

**Seventh 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**

7 December 2011

English only

Geneva, 5–22 December 2011

Item 10 of the agenda

**Review of the operation of the Convention
as provided for in its Article XII**

Implementation of Article X of the Convention

**Background information document submitted by the Implementation
Support Unit**

Addendum

Bulgaria

1. The Republic of Bulgaria is committed to implementing Article X and co-operates with the other States Parties to the BTWC in order to facilitate the exchange of equipment, materials, scientific and technical information concerning the use of bacteriological (biological) agents and toxins for peaceful purposes.
2. In 2006-2008 through twinning projects with The Netherlands and Italy (PHARE projects) aimed at strengthening the combat capacity against infectious diseases, the National Center for Infectious and Parasitic Diseases (NCIPD) received equipment for identification of highly pathogenic bacterial and viral agents. As a part of these twinning projects, an intensive post- graduate educational programme was implemented, involving epidemiologists, microbiologists and virologists working in the field of surveillance of infectious diseases with a focus on early warning.
3. In the period 2007-2011 NCIPD was designated as WHO Collaborating Center for research and training in surveillance of communicable diseases and antimicrobial resistance, among its tasks being the coordination and collaboration in this field with partners in countries in Southeast Europe, North Africa and Central Asia. The Center collaborated, *inter alia*, with NAMRO (Cairo) on hemorrhagic fevers, partners in the Republic of Macedonia on polio and swine flu diagnosis, in Turkmenistan, Uzbekistan, Kyrgyzstan, as well as in Armenia on malaria diagnosis.
4. The Republic of Bulgaria has collaborated with EU partners and participated in activities carried out through the Executive Agency for Health and Consumers, the European Center for Disease Prevention and Control (ECDC), the EU Early Warning and Response System, etc.

United States of America

A. Background

5. The United States is firmly committed to fulfilling all of its obligations under the Biological Weapons Convention, including those under Article X of the Convention. Relevant international cooperation and exchange, including assistance programs, encompasses a wide range of activities in support of the overall advancement of the life sciences.

6. Article X embodies an international commitment to partnership, sharing of information, networking, and the development of mutually beneficial outcomes. Formal “assistance” programs comprise only a part of this much larger undertaking. The United States has supported, and will continue to support, capacity building and other forms of assistance for those countries seeking it. Through our assistance and cooperation efforts, the United States and the international community have worked together collectively to pursue mutual goals, including, *inter alia*:

- (a) Improving global population health through the prevention, detection, and mitigation of disease;
- (b) Advancing educational and collaborative opportunities for global scientists; and
- (c) Contributing to the advancement of biological sciences for peaceful purposes.

7. We continue to invest significant resources in these efforts. In the U.S. system, exchange, cooperation, and assistance in fulfillment of our Article X commitments are provided in a variety of ways: bilaterally by the U.S. government to other national entities; through national contributions to international organizations; and by individuals, industry, foundations, and academia, all of which are critical players in American civil society.

8. We believe that the exchanges during the BWC intersessional process in 2009 and 2010 were extremely productive in building relationships and facilitating real assistance on issues of practical concern to States Parties. While the large number of U.S. programs and wide range of ongoing efforts underway contribute to our implementation of Article X, such efforts do not take place solely, or even primarily, in the BWC forum as previous Review Conferences have noted. Moving forward, we will continue to utilize this broad diversity of institutions, stakeholders, and fora in order to pursue our shared goals.

9. The breadth and scope of U.S. contributions and assistance precludes a comprehensive listing of each and every program in its entirety, but enclosed in this paper is a selection of examples demonstrating our commitment to fulfilling our obligations related to Article X of the BWC. On December 9, 2011, we look forward to providing some additional information in conjunction with the side event scheduled to focus on Article X-related U.S. Programs.

B. Bilateral, regional, and multilateral support for participation and exchange of biological equipment, materials, and information for peaceful purposes

10. The United States has been active through bilateral, regional, and multilateral engagement, and through these substantial interactions remains committed to the advancement of science for peaceful purposes. The U.S. government, in particular, provides

support that enables scientists to participate in and foster the exchange of ideas that advances our mutual understandings in the life sciences.

11. The United States is the world's largest economy and the largest exporter and importer of goods and services, with U.S. exports worth nearly \$1.6 trillion per year. Recently, the United States has undertaken the National Export Initiative (NEI), which has sought to improve conditions that directly affect the private sector's ability to export. The NEI seeks to double exports over five years by working to remove trade barriers abroad, by helping firms (especially small businesses) overcome the hurdles to entering new export markets, by assisting with financing, and in general by working with our international partners abroad, among other steps.

12. The Department of Health and Human Services (HHS) supports multiple international exchange programs for scientific research, including the following:

- (a) Food and Drug Administration (FDA)'s International Scientist Exchange Program;
- (b) FDA's Foreign National Training Program;
- (c) National Institute of Health (NIH)'s Visiting Program for scientists, designed to train and conduct collaborative research at NIH;
- (d) NIH/Fogarty International Center, which provides grants to train researchers and build sustainable research capacity in more than 100 low and middle income countries.
- (e) NIH/National Cancer Institute (NCI)'s Short Term Scientist Exchange Program; and
- (f) NIH/National Institute for Allergies and Infectious Disease (NIAID)'s International Centers of Excellence in Research program, which develops research programs in resource-poor countries through partnerships with local scientists to provide training and improve laboratory and clinical infrastructure.

13. The Department of State supports biological scientific engagement through a series of vehicles, including:

- (a) Through 54 bilateral science and technology agreements, which provide a formal mechanism for U.S. government departments and agencies to promote collaboration on scientific endeavors with partner nations; and
- (b) Through endowed science and technology funds used to support patents, publication, and commercial sales.

14. Our universities also engage in joint research collaborations with colleagues across the globe, and educate many of the world's emerging scientists through undergraduate, graduate, and post-graduate training. For example:

- (a) In 2009, there were more than 270,000 foreign graduate students enrolled in U.S. universities, with more than 158,400 enrolled in science and engineering studies and 17,830 specifically in the biological sciences; and
- (b) Also in 2009, there were 271,400 foreign students enrolled in U.S. undergraduate educational institutions, more than 80,000 of whom were enrolled in science and engineering programs and more than 12,000 of whom were specifically studying the biological sciences.

15. A compendium of training programs and references summarizing U.S. federal and federally-funded biosafety/biosecurity outreach, training, and awareness-raising activities, including a series of online training offerings, can be found in section E in this report.

C. Contributions to the development and application of scientific discoveries in the life sciences for the prevention of disease, and for other peaceful purposes

16. The United States is a world leader in life sciences research and development (R&D), accounting for up to one-third of global investment in life sciences R&D. Much of this work is undertaken by the private sector, although the federal government remains the largest funder of life sciences research at U.S. colleges and Universities.

Strengthening preparedness to prevent and detect naturally-occurring diseases is the best defense against the potential misuse of biological agents and toxins; thus, by helping other States Parties strengthen health care infrastructure and build disease surveillance capacity, we are contributing directly to the object and purpose of the BWC, as well as our Article X(i) undertaking. To this end, the United States has provided a wide range of assistance to international partners, including, *inter alia*, the following examples designed to reduce threats, improve global detection of disease, enhance capacity to investigate and diagnose biological emergencies, prevent and respond to disease outbreaks, and improve global health.

1. Threat reduction

17. The Department of State provided more than \$35 million in fiscal year 2011 funding for programs focused on laboratory biorisk management, disease detection and control, and cooperative research and development. These programs were supported in partnership with countries in Eurasia, Southeast Asia, South Asia, the Middle East and North Africa, sub-Saharan Africa, and Latin America. Specific activities included:

(a) Laboratory biorisk assessments that led to biosecurity upgrades in priority laboratories, particularly the enhancement of pathogen security systems and laboratory access controls; and

(b) Sustainable human capacity building in the form of training programs ranging from technical briefings to facilitating a broader awareness of biological nonproliferation issues.

18. The Department of Defense is projected to spend a total of over \$1.8 billion through its Cooperative Biological Engagement Program (CBEP) between fiscal year 2010 and fiscal year 2016, and devoted \$209 million to this effort in fiscal year 2011 alone. CBEP is focused on reducing the threat posed by especially dangerous pathogens and related materials and expertise, as well as other emerging infectious disease risks. CBEP provides assistance across the following areas:

(a) Strengthening the capacity for public health and veterinary health systems to detect, diagnose, and report infectious disease outbreaks;

(b) Increasing biosafety and biosecurity; and

19. Enhancing global health security and fostering safe, secure, and sustainable bioscience capacity through joint scientific collaborations designed to help prevent, detect, and respond to biological threats.

2. Disease surveillance and response

20. President Obama, in his speech to the United Nations General Assembly in September 2011, urged all nations to “join us in meeting the WHO’s goal of making sure all nations have core capacities to address public health emergencies in place by 2012. That is what our commitment to the health of our people demands.” The United States is

committed to this goal and multiple U.S. Government organizations, including the Centers for Disease Control and Prevention, the Department of Defense, the United States Agency for International Development, and the U.S. Department of Agriculture's Agricultural Research Service, have been working to support building disease surveillance capacity around the world.

21. The Department of Defense's Global Emerging Infections Surveillance and Response System (DOD-GEIS) has partnered with more than 80 countries in 2011 to support global public health security, including training, sentinel laboratory-based disease surveillance, and human capacity building. The emerging infectious diseases portfolio includes respiratory, enteric, sexually transmitted, vector-borne and antimicrobial resistant infections. GEIS supports respiratory infections surveillance efforts at more than 500 sentinel sites in Africa, Asia, Europe, the Middle East and the Americas, and has trained more than 3000 public health officials from 44 countries in 2011. GEIS has also worked with the International Committee of Military Medicine to bring together the military health officials from 39 countries to address coordination for rapid identification and reporting of public health emergencies of international concern.

22. The Centers for Disease Control and Prevention's Global Disease Detection and Response Program (GDD), through its regional centers located in every WHO region of the world, and its staff in Atlanta, is dedicated to infectious disease detection and response, by building capacity to detect and respond to emerging health threats around the world in the following areas:

- (a) Training in field epidemiology and laboratory methods;
- (b) Surveillance and response for emerging infectious disease threats;
- (c) Assistance with pandemic influenza preparedness;
- (d) Promotion of zoonotic disease investigations and control efforts;
- (e) Risk communications; and
- (f) Laboratory biosafety and improved laboratory systems.

23. In 2010, the total population of host countries receiving national surveillance technical support from CDC was 2,960,400,000. Between 2006 and 2010, GDD detected 54 new pathogens, and deployed 186 pathogen-specific tests to be made available to partner countries. GDD also participated in 655 outbreak responses from 2006-2010. Between 2006 and 2009, CDC experts deployed to 24 countries to support local response to outbreaks of infectious diseases, including cholera and plague, Ebola and Marburg, Rift Valley fever, polio, and unknown illnesses.

24. The U.S. Agency for International Development's Emerging Pandemic Threats program seeks to aggressively pre-empt or combat diseases that could spark future pandemics, emphasizing early identification of and response to dangerous pathogens in animals before they can become significant threats to human health. The EPT program draws on expertise from across the animal and human health sectors to build capacities for early disease detection, laboratory-based disease diagnosis, rapid disease response and containment, and risk reduction. Partners include organizations with specialized expertise in wildlife monitoring, field epidemiology and training, laboratory strengthening, and behavior change communications, as well as international partners from the World Health Organization, the UN Food and Agriculture Organization, and World Organization for Animal Health.

25. The Department of Agriculture's Agricultural Research Service (ARS) is actively engaged in implementing research programs that support global disease surveillance initiatives for plants and animals, including emerging disease and zoonotic agents that pose

a threat to human health. ARS actively collaborates with international partners worldwide on research projects dedicated to support disease surveillance programs. ARS is one of the founding members of the Global Foot-and-Mouth Research Alliance (GFRA), which supports the UN Food and Agriculture Organization and World Organization for Animal Health global efforts to control and eradicate foot-and-mouth disease.

3. Enhancing capacity

26. The United States supports the World Health Organization's International Health Regulations (2005), which, *inter alia*:

(a) Provide a framework for WHO alert and response activities that are implemented in collaboration with countries to control international outbreaks and other public health risks and emergencies;

(b) Allow the WHO to provide support for the implementation of national capacities for epidemic preparedness and response, including laboratory capacities and early warning alert and response systems; and

(c) Standardize approaches for readiness and response during a public health emergency of international concern, allowing the IHR Emergency Committee to issue travel and trade recommendations based on the best evidence available.

27. The Centers for Disease Control and Prevention established the Field Epidemiology (and Laboratory) Training Programs (FELTP) in 1980, and since then CDC has helped launch more than 40 programs around the world and produced more than 2,300 graduates. CDC currently supports 18 programs, covering 34 countries, which are designed to build human capacity to characterize disease burden, respond to outbreaks, provide diagnostic capacity, and address locally-identified public health challenges. In 2010, 67 epidemiologist and laboratories graduated from the FELTP program, 415 graduates remained in public health positions in their countries or regions after graduation, and more than 12,000 people participated in short-term public health training.

4. Improve global health

28. The United States government was the leading funder of global health assistance in 2010, with over \$7 billion in bilateral contributions. In addition, the United States is a major contributor to the Global Fund for AIDS, Tuberculosis, and Malaria, the World Health Organization, and the Global Access to Vaccines Initiative (GAVI) Alliance. The U.S. government's financial and technical contributions significantly improve and expand sustainable health systems. GAVI's work facilitates vaccine distribution in the least developed countries, preventing millions of cases of infectious diseases every year.

D. Efforts to avoid hampering economic or technological development, or international cooperation in the life sciences, including agents and equipment related to biological agents, for peaceful purposes

29. An effective system of national export controls continues to be essential to enhance the avenues of free trade necessary for the implementation of Article X. The United States government's export licensing system is designed to be fast, transparent, and effective, also in fulfillment of our Article III obligations. The Department of Commerce's Bureau of Industry and Security (BIS) implements the U.S. Government's export control system for dual-use items; those items that have chiefly commercial uses, but also can be used in conventional arms or weapons of mass destruction applications, terrorist activities, or human rights abuses. In August 2010, President Obama announced the foundation of a new

export control system designed to strengthen U.S. national security and increase the competitiveness of key U.S. manufacturing and technology sectors by reforming our existing system and adapting it to the changing economic and technological landscape. When completed, this export control reform initiative will result in a single control list, a single licensing agency, a single primary enforcement coordination agency, and a single information technology system.

30. To accomplish its objectives, BIS administers, and amends as necessary, the U.S. Export Administration Regulations (EAR). Given that the U.S. exports goods and services worth nearly \$1.6 trillion per year and that BIS processes export license applications valued at approximately \$60 billion per year, less than 4% of all exports are licensed. Of those 4%, 0.3% were exported under a special comprehensive license and 1.2% were exported under a license exception. Therefore, these regulations have a minimal impact on overall trade, consistent with our obligations under Article X of the BWC.

31. The Department of State's Export Control and Related Border Security program (EXBS) assists 60 partner nations in improving strategic trade control systems around the world, with the goal of ensuring that equipment, technology, software, and pathogens transferred between States are used for only peaceful purposes. The Department of Energy's International Nonproliferation Export Control Program (INECP) coordinates closely with EXBS, the Department of Commerce, and the Department of Homeland Security in working with partner governments to:

- (a) Adopt necessary national export control laws and related regulations;
- (b) Organize technical workshops and policy exchanges to encourage adoption of effective licensing procedures and comprehensive national control lists;
- (c) Establish and sustain robust government-industry outreach programs to ensure that state and private technology holders understand and implement national export control norms in coordination with national licensing authorities; and
- (d) Bolster national capacities to detect, deter, interdict, and prosecute illicit transfer of WMD components and weapons-related items.

32. The NIH Office of Biotechnology Activities (OBA) works to raise awareness of the implications of dual-use research among governments and government entities, the life science research community, and the scientific publishing community. Within the U.S. government, agencies that have a vested interest in life sciences research coordinate closely in developing approaches that will stimulate such research, while at the same time assuring that potential concerns are assessed and evaluated. The National Science Advisory Board for Biosecurity (NSABB) is a federal advisory committee chartered to provide advice, guidance, and leadership regarding biosecurity oversight of dual use research; a selection of NIH documents and NSABB recommendations can also be found in the Appendix attached at the end of this report.

E. Training programs

33. Building on the programs identified in the previous sections of this paper, below are some of the many federal or federally-funded training programs that conduct work with foreign scientists, or that are free and open to all. This list does not include the many additional resources available that have been developed by industry, foundations, academia, or other non-governmental entities.

1. Online training and educational materials

34. Online training and educational materials include:

(a) Emergency Preparedness and Response: The CDC provides resources that are intended to help professionals take an all-hazards approach to preparedness. These materials are available online at: <http://emergency.cdc.gov/hazards-all.asp>. A list of training resources related specifically to bioterrorism is available online at: <http://emergency.cdc.gov/bioterrorism/training.asp>.

(b) International Laboratory-related Resource and Activity Directory: This directory includes links to training materials, guidelines, manuals, and resources developed by CDC and partner organizations to promote quality laboratory practices in the global laboratory setting. These resources are available online at: <http://www.cdc.gov/dls/ILA/default.aspx>.

(c) The Public Health Training Network (PHTN): This is a distance learning network of people and resources that takes training and information to the learner. A listing of distance learning courses and resources is available online at: <http://www2.cdc.gov/PHTN/calendar.asp>.

(d) Training and Continuing Education Online (TCEO): TCEO is a distance learning network that allows participants to register for CDC-managed courses and track their progress online. TCEO is available online at: <http://www2a.cdc.gov/TCEOnline/index.asp>.

(e) Other learning resources are available online at the CDC Learning Connection Website (<http://www.cdc.gov/learning/index.html>). This is a newly established website, designed to help visitors locate public health learning products created by CDC and partners. It features a growing collection of free products in various media formats, including podcasts, e-learning, electronic publications, and live events.

2. In-person training programs

35. In-person training programs include:

(a) The National Biosafety and Biocontainment Training Program (NBBTP): <http://www.nbbtp.org>

(b) Emory University - Biosafety Training Course: Biosafety Level 4: This five-day training offers participants the opportunity to learn and practice new skills for BSL4 labs. <http://www.sph.emory.edu/CPHPR/biosafetytraining/bsl4.html>

(c) University of Texas Medical Branch (UTMB) - National Biocontainment Training Center (NBTC): This center is dedicated to preparing the worldwide community of infectious disease scientists to work safely in high-containment research laboratories. <http://www.utmb.edu/nbtc/>

(d) Select Agent Program Training Workshops: U.S Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) conduct a yearly training workshop to inform individuals of their legal responsibilities for implementing the Select Agent Regulations. <http://www.selectagents.gov/Training.html>

(e) Joint Criminal and Epidemiological Investigation Training Program: The Federal Bureau of Investigation (FBI) and the Centers for Disease Control and Prevention (CDC) jointly developed this program to improve efforts to identify and investigate potential overt or covert biological threats. Initially designed as a domestic program, FBI and CDC have expanded this training to international partner countries.

(f) The Field Epidemiology Training Program (FETP) and the Field Epidemiology and Laboratory Training Program (FELTP): CDC offers applied epidemiology programs to help foreign countries develop, set up, and implement dynamic public health strategies to improve and strengthen their public health system and

infrastructure. The FE(L)TP programs include biosafety and bioethics training in support of epidemiological activities. <http://www.cdc.gov/globalhealth/fetp/>

(g) FBI Synthetic Biology Program: FBI conducts outreach to public and private synthetic biology companies to raise awareness about the potential security risks inherent to the industry, and works with the companies to develop common standards and best practices for risk management. The international component of this program fosters dialogue between international companies and their respective government/law enforcement agencies to develop processes to mitigate the risk of misuse of harmful DNA sequences.

3 Additional online resources

36. Additional online resources include:

(a) The CDC Learning Connection: This site maintains a compendium of free learning products on a wide variety of health issues, including Emergency Management, Infectious Disease, Legal/Ethical Issues, Policy/Planning, Preparedness and Response, and Public Health. <http://www.cdc.gov/Features/CDCLearning/>

(b) The CDC Online Training Course: This course provides education regarding key principles for securing biological agents in research laboratories and biomedical facilities where loss, theft, release or intentional misuse of the agent might have significant public health or economic consequences. <http://www.cdc.gov/biosafety/biosecuritytraining/page1024.html>

(c) The FDA's Food Defense and Emergency Response-Training: The U.S. Food and Drug Administration (FDA) works with other government agencies and private sector organizations to help reduce the risk of tampering or other malicious, criminal, or terrorist actions on the food and cosmetic supply. Web-based training and additional educational resources are available at: <http://www.fda.gov/Food/FoodDefense/default.htm>

(d) NIH materials for Research Conduct and Ethics Instruction: NIH provides online materials including case studies for the 2010 theme (Science and Social Responsibility): <http://sourcebook.od.nih.gov/resethticscases/2010-cases.pdf>

(e) BSL-3 Facility Inspection videos: These informational videos are for entities or individuals who currently possess, store, or transfer Select Agents and those who are planning to begin work with Select Agents or toxins. <http://www.selectagents.gov/FIV.html>

(f) Emergency Preparedness and Biodefense: NIH Videocasting and Podcasting: NIH provides seminars and training events broadcasted live to a world-wide audience over the Internet and also recorded and made available for viewers to watch at their convenience as an on-demand video or a downloadable podcast. <http://videocast.nih.gov/PastEvents.asp?c=58>

(g) Global Biorisk Management Curriculum Development (GBRMC): CBEP is developing and implementing a biorisk management curriculum to address biosafety and biosecurity training. Users of the training materials can participate in a virtual network of trainers via a web-based portal, and provide lessons learned, updates, and feedback for the continual improvement of the materials. The network of trainers currently consists of more than 100 biosafety professionals active in the United States, Europe, Asia, and Africa.

(h) The Executive Office of the President, Office of Science and Technology Policy website: This site provides information to the public, academic and private sector research communities about government policies related to the safe and secure conduct of biological research and the technologies arising out of the application of the life sciences. <http://www.whitehouse.gov/administration/eop/ostp/nstc/biosecurity>

(i) The S3 (Science, Safety, and Security) website: This website provides information on biosafety, biosecurity, biocontainment, and biorisk management. <http://www.phe.gov/s3/Pages/default.aspx>

(j) NIH Dual Use Research video: <http://oba.od.nih.gov/biosecurity/biosecurity.html>

(k) NIH Dual Use Research Brochure: <http://oba.od.nih.gov/biosecurity/pdf/EducationalBrochureDualUseResearch.pdf>

(l) NSABB Oversight Framework Report: Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information: www.biosecurityboard.gov

(m) Biological Risk Management and Nonproliferation website: The Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), established this website to increase awareness of the BWC and UN Security Council Resolution 1540. <http://www.phe.gov/about/OPP/Pages/bwc.aspx>

(n) The FBI's International Biosecurity and Prevention Forum (IBPF): Currently under development, this website is intended to provide an international forum for the coordination and sharing of information and best practices related to the prevention and response to the misuse of biological agents as weapons of mass destruction.

F. Conclusion

37. International cooperation and exchange in the life sciences and in combating disease will continue to be a core objective for the United States, consistent with our obligations under Article X of the Biological Weapons Convention. International cooperation to support the advancement of biological sciences for peaceful purposes, assistance to improve global population health through the prevention, detection, and mitigation of disease, and developing capacity and collaborative opportunities for scientists across the globe are all areas in which the United States will continue to commit programs and resources. Furtherance of these aims has broad support across the range of the U.S. institutions, including the United States government, non-governmental institutions, industry, the scientific community, civil society, and the American people.
