis with input from the American public, and in 2010 began a major effort to improve and

rationalize our “Select Agent” pathogen security regulations and practices (Executive Order 13546). Additionally, HHS issued the *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA* (2010). These voluntary guidelines reflect the need to strike a balance between regulatory approaches and self-governance within the private sector, and take into account proactive efforts already underway within the industry to address potential biosecurity risks. It establishes a screening framework for use by providers of synthetic nucleic acids to minimize the risk that unauthorized individuals will gain access to DNA and organisms of concern through the use of nucleic acid synthesis technology.

5. Effective implementation also requires outreach to affected communities. We have established websites to better inform the public on some of our implementation activities. Examples of websites that may be of interest to the BWC community include:

- (a) The White House website on biosecurity (<http://www.whitehouse.gov/administration/eop/ostp/nstc/biosecurity>)
- (b) The Select Agent Program (<http://www.selectagents.gov>)
- (c) The Public Health Emergency Portal (<http://www.PHE.gov>).

6. The 2003 and 2007 Work Programs were useful in focusing our efforts to understand what measures could usefully be put in place to ensure effective biological risk management. We believe there needs to be a continued focus on national implementation in future intersessional work to promote the development, execution, and ongoing review of national legislative, regulatory and other frameworks for BWC implementation.

III. 2008 - Biosafety and biosecurity

7. Building on efforts initiated before the 2008 Work Program on biosafety and biosecurity, multiple entities of the United States Government (USG) have focused on building safe and secure laboratories, enacting appropriate legislation and regulations, and ensuring scientists are fully trained on dual use and security issues, both domestically and internationally. At the 2008 Meeting of Experts, the United States described efforts to enhance oversight of dual-use scientific research through the National Science Advisory Board for Biosecurity (NSABB), an advisory body established in 2004 to advise the USG on specific strategies for the efficient and effective oversight of Federally conducted or supported dual-use biological research, taking into consideration both national security concerns and the needs of the research community.

8. Since the 2008 presentation, the NSABB has fostered international outreach and discussion on these topics, including through webcasts of its meetings on dual-use research of concern and a series of international roundtables; and developed recommendations for USG strategies to enhance personnel reliability among individuals with access to Select Agents and to address the dual-use potential of synthetic biology. Based on NSABB recommendations, the USG will soon be releasing Federal Guidelines on the Oversight of Life Sciences Research with Dual Use Potential.

9. Dual-use bioethics education and the promotion of responsible scientific conduct, also highlighted by the U.S. during the 2008 meeting, continue to be a major focus both domestically and abroad, through government-sponsored training sessions, conferences and close collaboration with our national academies of science to develop best practices. Activities that should be taken to reinforce a culture of responsibility, awareness, and vigilance among all who utilize and benefit from the life sciences to ensure that they are not diverted to harmful purposes are also highlighted in the 2009 *National Strategy for*

Countering Biological Threats, an overarching framework for U.S. efforts to prevent the acquisition and use of biological weapons by state or non-state actors.

10. The guidance document published by CDC and NIH, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), currently in its 5th edition¹, is widely considered to set the standard for laboratory biosafety practices. It contains detailed descriptions of the work practices, administrative procedures, safety equipment, and engineering controls required for each of the biosafety level, along with guidance on performing risk assessments and suggested biosafety level assignments for infectious agents. The BMBL also provides a brief overview of biosecurity principles (including risk assessment/management, physical security, personnel reliability, inventory and accountability, information security, transport, accident and injury response plans, training, and re-evaluations).

11. In addition to the efforts spurred by NSABB on dual-use, research oversight, critical aspects of biosafety, biosecurity, and biocontainment have been reviewed by the U.S. Government and several policy and legislative initiatives are currently under consideration.

12. The U.S. National Institutes of Health have established a National Biosafety and Biocontainment Training Program (NBBTP) designed to prepare a cadre of highly trained biosafety and biocontainment professionals with the skills to provide guidance to research investigators on the use of safe practices in their studies of infectious agents requiring high or maximum biosafety level containment. The 2-year post-baccalaureate and postdoctoral NBBTP fellowships integrate traditional elements of academic learning with training at NIH and other research facilities. The program provides hands-on experience in biosafety level 3 and 4 facilities and prepares trainees to meet the needs of the biodefense and emerging diseases research fields in the 21st century.

13. The Department of State's Biosecurity Engagement Program (BEP), highlighted in a poster presentation in 2008, along with the Department of Defense's Cooperative Threat Reduction (CTR) program, have continued to conduct biosecurity assessments and upgrades to laboratories around the world. The United States has engaged partner countries to enhance biosecurity and biosafety, hosting training programs, supporting attendance at international meetings, and dedicating resources to building safe and secure labs. Recently, the United States hosted an international workshop on International Perceptions on Mitigating Laboratory Biorisk and a regional biosecurity workshop through the ASEAN Regional Forum. Additionally, the United States continues to support OECD and WHO efforts in the arena of biorisk management.

IV. 2009 - Infectious disease surveillance

14. The 2009 Meeting of Experts focused on assistance with building disease surveillance. U.S. presentations focused on our efforts to build global capacity to detect, report and respond to infectious diseases and emphasized the utility of WHO's International Health Regulations (2005) as a framework for identifying and assessing capacities nations need for disease surveillance and response. Discussions at the Experts Meeting also provided an invaluable channel to identify needs for assistance in building IHR core capacities and to match needs with funding sources such as BEP.

15. The 2009 meetings provided a unique opportunity to bring together the security and health communities to address a global threat, highlighting each community's unique role in the pursuit of similar goals in identifying and addressing infectious disease outbreaks.

¹ available at: <http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>

For the U.S., the meeting provided a catalyst to organize our global efforts in disease surveillance and response capacity building and focus our assistance to support both the BWC and the IHRs. Nearly a dozen USG entities provided over \$300 million in direct IHR assistance last year alone. The CDC's GDD program, the first WHO Collaborating Center for IHR implementation, has centers in every WHO region of the world, providing rapid response to disease outbreaks, discovering new pathogens, and building capacity to enable sustained disease detection capabilities through the development of almost 170 new diagnostic tests. Under CDC auspices, more than 103 million people outside the U.S. are under population-based surveillance for a wide variety of infectious diseases. Approximately 200 epidemiologists from around the world are trained every year through the Field Epidemiology Training Program (FETP) which has provided short-term training to more than 43,000 public health professionals worldwide since 2007. The Field Epidemiology and Laboratory Training Program (FELTP) offers an added laboratory component to the basic FETP aiming to build and strengthen the bridging between laboratory services and epidemiology and thus improve surveillance and outbreak response. Both FETP and FELTP are offered by HHS/CDC in collaboration with our partners to help foreign countries develop, set up, and implement dynamic, public health strategies to improve and strengthen their public health system and infrastructure.

16. The Department of Defense (DOD) has also engaged in large-scale efforts to enhance infectious disease surveillance capacity around the world. In 2009, DOD sponsored 123 training initiatives on infectious disease response in 40 countries, training 3,100 attendees. DOD also redirected funds to directly support IHR implementation efforts through capacity building in under-resourced environments. Multiple other agencies, supporting efforts in every corner of the globe, provided resources and technical expertise to enhance surveillance systems. This included the sharing of NASA satellite imagery to help predict disease outbreaks, and USAID's Emergency Pandemic Threats program.

17. Both naturally occurring and deliberate biological events over the past decade have brought home the value of the BWC as a forum to explore and coordinate our efforts with partners and to make available requested assistance to build national disease surveillance and response core capacities. These efforts not only support the WHO's IHRs, they strengthen a nation's ability to prevent, detect, diagnose and treat diseases - whatever their origin. The United States has continued to build on the foundation initiated in 2009, hosting a series of international meetings to support IHR implementation, bringing together both BWC and IHR experts. These meetings resulted in peer-reviewed journal articles highlighting ways in which health and security communities can collaborate to support disease surveillance capabilities that address needs of both communities, exploring best practices to engage the security community in building comprehensive disease surveillance capacity around the world.

V. 2010 - Investigating alleged use events

18. Effective capacity-building assistance and international response in the case of alleged use is important to our collective efforts to ensure biology is not used as a weapon, since effective response can blunt the impact of such weapons. At the 2010 August Meeting of Experts, the FBI and CDC described the active training they have provided worldwide on joint public health and law enforcement investigations. These joint efforts, as well as those explored in the U.S.-Swiss Black Ice II multilateral bioterrorism exercise; the Southern Caucasus Workshop on *Public Health, Security, and Law Enforcement Partnership in Bio-Incident Pre-Planning and Response* and associated Southern Caucasus BioShield 2010 tabletop exercise; and the Trilateral (US-Romania-Moldova) Civilian-Military Forum on *Outbreak Response and Bioterrorism Investigation*, emphasize how

critical determining how we react to a bio-incident has become. These meetings and exercises demonstrate the importance of prevention and pre- and post- planning efforts to ensure efficient inter-sectoral and cross-domain action when necessary.

19. The United States has stepped up our internal efforts to coordinate our broad ranging disease surveillance, detection and diagnosis activities in 2010, further developing national and international health infrastructure to be prepared for a natural or man-made threat. These efforts build off the 2009 Work Program focus on disease surveillance capacity building, but also strengthen the ability to detect and respond to alleged use events. The United States also continues to work on bringing together the public health, security, and law enforcement communities, participating in multiple workshops and training session around the world to promote enhanced collaboration between the communities.

VI. Summary

20. The BWC Work Program through its annual expert and political-level meetings and the broad range of supporting activities organized by State Parties has provided a forum for bringing together interested communities, sharing ideas, and building the relationships necessary to take action to improve our collective security and safety. The BWC is the only multilateral forum that successfully brings together the health, law enforcement, scientific and security communities, and this gathering of experts and exchange of ideas has provided a foundation for a host of international activities. The United States has taken advantage of this forum and the topics raised in the Work Program to focus our international assistance, strengthen relationships, and contribute to global health and security. The role of the intersessional Work Program as a catalyst to enhance global efforts and focus assistance in biosecurity, biosafety, disease surveillance and response, and alleged use investigations should not be underestimated.

21. Looking toward the Review Conference in 2011, it will be important to address ways to strengthen the intersessional process, such as increased flexibility and decision-making authority, but it will also be important to retain the atmosphere and collaborative approach of the current Work Program.
