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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

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Item 10 of the agenda
Review of the operation of the Convention as provided for in its Article XII

Compliance by States Parties with their obligations under the Convention

Background information document submitted by the Implementation Support Unit

Addendum

Contents

Brazil

A. Introduction

1. The text of the Biological and Toxin Weapons Convention (BTWC) was approved in Brazil by Legislative Act no. 89 of December 5, 1972, and enacted by Executive Act no. 77374 of April 1, 1976. Through the General Coordination for Sensitive Goods (CGBE), the Ministry of Science, Technology, and Innovation (MCTI) acts as the National Authority for the implementation of relevant provisions related to disarmament and non-proliferation regimes and treaties on Weapons of Mass Destruction (WMD) to which Brazil is a Party, including the BTWC, as well as United Nations Security Council Resolution 1540 (2004).

B. Structure of the CGBE

2. The General Coordination for Sensitive Goods is tasked primarily with coordinating and following up on the implementation of transfer (export and import) control policies and regulations for sensitive goods and services directly connected to the chemical, nuclear, biological, and missile technology fields. In this context, the CGBE performs the following functions and duties: Executive Secretariat of the Inter-Ministerial Commission on Export Controls for Sensitive Goods (CIBES), pursuant to Bill no. 9112 of October 10, 1995 and Executive Act no. 4214 of April 30, 2002; and coordinating body for all activities in connection with the Convention's implementation, in its capacity as the Focal Point for the Biological and Toxin Weapons Convention (BTWC) in Brazil. The CGBE is composed of four specific coordinating units, namely: Coordinating Unit for Implementation, Monitoring, and Control in the Biological Area, and three other units dealing with the Chemical, Nuclear and Missile Technology Areas.

C. Activities undertaken in compliance with the BTWC

1. Implementation of Confidence Building Measures (CBMs)

3. The CGBE has primary responsibility for requesting information from other agencies, compiling data, and distributing CBM forms. The CBGE's Coordinating Unit for the Biological Area has endeavored since 2010 to promote discussions on CBMs and to raise awareness on their importance. In 2011, the General Coordination included information in the CBM form on the BL3 Public Health Laboratories (the highest level containment facilities in the country). On June 14, 2011, a CBM workshop was held with the participation of several agencies under the Ministries of Health; Agriculture, Livestock, and Food Supply; Defense; External Relations; Science, Technology, and Innovation, as well as the National Health Surveillance Agency, and the Brazilian Intelligence Agency.

2. Export Controls on Goods Relating to the Biological Area

4. Since 2007, Brazil has maintained a list of controls on goods relating to the Biological Area, The latest update was published in CIBES Resolution no. 13 of March 10, 2010. Through the CGBE, the Ministry of Science and Technology serves as the consenting body for export of the goods listed in the Integrated Foreign Trade System (SISCOMEX).

3. Sensitive Goods Training Courses

5. In 2007, the CIBES established an Inter-Ministerial Working Group with the purpose of developing and implementing a training programme on Sensitive Goods. The

Sensitive Goods Training Course was based on the Strategic Commodity Identification Training (CIT), a programme developed by the US Department of Energy (DoEIUSA) and held in Brazil in 2007 and 2008 under the auspices of an international cooperation programme called "International Nonproliferation Export Control Programme". The general goal of the Training Programme is to strengthen training for public officials involved in the application of national control and enforcement mechanisms on the transfer (export and import) of sensitive goods and technologies. The programme aims to disseminate information on the controls established under Brazilian legislation and to provide capacity building for public officials in charge of maintaining controls on sensitive goods, with a view to identifying those items with the potential for use in the development and production of WMD. In 2009, the first training programme conducted entirely by national instructors was held at Santos, Latin America's largest port facility, with the participation of a significant number of customs and federal police agents.

4. Awareness-raising and information

6. In 2004, the Brazilian Intelligence Agency (ABIN), acting in response to the provisions of UN Security Council Resolution 1540 (which called on States to, inter alia, develop guidance for industries, companies, universities, research centres, and the public in general on the applicable legislation restricting the sale of sensitive materials) created and implemented the National State-Private Industry Integration Programme for Sensitive Goods (PRONABENS), in partnership with CGBE. The programme aims at advising Brazilian companies and institutions on their obligations in connection with the implementation of the pertinent international regimes, including the BTWC. The primary focus is the implementation of outreach activities for industries, research centres, universities, and public agencies engaged in the development of sensitive equipment or dual-use equipment, with a view to offering guidance on government controls regarding the transfer of sensitive goods and services; disseminating the lists of sensitive goods; and demonstrating the importance of joint efforts between the State and the private sector in ensuring the fulfilment of Brazil's international commitments.

7. The activities of PRONABENS paved the way for the development and approval of the "List of Sensitive Goods and Controlled Equipment in the Biological Area" in Resolution no. 10 of March 13, 2008. Since its implementation, PRONABENS has allowed for 350 technical visits, lectures, and training programmes in universities, laboratories, research centres, and incubators engaged in developing, manipulating, storing, selling, and transporting biological materials with the potential to be used as inputs in WMD.

5. Workshop on National Capacities in Biological Security

8. Centered on promoting the exchange of information and integrating BTWC implementation measures, the Workshop was held on November 4, 2010, with representatives from the Ministries of External Relations; Science, Technology, and Innovation; Health; Defence; as well as the Federal Police, the National Health Surveillance Agency, and the Brazilian Intelligence Agency. The workshop helped assessing the range of existing measures and promoting integration and crosscutting actions between various governmental sectors.

6. Other developments

9. The Air Force Command established in 2010, together with the Airspace Medical Institute, the Chemical, Biological, Nuclear and Radiological Defence Section (DQBNR), with the aim of promoting research and analysis related to Brazil's obligations and commitments pursuant to the BTWC, and other instruments and regimes. In turn, the Navy

Command has developed and acquired biodefence decontamination, detection and protection equipment.

Bulgaria

A. Introduction

10. The Republic of Bulgaria ratified the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (BTWC) on 30 June 1972 before its entry into force on 26 March 1975. The Government of the Republic of Bulgaria remains fully committed to implementing the Convention. In accordance with the Constitution of the Republic of Bulgaria (Art.5, para. 4), the BTWC is a constitutive part of the country's domestic legislation. The Convention has a priority over any domestic legal norms, which could contradict it.

11. The full compliance of the Republic of Bulgaria with the BTWC is reflected in its compliance reports, annual declarations on the confidence-building measures, agreed at the Second and Third BTWC Review Conferences, and in its report to the UN Security Council 1540 Committee.

B. Articles I and II

12. The Republic of Bulgaria has never developed, produced, stockpiled or otherwise acquired or retained:

(a) 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;

(b) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

C. Article III

13. The Republic of Bulgaria fully complies with the obligations under Article III. It does not support, nor incite or encourage any State, group of States, international organizations or non-State actors to produce or acquire biological agents, toxins and weapons related to them. Such acts are punishable under Bulgarian Law.

14. The Republic of Bulgaria is a Member State of the European Union and a state participating in all international export control regimes, including the Australia Group, and fully complies with and adheres to the common standards, rules, procedures and documents adopted therein. Export, import, transfer, transit and brokering of dual-use items and technologies and arms (military equipment) and are regulated by the Law on the export control on arms and dual-use items and technologies and the Regulation for its implementation. The law, which was adopted in 2007 (last amended in February 2010), replacing previous Arms and Dual-use gods Export control Law (adopted in 1995), serves as the basis of the export control system of the Republic of Bulgaria. The current legislation reflects the relevant EU acquis in the sphere of export control, including the criteria and principles stipulated in the Council Regulation 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items. The List of controlled dual-use items and technologies (Annexes I and IV of the Council Regulation

428/2009) is directly applicable in the national legislation. The national Munitions List of controlled military equipment is fully compatible with the Common Military List of the European Union and includes additional control at national level on provision of technical assistance related to repairs, development, assembly, testing, maintenance, education, training, provision of consulting services or any other technical service-related items controlled by the Military List. Also, the List of arms and the List of dual-use items and technologies, subject to import controls, were adopted by Decree of the Council of Ministers № 147/26.05.2011 in implementing the above mentioned law. The latter includes any bacteriological, biological, chemical and toxic substances and their precursors, which may be used for weapons of mass destruction.

D. Article IV

15. In accordance with Article IV, the requirements of Article I of BTWC have been duly introduced into Bulgarian law, under which manufacturing, development, processing, alteration, storage, trade, transport, imports or exports of chemical and biological weapons is prohibited and punishable (Articles 337 and 339 of the Penal Code).

16. Comprehensive information on the full compliance of the Republic of Bulgaria with the obligations under Articles I – IV of the BTWC, and under the UN Security Council resolution 1540 (2004) of 28 April 2004 is contained in the national report to the UN Security Council 1540 Committee (dated 18 November 2004, Addendum 1 of 10 March 2006, Addendum 2 of 14 December 2007 and Addendum 3 of 04 January 2008).

E. Article V

17. The Republic of Bulgaria has not invoked Article V, nor has any other State Party invoked it in order to engage the Republic of Bulgaria in consultation.

18. The Republic of Bulgaria fully supports the efforts to further strengthen the BTWC and contributes to this end by regularly submitting annual Confidence Building Measures (CBMs) declarations (1988, 1989, 1990, 1991, 1992, 1993, 1994, 1995, 1996, 1997, 1998, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011).

19. As a Member State of the European Union, the Republic of Bulgaria supports the EU Strategy against proliferation of WMD and the EU Joint Action in support of the BTWC.

F. Article VI

20. The Republic of Bulgaria has not invoked Article VI, nor has any other State Party invoked it against the Republic of Bulgaria.

21. In 2011 the Republic of Bulgaria submitted to the UN updated list of experts and laboratories, which the UN Secretary-General may use for the purposes of investigations of the reports of alleged use of chemical and biological weapons, and contributed to the EU Action Plan, which supports increasing the effectiveness of the Secretary-General's investigative mechanism.

G. Article VII

22. The Republic of Bulgaria has not received requests to provide assistance under Article VII, no has it invoked Article VII to receive assistance.

H. Article VIII

23. In 1932 Bulgaria ratified the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases and of Bacteriological Methods of Warfare, signed on 17 June 1925. In 1991 the Republic of Bulgaria withdrew its reservations concerning its application.

I. Article IX

24. The Republic of Bulgaria has signed the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction on 13 January 1993 and ratified it on 29 June 1994 before its entry into force on 29 April 1997.

25. Pursuant to Article VII of the Convention, the Law for Prohibition of the Chemical Weapons and for Control over the Toxic Chemical Substances and their Precursors was adopted and promulgated on 28 January 2000 (amended in 2002, 2007, 2009, 2011).

J. Others

26. In 2005, the National Code of Conduct of the Bulgarian Scientists for the Prevention and Combat of Bioterrorism was adopted.

27. A national point of contact on CBMs has been established with the Ministry of Foreign Affairs.

28. With regard to biosafety and biosecurity, laboratories fully comply in their activities with National Standards for microbiology, virology and parasitology, approved by the Minister of Health. These laboratories are under constant control and monitoring on the basis of the National System of Accreditation. National Reference Laboratories meet quality control requirements of WHO (European Office), INSTAND accreditation system (Germany) and have international accreditation on the base of EN/ISO/IES 17025:2001. Also, in 2011 the newly established Bulgarian Agency for Food Safety (BAFS) set up a Council on Biosafety and Biosecurity, which controls and provides guidance to laboratories under BAFS. Competent Bulgarian bodies fully comply with norms and guidelines of WHO, OIE, FAO.

29. The well-established national notification reporting system covers 65 infectious diseases.

United States of America

A. Introduction

30. The United States signed the Biological and Toxin Weapons Convention (BWC) on 10 April 1972 and ratified the Convention on 26 March 1975. The United States is in full compliance with all of its obligations under the BWC and has extensive measures in place to ensure that all activities on its territory are treaty-compliant and that prohibited activities are deterred and detected and perpetrators punished.

31. The United States Government is committed to reducing the risks of acquisition or use of biological agents 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 *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 detect and respond to outbreaks as they occur; and instituting a suite of coordinated activities that collectively help to influence, identify, inhibit, and/or interdict those who seek to misuse the life sciences.

32. The United States supports a robust approach to implementing BWC obligations. The passage of implementing legislation and promulgation of regulations is a necessary step but not, in itself, sufficient. The United States uses an evolving array of mutually reinforcing tools including legislation, regulations, policy and guidance, outreach and education, investment, and assistance to achieve the aims of the Convention. Policy, established at the national level (by the President or Congress) or local level (by Federal Departments, Federal Agencies, institutions, etc.), is the principal guide to action. Laws[2] enable the enforcement of policies and include penal sanctions which establish crimes and punishment. Regulations[3], generally authorized by legislation, are developed and promulgated by regulatory agencies to implement laws and have the force and effect of law. Guidance establishes and reinforces best practices; while it lacks the legal force of laws or regulations, government-promulgated guidance documents provide useful flexibility and can be developed, implemented, and updated more rapidly. Guidance may be purely advisory (as in the case of the *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA*[4]), or compliance may be a condition of relevant federal funding (e.g., the *National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines)[5]. A third type of guidance is provided by the Select Agent Programs to assist the regulated community in meeting the requirements of the select agent regulations. Finally, outreach to affected communities is a critical element of effective implementation of the Convention. Awareness-raising, education, and the development of resources and reference materials for use by affected groups help to ensure broad-based, meaningful implementation.

33. Key elements addressed in this paper (which is extensive but not necessarily exhaustive) include prohibitions criminalizing the development, acquisition, or use of biological weapons; measures to guard against the misuse of the life sciences (including import/export controls, biorisk management practices and the promotion of biosafety, biosecurity and the responsible conduct of science); preparedness and assistance; and measures to promote the life-sciences and international exchange for peaceful purposes. It should be noted, however, that despite these categorizations, measures are often mutually reinforcing and fulfill more than one purpose. 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.

34. 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

[1] http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf

[2] The United States Code is the codification by subject matter of the general and permanent Federal laws of the United States. http://www.gpoaccess.gov/uscode/

[3] The Code of Federal Regulations (CFR) is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. http://www.gpoaccess.gov/cfr/

[4] http://www.phe.gov/preparedness/legal/guidance/syndna/Pages/default.aspx

[5] http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.pdf

adequate resources to implement and enforce laws, regulations, and other measures once adopted. Moreover, changes in technology, industry, and the nature of the bioweapons threat require States Parties to regularly review laws, regulations, policies and guidance to ensure they remain relevant and effective. Laws or policies once well suited to addressing the biological weapons threat may become less so over time and require modification or augmentation. Although the United States considers its approach comprehensive, we continue to look for ways to better address the biological weapons threat and improve national implementation of the BWC. Advisory committees[6], federal[7] and non-governmental studies[8], mandated review cycles[9] and other resources and processes are critical components of this process.

B. Prohibit Biological Weapons

35. Article I commits 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; Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict." United States measures in support of Article I include:

1. BWC Implementing Legislation

36. Biological Weapons Antiterrorism (BWAT) Act of 1989 (P.L. 101-298): The purpose of BWAT is to "implement the Biological Weapons Convention" and to "protect the United States against the threat of biological terrorism." It establishes BWC violations as federal crimes in the United States. (Excerpt: "Whoever knowingly develops, produces, stockpiles, transfers, acquires, retains, or possesses any biological agent, toxin, or delivery system for use as a weapon, or knowingly assists a foreign state or any organization to do so, or attempts, threatens, or conspires to do the same, shall be fined under this title or imprisoned for life or any term of years, or both.")

37. This Act was codified in the federal criminal code in 18 U.S.C. 175-178, and amended as part of the USA PATRIOT Act of 2001. It includes several prohibitions. It is a crime to:

(a) Develop, produce, stockpile, transfer, acquire, retain or possess any biological agent, toxin or delivery system for use as a weapon or knowingly assist a foreign state or any organization to do so, or attempt, threaten, or conspire to do so; "for use as a

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[6] For example: The National Science Advisory Board for Biosecurity (NSABB) 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. The NSABB advises on and recommends specific strategies for the efficient and effective oversight of federally conducted or supported dual use biological research, taking into consideration national security concerns and the needs of the research community.

[7] For example: *Report of the Working Group on Strengthening the Biosecurity of the United States* (2009)

[8] For example: National Research Council report – *Responsible Research with Biological Select Agents and Toxins, http://www.nap.edu/catalog.php?record_id=12774*

[9] For example: The biennial review and republication of the list of select agents and toxins and the revision of the list as necessary by the Departments of Agriculture (USDA) and Health and Human Services (HHS). USDA and HHS are conducting a significant overhaul of the nation's regulations concerning the handling and security of pathogens on the U.S. Select Agent List to improve security and minimize the adverse impact on legitimate use. http://www.selectagents.gov/

weapon" is defined as any purpose other than "prophylactic, protective, bona fide research or other peaceful purposes," establishing the broad, intent-based definition of the BWC in U.S. law.

(b) Knowingly possess "any biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstance, is not reasonably justified by a prophylactic, protective, bona fide research or other peaceful purpose." (Sec. 175)

(c) Knowingly possess or transfer biological agents and toxins to unregistered persons and the knowing possession or shipment of Select Agents to restricted persons defined in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) (Sec. 175).

2. Additional Legislation/Legal Authorities

38. Additional U.S. laws prohibiting persons or entities from engaging in biological weapons activities related to manufacturing, production, acquisition, possession, stockpiling/storage, development, transportation, transfer, or use include the following:

(a) Arms Export Control Act of 1976 (22 U.S.C. 2778)

(b) Violent Crime Control and Law Enforcement Act of 1994, as amended, 18 USC § 2332a

(c) Antiterrorism and Effective Death Penalty Act of 1996 (directs the Department of Health and Human Services (HHS) to establish a list of select agents and toxins, transfer procedures, and training requirements; creates civil and criminal penalties for violations.)

(d) Chemical Weapons Convention Implementation Act of 1998 (prohibits any person from knowingly developing, producing, otherwise acquiring, transferring directly or indirectly, receiving, stockpiling, retaining, owning, possessing, or using, or threatening to use, any weapon defined by the Chemical Weapons Convention. This encompasses toxin weapons, which are also prohibited by the BWC).

(e) Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act) (places restriction on persons who can access select agents and toxins, and provides penalties for possession of such agents that cannot be justified for specified peaceful purposes.)

(f) Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Title II, Subtitle A) (requires that entities such as private, State, and Federal research laboratories, universities, and vaccine companies that possess, use, or transfer agents or toxins deemed a threat to public health register with the department of HHS.)[10]

(g) Agricultural Bioterrorism Protection Act of 2002 (a subpart of the Public Health Security and Bioterrorism Preparedness Response Act of 2002, this law requires that entities such as private, State, and Federal research laboratories, universities, and vaccine companies, that possess, use, or transfer agents or toxins deemed a threat to animal or plant health or products register with the U.S. Department of Agriculture (USDA).)[10]

(h) U.S. Criminal Code, Title 18

(i) Sec. 371 – Criminalizes conspiracy to commit an offense or to defraud the United States

[10] Persons and entities that possess, use, or transfer biological agents or toxins that are a threat to both humans and animals can register with either HHS or USDA.

(ii) Sec. 842 – Criminalizes the import, manufacture, or dealing in explosive materials without a license; criminalizes teaching or demonstrating use of or making of Weapons of Mass Destruction (WMD) material

(iii) Sec. 2332a – Criminalizes the use (or conspiring, threatening, or attempting to use) of a WMD

(iv) Sec. 2339A/B– Criminalizes the provision of material support or resources to terrorists or designated foreign terrorist organizations

3. Regulations

39. Regulations include:

(a) HHS Select Agent and Toxin Regulations, 42 CFR part 73

(b) USDA Select Agent and Toxin Regulations (animal) 9 CFR part 121

(c) USDA Select Agent and Toxin Regulations (plants) 7 CFR part 331

(d) WMD Proliferators Sanctions Regulations, 31 CFR part 544 as amended in April 2009

4. Relevant Policies, Strategies, and Executive Orders

(a) National Counterterrorism Strategy (2011) http://www.whitehouse.gov/sites/default/files/counterterrorism_strategy.pdf

(b) National Security Strategy (2010) http://www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf

(c) National Strategy for Countering Biological Threats (2009) http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf

(d) National Intelligence Strategy (2009)

5. Homeland Security Presidential Directives (HSPDs)[11]

(a) HSPD-9: National Strategy for Defense of United States Agriculture and Food (2004)

(b) HSPD-10: National Biodefense Strategy (2004)

6. Executive Orders (EOs)[12]

(a) EO 11958: Administration of arms export controls (1977).

(b) EO 13382: Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters (2005) http://edocket.access.gpo.gov/2005/pdf/05-13214.pdf

[11] HSPDs are issued by the President on matters pertaining to Homeland Security. HSPDs can be found at: http://www.dhs.gov/xabout/laws/editorial_0607.shtm

[12] Executive Orders can be found at http://www.archives.gov/federal-register/executive-orders/disposition.html.

C. Eliminate Biological Weapons (Article II)

40. The U.S. bioweapons program was dismantled in 1969 following President Richard M. Nixon's statement renouncing the use of bioweapons[13] and the issuance of National Security Decision Memorandum 35[14].

".. 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."[6]

41. In 1970, the U.S. ban on biological weapons was extended to cover toxins, regardless of their means of production.[15] [16]

D. Prevent transfer of agents/technology

42. Article III commits BWC States Parties "not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of this Convention." The United States has measures in place to account for and secure production, use, storage, transport and transfer of particularly dangerous pathogens as well as enforcement measures enabling the prosecution and punishment of offenders. Additionally, the United States conducts domestic and international outreach/education and capacity building.

1. Legislation/Legal Authorities

(a) Antiterrorism and Effective Death Penalty Act of 1996: Title V, subtitle B authorizes HHS to develop a list of agents that threaten the public health, and to establish appropriate safeguards for the handling of these agents (the Select Agent List).

(b) Arms Export Control Act (22 U.S.C. 2778) of 1976 and Executive Order 11958 of 1977as amended.

(c) Export Administration Act of 1979, as amended and EO 13222 of 2001 as extended in 2010, continues the provisions of the Export Administration Act under authority of the International Emergency Economic Powers Act.

(d) International Emergency Economic Powers Act, as amended

(e) Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act). Excerpt: "No restricted person described in subsection (b) shall ship or transport interstate or foreign commerce, or possess in or affecting commerce, any biological agent or toxin, or receive

[13] President Richard Nixon, "Statement on Chemical and Biological Defense policies and Programs, November 25, 1969," Public Papers of the Presidents. Washington DC. U.S. Government Printing Office, 2004. 968-969

[14] National Security Decision Memorandum 35, Washington DC, November 25, 1969 in FRUS, document 165. www.state.gov/r/pa/ho/frus/nixon/e2/83596.htm

[15] 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

[16] National Security Decision Memorandum 44, Washington DC, February 20, 1970 in FRUS, document 190. www.state.gov/r/pa/ho/frus/nixon/e2/83628.htm

any biological agent or toxin that has been shipped or transported in interstate or foreign commerce, if the biological agent or toxin is listed as a select agent." per 18 USC 175b

(f) Chemical Biological Weapons Control and Warfare Elimination Act of 1991: Title V, section 504 directs the President to use his authorities under the Arms Export Control Act and Export Administration Act of 1979 to control the export of those goods and technology that the President determines would assist the government of any foreign country in acquiring the capability to develop, produce, stockpile, deliver, or use chemical or biological weapons.

(g) 18 U.S.C. 175-178

2. Regulations

(a) Select Agent Regulations (7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73)

(b) The Select Agent Regulations (SAR) regulate the possession, use, or transfer of select agents within the United States.

http://www.selectagents.gov/Regulations.html

(c) The Interstate and Foreign Quarantine Regulations (42 CFR Parts 70 and 71) (42 USC Sec. 264). These regulations are issued to implement the statutory mandate under the Public Health Service Act: "..to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession." per 42 U.S.C. 264

(d) The Department of Transportation (DOT) Hazardous Materials Regulations (49 CFR 171-180: Regulates the shipment of infectious substances.

(e) Export Administration Regulations (EAR) (15 CFR part 774 supplement 1): Export controls on pathogens and biological equipment.

(f) International Trafficking in Arms Regulations (ITAR) (22 CFR part 121): Export and import control on defense-related articles and services on the United States Munitions List (USML). http://www.pmddtc.state.gov/regulations_laws/itar_official.html

3. Policies/Strategies

(a) Executive Orders (EOs)**Error! Bookmark not defined.**

(b) EO 11958: Administration of arms export controls (1977)

(c) EO 13222: Continuation of Export Control Regulations (2001 as extended in 2010)[17]

(d) EO 13546: Optimizing the Security of Biological Select Agents and Toxins in the United States (2010)

http://edocket.access.gpo.gov/2010/pdf/2010-16864.pdf

4. Guidance

(a) The Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA (2010)

http://www.phe.gov/preparedness/legal/guidance/syndna/Pages/default.aspx

[17] http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2001_register&docid=fr22au01-130.pdf

(b) "Applicability of the Select Agent Regulations to Issues of Synthetic Genomics" The Select Agent Program guidance document.

"Know Your Customer Guidance" (Supplement No. 3 to Part 732 of the EAR)

5. Domestic and International Outreach/Awareness-Raising/Education/Training[18]

(a) Select Agent Program outreach at scientific and professional meetings and training http://www.selectagent.gov/Training.html

(b) FBI Synthetic Biology Program

(c) Export Control and Related Border Security (EXBS): The EXBS Program assists 60 partner countries with improving their strategic trade control systems with the goal of stemming the proliferation of weapons of mass destruction (WMD) and their delivery systems. EXBS works with partner countries to:

(i) Adopt legislation consistent with international standards to enable regulation of proliferation-sensitive transfers, including equipment and materials that may be used in development of biological weapons. EXBS organizes technical workshops and policy exchanges to encourage adoption of effective licensing procedures and comprehensive national control lists, including the Australia Group control list, which includes bio equipment, related technology, and software, as well as human, animal, and plant pathogens.

(ii) Prevent the inadvertent authorization of transfers of controlled items to end-uses and end-users of proliferation concern. To that end, EXBS works with partner governments to establish robust government-industry outreach programs.

(iii) Bolster their capacities to detect, deter, interdict, and prosecute illicit transfers of WMD components and weapons-related items through specialized training programs. EXBS also donates inspection and detection equipment to frontline enforcement agencies.

E. Measures to prevent the use of the life sciences for prohibited purposes

43. In addition to the measures described in Part I, the United States is actively involved in ongoing efforts to reduce the risk of misuse of the life sciences that could result in the deliberate or inadvertent release of biological material in a manner that sickens or kills people, animals, or plants, or renders unusable critical resources. These biorisk management measures include but are not limited to: safety and security measures for laboratories; containment measures; measures to facilitate ongoing monitoring of life sciences activities and domestic policy; and outreach and education.

1. Policies/Strategies

(a) U.S. Government Policy on the Oversight of Dual Use Life Sciences Research (Pending) :Sets forth performance standards for oversight of dual use life sciences research conducted or funded by agencies of the United States Government to reduce the potential that knowledge, information, products, or technology derived from that research

[18] Additional information on United States outreach, awareness-raising, education, training efforts can be found in the United States National Report on Implementation of Article X and the U.S. Annex of the Working Paper on Possible Approaches to Education and Awareness-raising among Life Scientists (BWC/CONF.VII/WP20).

could be misapplied to threaten public health and safety or other aspects of national security.

(b) National Institutes of Health (NIH) researchers must complete the Publication and Abstract Clearance Form (includes a Dual Use Questionnaire)

(c) CDC's Oversight and Clearance of Dual Use Research of Concern: http://www.cdc.gov/od/foia/policies/policy516.pdf

2. Guidance

(a) NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) specify practices for constructing and handling recombinant DNA molecules and organisms containing recombinant DNA.

(b) Biosafety in Microbiological and Biomedical Laboratories, 5th edition

(c) NIH Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities

(d) Agricultural Research Service Facilities Design Standards

(e) Applicability of the Select Agent Regulations to Issues of Synthetic Genomics

(f) NIH Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities

(g) Agricultural Research Service Facilities Design Standards

(h) New Directions: Ethics of Synthetic Biology and Emerging Technologies (Presidential Commission for the Study of Bioethical Issues)

(i) National Science Advisory Board for Biosecurity (NSABB) Documents. The NSABB is a Federal advisory committee chartered 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.

http://oba.od.nih.gov/biosecurity/biosecurity_documents.html

(i) Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility (2011)

(ii) Strategies to Educate Amateur Biologists and Scientists in Non-life Science Disciplines about Dual Use Research in the Life Sciences (2011)

(iii) Enhancing Personnel Reliability Among Individuals with Access to Select Agents (2009)

(iv) Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information (2007)

3. Domestic and International Outreach/Awareness-Raising/Education/Training[19]

(a) The NIH/Office of Biotechnology Activities (OBA) has developed a series of products to foster awareness of the dual use issue. These include a brochure "Does Your

[19] Additional information on United States outreach, awareness-raising, education, training efforts can be found in the United States National Report on Implementation of Article X and the U.S. Annex of the Working Paper on Possible Approaches to Education and Awareness-raising among Life Scientists (BWC/CONF.VII/WP20).

Research Have Dual Use Potential" and a video with leading experts titled "Dual Use Research: A Dialogue." In addition, NIH/OBA staff attends or supports professional and scientific meetings, providing outreach on the dual use issue. The United States Government has sponsored, with hosting by the NSABB, a series of three International Roundtables, live interactive webcasts, bilateral video-teleconferences and roundtables with international attendees. This has included regionally focused events for the Americas, Europe, and the broader Middle East/North Africa area. A future workshop with a focus on Asia and Western Pacific is planned for December 2011. Videos of these activities and written summaries of the International Roundtables are available at http://oba.od.nih.gov/biosecurity/biosecurity.html

(b) FBI/HHS/AAAS Workshops on Synthetic Biology (2009-2011)

(c) ASPR/OPP outreach at scientific and professional meetings: http://www.phe.gov/about/OPP/Pages/bwc.aspx

(d) S3: Science, Safety, Security campaign: http://www.phe.gov/S3

(e) FBI Biological Scientific Outreach Program

(f) FBI Amateur (Do-It-Yourself) Biology Initiative

(g) University Policy Centers: These centers play a vital role in forming sound domestic and international policy by exploring policy options, evaluating current policy and providing accurate information to the public. In addition, many of these centers offer biosecurity- and biodefense-focused degrees.

http://www.fas.org/programs/bio/university.html

(h) Development, and sustainable adoption of biorisk management practices including the development of training programs and materials (OECD; WHO)

(i) Promote the establishment of international biosafety/biosecurity associations

(j) Virtual Biosecurity Center (VBC): A global multi-organizational initiative, spearheaded by the Federation of American Scientists (FAS), committed to countering the threat posed by the development or use of biological weapons and the responsible use of science and technology.

http://virtualbiosecuritycenter.org/

(k) White House Office of Science & Technology Policy-Biosecurity: http://www.whitehouse.gov/administration/eop/ostp/nstc/biosecurity

F. Detection/response to biological incidents

44. Article VII of the Biological Weapons Convention commits BWC States Parties to provide assistance upon request to any State Party exposed to danger as a result of violation of the Convention. National capacity to detect and respond to biological incidents regardless of cause are critical not only to effectively address an event directly, but to maximize a country's ability to rapidly identify needs, seek assistance, oversee international response, and recover. The United States actively builds both domestic and international capacity to respond to biological incidents.

1. Legislation/Legal Authorities

45. Federal laws and legal authorities address a variety of concerns central to public health emergencies, such as emergency declarations, quarantine and isolation, and mutual

aid, among others. These laws involve multiple federal agencies and appear in many different official documents.

(a) Public Health Service Act, including sections such as:

(b) Section 311: Federal-State Cooperation (42 U.S.C. § 243)

(c) Section 319: Public Health Emergencies (42 U.S.C. § 247d).

(d) Section 319F-2: Strategic National Stockpile (42 U.S.C. § 247d-6b): Authorizes HHS to maintain a stockpile of drugs, vaccines, biological products, medical devices and other supplies to provide for the emergency health security of the United States.

(e) Section 361: Regulations to Control Communicable Diseases (42 U.S.C. § 264)

(f) Section 362: Suspension of Entries and Imports from Designated Places to Prevent Spread of Communicable Diseases (42 U.S.C. § 265)

(g) Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. No. 107-188)

(h) Pandemic and All-Hazards Preparedness Act of 2006 (Pub. L. No. 109-417)

(i) Public Readiness and Emergency Preparedness (PREP) Act of 2005 (Pub. L. No. 109-148; 42 U.S.C. §§ 247d-6d, 247d-6e)

(j) Project BioShield Act of 2004 (Pub. L. No. 108-276; 21 U.S.C. 360bbb-3)

(k) Penalties for Violation of Quarantine Law (42 U.S.C. § 271)

(l) Emergency Medical Treatment and Active Labor Act (42 U.S.C. § 1395dd)

(m) State Health Laws Observed by United States Officers (42 U.S.C. § 97)

(n) Immigration Authority (8 U.S.C. §§ 1182 and 1222, 42 U.S.C. § 252)

2. Regulations

(a) Interstate Quarantine (42 C.F.R. Part 70)

(b) Foreign Quarantine (42 C.F.R. Part 71) to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the States or possessions of the United States

(c) Medical Examination of Aliens (42 C.F.R. Part 34)

3. Policies/Strategies

(a) National Response Framework (2008): The National Response Framework is a guide to how the United States conducts all-hazards response, and is intended to capture specific authorities and best practices for managing incidents that range from the serious but purely local, to large-scale terrorist attacks or catastrophic natural disasters.

http://www.fema.gov/pdf/emergency/nrf/nrf-core.pdf

(b) National Strategy for Countering Biological Threats (2009)

http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf

(c) National Health Security Strategy (2009): The National Health Security Strategy (NHSS) is intended to help galvanize efforts to minimize the health consequences

associated with significant health incidents. It provides the framework for how the nation will seek to achieve national health security over the next four years.

http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf

(d) National Research and Development Strategy for Microbial Forensics (2009)

http://www.whitehouse.gov/files/documents/ostp/NSTC%20Reports/National%20MicroForensics%20R&DStrategy%202009%20UNLIMITED%20DISTRIBUTION.pdf

(e) National Biosurveillance Strategy for Human Health (2010) http://www.cdc.gov/osels/pdf/NBSHH_V2_FINAL.PDF

(f) Global Health Security Initiative (GHSI) http://www.phe.gov/preparedness/international/ghsi/pages/default.aspx

(g) Biomedical Advanced Research and Development Authority (BARDA) Strategic Plan 2011-2016

https://www.medicalcountermeasures.gov/Barda/documents/BARDAStrategicPlan9-28--508.pdf

(h) Homeland Security Presidential Directives (HSPDs)**Error! Bookmark not defined.**

(i) HSPD-18: Medical Countermeasures against Weapons of Mass Destruction

(ii) HSPD-21: Public Health and Medical Preparedness

(i) Executive Orders (EOs)**Error! Bookmark not defined.**

(i) EO 13527: Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack (2009)

(ii) EO 13295: Revised List of Quarantinable Communicable Diseases (2003)

(iii) EO 13375: Amendment to Executive Order 13295 Relating to Certain Influenza Viruses and Quarantinable Communicable Diseases (2005)

4. Additional Measures

(a) HHS has developed Concept of Operations Plans (CONOPS) that provide the framework for its management of the public health and medical response to an emergency or disaster. http://www.phe.gov/Preparedness/support/conops/Pages/default.aspx

(b) U.S. Civilian Response Corps (CRC): http://www.phe.gov/Preparedness/international/crc/Pages/deployments.aspx

(c) The CDC's Office of Public Health Preparedness and Response, Division of State and Local Readiness administers funding ($613 million this year) through the Public Health Emergency Preparedness (PHEP) cooperative agreement to help public health departments strengthen their abilities to respond to all types of public health incidents and to build more resilient communities.

(d) HHS, Department of Homeland Security (DHS), and United States Postal Service (USPS) are working together to establish a National USPS Medical Countermeasure dispensing model that would provide residential delivery of medical countermeasures following a biological attack, with the goal of providing preventive antibiotics to 100 percent of the potentially exposed population as quickly as possible, ideally within 48 hours.

(e) Food and Drug Administration (FDA) - Food Defense and Emergency Response: The 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.

(f) Food and Drug Administration (FDA) – Strategic Plan for Regulatory Science: A strategic plan for the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products.
http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RegulatoryScience/UCM268225.pdf

(g) Regional Center of Excellence for Biodefense and Emerging Infections (RCE): Ten regional centers established by the National Institute of Allergy and Infectious Diseases (NIAID) to develop new vaccines, therapies, and diagnostics for emerging infections and biodefense threats.

http://www.niaid.nih.gov/labsandresources/resources/rce/Pages/default.aspx

(h) HHS/CDC Laboratory Response Network (LRN): The LRN's purpose is to operate a network of labs that can respond to biological and chemical terrorism, and other public health emergencies. The LRN includes state and local public health, veterinary, military, and international labs. http://www.bt.cdc.gov/lrn/factsheet.asp

5. Domestic and International Outreach/Awareness-Raising/Education/Training Error! Bookmark not defined.

46. The United States also aims to improve regional and global partnerships in preparedness and response to biological incidents, whether natural, accidental, or deliberate in nature, and to link prevention and nonproliferation to preparedness and response. Recent activities include the following.

(a) FBI/CDC Joint Criminal and Epidemiological Investigations Training Program

(b) The Southern Caucasus Workshop on Public Health, Security, and Law Enforcement Partnership in Bio-Incident Pre-Planning and Response and the associated Southern Caucasus BioShield Tabletop Exercise (Tbilisi, Georgia, 11-12 May 2010).

(c) The Trilateral (US-Romania-Moldova) Civilian-Military Forum on Outbreak Response and Bioterrorism Investigation (ORBIT Forum) (Chisinau, Republic of Moldova October 19-21, 2010).

(d) Countering Biological Threats: National Implementation of the Biological Weapons Convention and Multinational Outbreak Response and Bioterrorism Investigation Demonstration (Tbilisi Georgia, 17-19 May 2011).

(e) Black ICE (2006)/Black ICE II (2009): Co-hosted with the Government of Switzerland. Tabletop exercises to examine the critical cooperation and coordination issues for international entities response to an international bioterrorism attack. http://merln.ndu.edu/archivepdf/wmd/State/79521.pdf

G. Encourage peaceful use of science and tcehnology

48. A robust and productive scientific enterprise is vital to improving public health, agriculture, and the environment, and to maintaining and strengthening national security and the economy. The U.S. encourages the peaceful use of the life sciences through many

means. These are detailed in the United States National Report on implementation of Article X[20].

[20] See BWC/CONF.VII/INF.8/Add.1