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National Legislative Measures to Prevent the Proliferation of Biological Weapons

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National Legislative Measures to Prevent the Proliferation of Biological Weapons

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Abstract

The dangers of biological weapons (BW) are real and immediate – a fact the anthrax attacks of 2001 tragically reiterated. Since those events, the international community has redoubled its efforts to implement strategies that aim to prevent the proliferation of these weapons. The Biological Weapons Convention (BWC), which does not contain a verification regime, requires each individual State Party to uphold its provisions banning the stockpiling and transfer of biological weapons. States generally fulfill these requirements by passing laws that 1) implement the conditions of the BWC and 2) place export controls over BW-related materials. Recently, a third legislative option has been explored with the goal of protecting dangerous biological materials against theft and sabotage. This strategy is typically called “biosecurity.”

Unfortunately, relatively few States Parties of the BWC have passed any of these types of legislation, despite repeated requests from the Convention to do so. This paper explores the benefits afforded to biological weapon nonproliferation by states’ passage of BWC implementation legislation, export controls, and legally binding biosecurity guidelines. The appendices outline the legislative progress made by States Parties and give summaries of a sample of model laws passed by various countries.

Introduction

The threats posed by biological weapons (BW) are mitigated primarily by unilateral actions undertaken by individual states. This is inconsistent with chemical weapon and nuclear weapon nonproliferation strategies, which are generally agreed to and carried out internationally by the respective verification regimes of the Chemical Weapons Convention (CWC) and the Treaty on the Non-Proliferation of Nuclear Weapons (NPT). Conversely, the Biological Weapons Convention (BWC) lacks completely the means by which to establish an international verification regime. Rather, to facilitate member compliance, the treaty contains a provision that obligates States Parties to legally enforce treaty prohibitions in areas under state jurisdiction.

Article IV of the Convention codifies the BWC's dependence on national mechanisms to enforce treaty requirements. It mandates that States Parties act "in accordance with their constitutional processes... to prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere." Typically, States Parties fulfill this requirement by ratifying national legislation that reaffirms the nonproliferation goals of the BWC and criminalizes acts in contravention to those prohibitions.

Legislation that implements the BWC constitutes a fundamental component of a comprehensive and global BW nonproliferation strategy. However, BWC implementation alone is not sufficient to stop proliferation. Other measures, including additional types of national legislation, are necessary to further this difficult but critical objective. Whereas BWC implementation legislation criminalizes proliferation, other laws aim to prevent proliferation, such as export controls over certain biological materials and equipment, and biosecurity regulations that protect legitimate but potentially dangerous microbiological agents from theft.

Ratification of these three types of laws – BWC implementation, export control, and biosecurity – represents an affirmation of that state's commitments to BW nonproliferation and to the BWC. Because the BWC lacks an international verification regime, passage and enforcement of these laws by individual states is essential to punish actions that do not comply with treaty requirements. Unfortunately, too few countries have enacted such legislation – especially BWC implementation and criminalization measures – leaving the production of biological agents for use as weapons technically illegal, but not punishable in most parts of the world. This weakness has resulted in many critics arguing that the Convention is little more than a "gentlemen's agreement," unable to prevent the proliferation of BW.

Fortunately, a number of countries have enacted comprehensive BW-related legislation. And while the numbers remain small, these few countries have set an international precedent and have created model legislation that other countries can follow. In an attempt to facilitate this type of legislative mentoring, the BWC has established a

mechanism to encourage states to share information related to their national legislative actions through a depository at the United Nations (UN). Formal requests calling on countries to share their legislation information have been repeated at each and every penta-annual Review Conference of the BWC, the principal official forum States Parties use to discuss treaty matters. In 2003, BWC implementation was one of only two topics (along with biosecurity) discussed at a two-week “experts group” meeting of the Convention. Dedicating the first annual Experts Group Meeting of the BWC to national implementation/criminalization and biosecurity attests to the critical importance of these two nonproliferation tools.

Also setting an international standard is the work of the Australia Group (AG) – a multilateral export control regime composed of 33 countries dedicated to regulating the export of certain biological agents, toxins, and dual-use equipment. The recommendations of this group have significantly influenced export control laws in much of the world, including many countries outside its list of members.

This paper analyses how national legislative measures such as BWC implementation, export control, and biosecurity improve and further global BW nonproliferation. In addition, it identifies legislative trends throughout the world, and highlights opportunities to promote BW-related laws within the international community.

Appendix A is a compilation of BW-related legislative measures taken by various countries. This list – compiled from data collected by the Secretariat of the 2003 Meeting of the States Parties to the Biological Weapons Convention, Member State responses to BWC confidence-building measures, and world-wide-web research – is not a comprehensive legislative survey of all countries or BWC Member States. Rather, Appendix A has gathered information from those states that have made their legislation available and transparent. Appendix B summarizes specific legislation from 15 of these countries. Viewing these laws and regulations in detail brings to light some features of what effective BW-related legislation may contain.

National Measures to Implement the Prohibitions of the BWC

Of the three BW-nonproliferation legislation measures, laws that prohibit acts in contravention to the BWC are the most fundamental and straightforward. These laws, which amalgamate the BWC into the national legal system, prohibit the production, stockpiling, acquisition, and transfer of BW and BW-related goods. These laws should be binding on governmental agencies, corporate and private entities, and individuals.

Passage of these laws is one of the general requisites of the BWC. Specifically, Article IV of the Convention mandates that:

Each State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention

of the agents, toxins, weapons, equipment, and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.

Article IV thus places the impetus on States Parties to regulate the prohibitions of the BWC in areas under their jurisdiction. Although the word “legislation” is not explicitly stated, countries that have met the terms of this Article IV have most commonly ratified new national laws or amended existing laws to include BWC-related actions. But there are options other than passing or amending legislation. Cambodia and Columbia have outlawed BW within the text of their respective Constitutions. Either approach suffices but most states have complied with Article IV by passing legislation in accordance with their constitutional practices.

Adopting BWC implementation legislation – which should include criminal penalties – is vital to the Convention’s success and has been underscored by the BWC at least every five years. For example, the Second Review Conference, held in 1986, declared that it was necessary for “all States Parties which have not yet taken any necessary measures in accordance with their constitutional processes, as required by the Article, to do so immediately.”¹

Despite this request, a United Nations Institute for Disarmament Research (UNIDIR) report compiled for the 1990 Third Review Conference noted that “very few” states had complied with Article IV and passed legislative or other measures implementing the Convention.²

To facilitate the passage of national implementation legislation, States Parties at the Second and Third Review Conferences agreed to cooperate in a variety of confidence-building measures (CBMs) to mitigate suspicions of non-compliance and improve international cooperation and communication. Specifically, CBM Measure E required states to submit annual declarations of BWC-related legislation, including BWC implementation and import/export regulations, to the United Nations Department for Disarmament Affairs. Completing Form E, which is a short pro forma composed of twelve “yes or no” questions, States Parties can disclose information related to BWC legislation.

¹ United Nations, *The Second 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*, Geneva 8-26 September 1986, BWC/CONF.II/13/11, 26 September 1986.

² Jozef Goldblat and Thomas Bernaure, *The Third Review of the Biological Weapons Convention: Issues and Proposals*, UNIDIR Research Paper No. 9, New York: United Nations, 1991, p.22.

Form E³

<u>Declaration of Legislation, Regulations, and Other Measures</u>				
<u>Relating to</u>	<u>Legislation</u>	<u>Regulations</u>	<u>Other Measures</u>	<u>Amended Since Last Year</u>
a) Development, production stockpiling, acquisition or retention of biological agents or toxins, weapons, equipment and means of delivery specified in Article I	YES / NO	YES / NO	YES / NO	YES / NO
b) Exports of micro-organisms and toxins*	YES / NO	YES / NO	YES / NO	YES / NO
c) Imports of micro-organisms and toxins*	YES / NO	YES / NO	YES / NO	YES / NO
*Micro-organisms pathogenic to man, animals, and plants in accordance with the Convention.				

Although States Parties have had more than 17 years to submit information under CBM Measure E, responses are uncommon. Legislative data has been submitted by 32 States Parties, of which only 19 countries have passed national implementation legislation.⁴ Out of 146 Member States, 114 either have not responded to CBM Measure E or have answered that they have no relevant legislation. Therefore, only 22 percent of States Parties have responded to CBM Measure E with only 13 percent of States Parties adopting the prohibitions of the BWC into their national legal system.

The amount of detail provided by the states that have responded to CBM Measure E varies greatly. Certain countries, such as Australia, Brazil, Canada, Germany, and the United States, listed the names of their relevant legislation and attached detailed explanatory notes.⁵ However, most countries completed the minimum requirement –

³ United Nations, *Annex to Final Declaration on Confidence-building Measures*, Geneva, 1991, BWC/CONF.III/23 Annex.

⁴ See Appendix B for a complete listing of CBM-E responses, including country name and type of legislation.

⁵ See, for example, *Background Information on the Compliance of Article IV, Brazil*, BWC/CONF.V/10, 23 November 2001.

answering “yes” or “no” to the questions – but provided little, if any, information regarding the title, nature, or scope of the legislation or regulatory measures.

The continuing lack of compliance with Article IV and CBM Measure E was addressed once more at the Fifth Review Conference in 2001. To highlight its importance to the Convention, BWC implementation was set as the first item to be discussed at the subsequent meeting of States Parties. The Final Declaration of the Fifth Review Conference stated that the August 2003 meeting would “discuss and promote common understanding and effective action on [*inter alia*]: the adoption of necessary national measures to implement the prohibitions set forth in the Convention, including the enactment of penal legislation.”⁶

Time will tell if additional States Parties were persuaded during the 2003 meetings to begin the process to enact national implementation legislation, or to provide information on existing legislation through CBM Form E to the UN Center for Disarmament Affairs.

Export Controls

In addition to BWC implementation legislation, the Convention requires that States Parties prohibit the export of BW and BW-related goods. Article III of the Convention states:

Each State Party to this Convention undertakes 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 the Convention.

Export controls covering sensitive materials and technology are a key policy instrument in the global strategy to mitigate the spread of weapons of mass destruction (WMD). Export controls allow countries to prohibit the exportation of certain goods that could jeopardize national security or contravene a commitment to an international agreement. Thus, export controls are created and implemented both unilaterally and multilaterally, in conjunction with treaties and export control regimes. For example, export controls over sensitive materials are a primary component of the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) and the Convention on the Prohibition of Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction (CWC).

Multilateral export control regimes, such as the Australia Group (AG), the Missile Technology Control Regime (MTCR), the Nuclear Supplier Group (NSG), and the

⁶ United Nations, *Fifth Review Conference of the States Parties to the Convention on the Prohibition on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction: Final Document*, Geneva, 2001-2002, BWC/CONF.V/17.

Wassenaar Arrangement, have also played essential roles in formulating comprehensive and efficient export controls around the globe. These international organizations work to coordinate and homogenize export control practices of certain goods and technologies among their Member States. Policies created by these regimes aim to prevent the proliferation of WMD-related goods and information to states and terrorists.

Although these regimes are voluntary and non-binding, their recommendations are generally adhered to by Member States. Even non-Member States occasionally implement export controls reflecting the recommendations of these groups. Specifically, the policies adopted by the AG, which emphasize export controls over chemical and biological materials and related dual-use goods, have become a universal standard. For example, although not members of the AG, countries such as China, Kazakhstan, Russia, and South Africa, among others, have adopted export control policies regulating many of the same biological and chemical items listed on the AG's Common Control Lists.⁷

The AG, like the BWC, does not possess an enforcement regime. The onus of regulating compliance is placed on the regime member, although a state that does not comply would be at risk of losing its membership, and thus lose the ability to import certain materials from Member States. Member States of the AG agree to enact national legislation implementing the requisites of the organization. This legislation typically includes the establishment of an official export authority, export control regulations – including criminal penalties for acts in contravention to the established rules – and official export control lists detailing which items are subject to governmental export control.

Biosecurity^{8,9}

Creating legally binding biosecurity regulations that reduce the likelihood that potentially dangerous pathogens, toxins, and related information could be stolen or diverted for malicious purposes is a third component states can implement to augment their BW nonproliferation strategies. Establishing security and oversight over these agents negates one path a would-be proliferator could use to gain access to pathogenic microbiological material, the necessary precursor for BW. Biosecurity aims to mitigate the BW threat at the source. Although biosecurity is currently in an initial stage of development, it recently has received an increasing amount of global attention and recognition as an effective means of preventing BW development and proliferation.

The investigations following the 2001 bioterrorist attacks against the United States have generated a theory that, at some point prior to the attacks, the perpetrator – or perpetrators – illegally acquired *Bacillus anthracis* from a legitimate bioscience research facility.

⁷ AG Common Control Lists are published on-line at: <http://www.australiagroup.net/agcomcon.htm>

⁸ Sandia National Laboratories defines *biosecurity* as the protection of high-consequence pathogens and toxins from theft or malicious diversion in a laboratory setting or during transport.

⁹ For a complete systems-wide approach to biosecurity see Reynolds M. Salerno, Natalie Barnett, and Jennifer G. Koelm, *Balancing Security and Research at Biomedical and Bioscience Laboratories*, SAND No. 2003-0701C, 2003.

This suspicion led U.S. legislators to question how difficult it would be to steal anthrax or other pathogenic materials from microbiological facilities. The dissatisfactory answers gleaned at Congressional hearings and from other investigations prompted the passage of more effective biosecurity legislation than was previously in force.¹⁰

The post-September 11th environment in the United States reflects a new awareness that pathogens may be targeted for theft, but the realization of the threat posed by the diversion of biological materials is not new. Biosecurity legislation was originally addressed in 1996 at the Fourth Review Conference, which stated that: “The Conference notes the importance of: ..Legislation regarding the physical protection of laboratories and facilities to prevent unauthorized access to and removal of microbial or other biological agents or toxins.”¹¹ Despite this statement, no official recommendation was issued either describing the components or implementation strategy of an effective biosecurity system. This lack of attention resulted in little being achieved internationally to secure biological materials. Further, BWC debates since 1996 have been dominated by attempts to establish a verification protocol.

The collapse of the efforts to develop a protocol in 2002 has encouraged the development of additional nonproliferation strategies. Within the BWC, a redoubled effort is underway to focus attention on the importance of securing dangerous pathogens and toxins from theft and malicious diversion.

The August 2003 Experts Working Group meeting of the BWC inaugurated this resurgence in efforts to establish international biosecurity. As mandated by the Final Document of the Fifth Review Conference of the BWC, this symposium dedicated one week to the “security and oversight of pathogenic microorganisms and toxins.”¹² Although no formal or binding decisions could be made at these meetings, the international community shared their views and accomplishments on this specific topic. Moreover, the World Health Organisation (WHO) expressed interest in creating biosecurity guidelines, which would set the international security standard for bioscience facilities and personnel.

While welcome, the WHO standards would not be legally binding. It would be the responsibility of each individual state to pass national legislation enforcing a minimum standard of biosecurity at facilities that handle, use, or transport dangerous biological materials. The WHO standards would help by providing guidance to states that still need to create appropriate biosecurity laws.

¹⁰ The *Antiterrorism and Effective Death Penalty Act of 1996* contained rudimentary security requirements for Select Agents and Toxins. The requirements of this act have since been expanded by the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*.

¹¹ United Nations, *Fourth Review Conference Final Declaration*, Geneva, 1996, BWC/CONF.IV/9 Part II.

¹² United Nations, *Fifth Review Conference of the States Parties to the Convention on the Prohibition on the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction: Final Document*, Geneva, 2001-2002, BWC/CONF.V/17.

Without adroit and vigilant persistence from organizations, such as the BWC, the AG, and the WHO, compelling States Parties to pass biosecurity legislation, very few states will likely act. Although pressure from these organizations will not guarantee that biosecurity will be implemented in all parts of the world, their influence is significant and desired. Further, individual states that pass comprehensive and efficient legislation may also foster a broad endorsement of biosecurity.

To date only two countries, the United States¹³ and the United Kingdom,¹⁴ have passed wide-ranging legislation concerning the security and oversight of dangerous pathogens and toxins. While these two countries represent only a small minority of those nations with laboratories and other facilities that have dangerous pathogens and toxins, their laws may serve as a template for other states to follow. Although only the United States and the United Kingdom have instituted biosecurity regulations, other states have shown official interest in biosecurity including, but not limited to, Brazil,¹⁵ Canada,¹⁶ and Japan.¹⁷

Codified biosecurity requirements represent a new generation of BW-nonproliferation legislation. BWC implementation and export controls focus on preventing state-based proliferation. Securing pathogens from theft also addresses the terrorist or non-state affiliated threat. By preventing unauthorized acquisition of dangerous pathogens and toxins, biosecurity provides the first line of defense against both state-based BW proliferation and bioterrorism.

Conclusion

Many experts and scholars have emphasized the significance of the biological weapons threat. The initial building block of a biological weapon – a single cell of a pathogenic organism – is easy to safely transfer and virtually impossible to detect remotely with current technologies. Dangerous pathogens are naturally occurring and located throughout the world; the equipment required to grow and process such organisms are commonly used in many bioscience research laboratories; and many tools for disseminating biological weapons are commercially available.

For these reasons, preventing BW proliferation, biological warfare, and bioterrorism is dependent on a concerted multinational strategy. The international community cannot rely on only a small number of states to stem BW proliferation or bioterrorism.

¹³ Reynolds M. Salerno and Cheryl Miller, *Analysis of U.S. Bioterrorism Legislation*, SAND No. 2002-3130P, 2002.

¹⁴ Appendix A contains summaries of the BW legislation of the United Kingdom et al.

¹⁵ United Nations, *Statement: Ambassador Celina M. Assumpção do Valle Pereira, Fifth 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*, Geneva, 2001 explaining upcoming biosecurity legislation.

¹⁶ Health Canada statement, <http://www.hc-sc.gc.ca/english/epr/faq.html#10>.

¹⁷ Simon Collard-Wexler, “Comparative Review of Biosecurity-Related Legislation,” Monterey Institute of International Studies, 2002, on-line at: <http://cns.miiis.edu/research/cbw/biosec/pdfs/biolaw.pdf>.

Legislative measures including BWC implementation, export control, and biosecurity requirements are crucial in the fight against the proliferation of biological weapons. Because the BWC has no enforcement regime, the impetus is on individual states to ensure compliance within areas under their jurisdiction. Unfortunately, only a few states have followed through with the admonitions of the Conference, thus leaving BW production technically illegal, but not punishable in most parts of the world.

The anthrax attacks in the United States in the fall of 2001 raised the awareness to the threats posed by the use of BW around the globe. Since that time, many states have reappraised their national legislation in regards to bioterrorism. And since the collapse of efforts to develop a verification protocol, many states have looked increasingly toward the BWC for additional and novel measures to limit the treats posed by BW, such as biosecurity and detailed penal legislation.

This is a time of great opportunity. The international community must redouble its efforts to end BW proliferation and stem the BW threat by introducing new concepts, such as biosecurity, and pressuring states that have not instituted the prohibitions of the BWC or biological export control. Promoting national legislation throughout the world as a critical nonproliferation tool is the responsibility of the international community, interested international organizations, and especially those nations that have already implemented this legislation, such as the United States the United Kingdom.

Appendix A
Legislative Actions ¹

MEMBER STATE	CBM E RESPONSE	BWC IMPLEMENTATION	PENAL LEGISLATION	EXPORT REGULATIONS	IMPORT REGULATIONS	BIOSECURITY REGULATIONS
Argentina	No	No	No	Yes	Yes	No
Australia*	Yes	Yes	Yes	Yes	Yes	No
Austria	Yes	Yes	Yes	Yes	Yes	No
Belarus	Yes	Yes	No	Yes	Yes	No
Belgium*	No	Yes	Yes	Yes	Yes	No
Brazil*	Yes	Yes	Yes	Yes	No	Yes
Bulgaria*	Yes	Yes	Yes	Yes	Yes	No
Canada*	Yes	No	No	Yes	Yes	No
Chile	No	No	No	Yes	No	No
China*	No	No	No	Yes	Yes	No
Columbia	No	Yes	No	No	No	No
Croatia	No	No	Yes	Yes	Yes	No
Cuba	No	No	No	Yes	Yes	No
Czech Republic	Yes	No	No	No	No	No
Denmark	No	No	No	Yes	No	No
Estonia	Yes	Yes	Yes	Yes	Yes	No
Finland	Yes	Yes	Yes	Yes	No	No
France*	Yes	Yes	Yes	Yes	No	No
Georgia	Yes	No	No	No	No	No
Germany*	Yes	Yes	No	Yes	No	No
Hungary	Yes	Yes	No	Yes	Yes	No
India	No	No	No	Yes	Yes	No
Iran (Islamic Republic of)	No	No	No	No	Yes	No
Italy	Yes	Yes	No	Yes	Yes	No
Japan*	Yes	Yes	Yes	Yes	No	No
Kazakhstan	No	No	No	Yes	Yes	No
Latvia*	No	Yes	Yes	Yes	Yes	No
Liechtenstein	Yes	Yes	Yes	Yes	Yes	No
Lithuania*	Yes	Yes	Yes	Yes	Yes	No

Mexico	No	No	No	No	No	No
Netherlands	No	No	No	Yes	No	No
New Zealand	Yes	Yes	Yes	Yes	Yes	No
Norway	Yes	Yes	Yes	Yes	Yes	No
Poland	No	No	No	Yes	No	No
Republic of Korea	Yes	No	No	Yes	No	No
Romania	No	No	No	Yes	Yes	No
Russian Federation*	Yes	Yes	Yes	Yes	No	No
South Africa	Yes	Yes	Yes	Yes	Yes	No
Spain	Yes	No	No	No	No	No
Sweden	Yes	No	No	Yes	No	No
Switzerland	Yes	Yes	Yes	Yes	Yes	No
Tajikistan*	No	No	No	No	No	No
Ukraine	Yes	No	No	Yes	Yes	No
United Kingdom*	Yes	Yes	Yes	Yes	Yes	Yes
United States*	Yes	Yes	Yes	Yes	Yes	Yes

¹ Data collected with help from: "BWC information repository CD-ROM (version 1)," compiled by the Secretariat of the 2003 Meeting of the States Parties to the Biological Weapons Convention (not an official document), 2003; "Annual information exchange of States Parties on confidence-building measures, as agreed at the Third Review Conference of the parties to the Convention," collected by the UN Department of Disarmament Affairs, DDA/BWC/2000/CBM, 2000; and official internet (world wide web) sources.

* See Appendix B for detailed summaries of specific legislation

Appendix B

Summarized Laws By Country

Australia

Crimes (Biological Weapons) Act (1976) and Regulations (1980)

In accordance to Article IV of the BWC, the Crimes (Biological Weapons) Act implements the treaty's requirements banning the development, production, and stockpiling of BW and their means of delivery. This act prohibits individuals or entities, including governmental agencies, "to develop, produce, stockpile or otherwise acquire... biological agents...that have no justification." The handling of confiscated BW is regulated by this act and may be stored and transported only by "authorized persons." This act is binding on the state, Australian territory, and citizens of Australia living or traveling abroad. Those convicted of an act in contravention of this Act face steep fines and up to life imprisonment.

Weapons of Mass Destruction (Prevention of Proliferation) Act (1995)

This act defines weapons of mass destruction (WMD) as any "nuclear, biological, or chemical weapon or missiles capable of delivering such weapons." Under the WMD (Prevention of Proliferation) Act, the proliferation of WMD, their precursors, or any aid toward their production is illegal and punishable by up to life imprisonment.

The Customs Act (1901) (as amended 1996)

The 1996 amendment to the Customs (Prohibited Exports) Regulations placed the Department of Defense in control regarding the export of defensive and strategic goods. These goods are listed in the Defensive and Strategic Goods List, which is current with Australia Group Common Control Lists.

National Health Act (1953):

Constitution of the National Pathology Accreditation Advisory Council (1997)

As an amendment to the National Health Act, the Constitution creates the National Pathology Accreditation Advisory Council (NPAAC). The duties of the NPAAC include "introducing and maintaining uniform standards of practice in pathology laboratories throughout Australia." Although the NPAAC has not yet addressed laboratory biosecurity standards, the council could act as the conduit to instituting biosecurity practices in the Commonwealth of Australia.

Belgium

Law of 10 July 1978

Enacting the provisions of the BWC, the Law of 10 July 1978 outlaws the development, production, stockpiling and otherwise acquiring BW. The law includes relatively soft penalties such as a maximum prison sentence of not more than one year and trivial monetary fines.

Brazil

Decree No. 77,374 (1976)

This decree implements the prohibitions of the BWC into Brazilian law. Acts in contravention to the Convention are punishable offences.

Law No. 9,112 (1995)

This law places export controls over certain biological and toxin agents and dual-use equipment to mitigate the proliferation of BW.

Directive No. 4602 (2003)

This directive, issued in response to the September 11th attacks and subsequent anthrax mailings obliges all laboratories in Brazil to notify the existence of *Bacillus anthracis* in their facilities. Further, all biological institutions “will be submitted to inspections and specific measures of biosecurity will be defined for each of them.”¹⁸

Bulgaria

The Constitution of the Republic of Bulgaria (1991)

Although BWC implementation is most typically instituted by legislative means, some countries, including Bulgaria, Cambodia, and Columbia, have placed the prohibitions of the BWC directly into their constitutions. For example, Bulgaria’s constitution implements the prohibitions of the BWC and all other international treaties ratified by the Republic.

Article V, paragraph 4 states that:

¹⁸ United Nations, *Statement: Ambassador Celina M. Assumpção do Valle Pereira, Fifth 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*, Geneva, 2001 explaining upcoming biosecurity legislation.

The international instruments ratified in the manner established by the Constitution, promulgated and entered into force in the Republic of Bulgaria shall be part of the country's domestic law. They shall enjoy superiority over such norms of domestic law that contradict them.

Acts in violation of the Constitution are subject to criminal punishment.

Law on the Control of Foreign Trade Activity in Arms and Dual-Use Goods and Technologies (1995)

Following the recommendations of the AG, Bulgaria has implemented export controls over those goods listed in the Australia Group's Common Control Lists in addition to a "Catch All" clause banning the export of any materials not listed, but intended to be used in a proscribed weapons program. Criminal penalties include monetary fines and up to 8 years imprisonment.

Canada

Export and Import Permits Act (1985)

The export act mandates the creation of an Export Control List (ECL), an Import Control List (ICL), and an Area Control List (ACL). These lists are current with AG lists. Canada requires that pathogens and dual-use materials listed on the ICL and ECL be accompanied by a permit given by the appropriate Minister. Contravention of this act may result in a ten-year incarceration and/or a fine of 25,000 Canadian dollars.

Health of Animals Act 1990 (and Regulations)

This Act addresses the need to quickly curtail any infectious animal or epizootic outbreak considered a "reportable disease." Duties under the law require expeditious disclosure by the handler of an animal to a veterinarian of any of the 32 reportable diseases. Noncompliance with these regulations carries a maximum penalty of \$50,000 (Canadian) and/or 6 months in prison. This act also establishes the powers of "veterinary inspectors," which include the decision to quarantine an animal or an infected area in case of disease outbreak.

Within this Act, import regulations are established which forbid the importation into Canada of any animal or animal product from a country (other than the US) with reported cases of Foot and Mouth disease (FMD), Newcastle disease, or any "serious epizootic disease."

Transportation of Dangerous Goods Act 1992 (and Regulations)

Transportation of infectious materials in Canada is subject to the regulations associated with the Transportation of Dangerous Goods Act 1992. These regulations specify the quality standards of packaging within which an infectious substance must be shipped in, but do not mention security measures to be taken while transporting dangerous goods. These regulations are in place to minimize the occurrence of accidental releases of dangerous goods.

Human Pathogens Importation Regulations (1994)

The importation of certain human pathogens (Risk Group II, III, and IV as designated by the *Laboratory Biosafety Guidelines*) into Canada requires a permit given by the Assistant Deputy Minister, Health Protection Branch, Department of National Health and Welfare (the Director). Proper laboratory biosafety containment and a legitimate need for the pathogen are requisite to obtain an importation permit. Failure to receive an expected pathogen must be notified to the Director.

Public Safety Act (2002) (Not yet entered into force)

Following the events of September 11th, Canada began drafting legislation to counter and deter acts of terrorism. There has been much debate within parliament over many items, thus the bill has appeared in many revised forms. One measure that is not widely contested and has survived through all of the conceptions of the Public Safety Act is the *Biological and Toxin Weapons Convention Implementation Act*. If enacted, this act would prohibit biological weapons proliferation and codify regulations on dual-use equipment and biological agents as mandated by the BTWC. Further this act “would enable the establishment of a domestic compliance regime that could include a responsible authority, submission of declarations and facility inspections.”¹⁹

France

Act of 9 June 1972

Pursuant to Article I of the BWC, this act prohibits “developing, producing, possessing, stockpiling, buying and selling biological or toxin-based weapons.

¹⁹ United Nations, *Background Document on Compliance by States Parties with all their Obligations Under the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction: Canada*, BWC/CONF.V/3/Add.6, November 2001

Vigipirate/BIOTOX (1978/2001)

Vigipirate, France's anti-terrorism security plan, allows the mobilization of police, gendarme, and military to strengthen security in the event of a terrorist attack in France. Under this plan, BIOTOX was created in 2001 to specifically deal with bio-terrorist attacks. According to the French Government Tourist Office, "measures [of this plan] include security pharmaceutical plant stockpiles of medication and vaccines [and] intensifying security for France's water and food distribution systems." The BIOTOX plan also addresses "enhancing security at facilities for the production, storage and transport of hazardous biological materials."²⁰

Ministerial Order of 22 September 2001 concerning the importation, the export, the holding, the distribution and the transport of highly pathogenic microorganisms (2001)

In a reaction to the events of September 11th, France issued a Ministerial Order requiring each French laboratory handling strains of highly pathogenic biological agent to register with the Agence Francaise de Security Sanitaire des Produits de Sante (AFSSAPS). The AFSSAPS is responsible for the licensing of these laboratories and facilities. Additionally, the transport of pathogenic agents from one licensed laboratory to another, whether French or otherwise, must be authorized by the AFSSAPS prior to shipment

Germany

War Weapons Control Act of 1961 (as amended 1998)

Under the War Weapons Act, "it is forbidden to develop, produce or trade in biological or chemical weapons, to acquire them from or transfer them to another person, to import or export them, to transport them through or otherwise bring them into or out of federal territory, or otherwise to exercise <sic> actual control over them." In effect, implementing the BWC. In an addendum to the Act, the War Weapons Control List contains a definition of biological weapons and a list of pathogens and toxins considered to be potential biological warfare agents. The list is current with AG lists.

Foreign Trade and Payments Act of 1961 (as amended 2001)

Export control regulations for biological agents and toxins, as well as dual-use equipment, are codified in this Act and the accompanying Export List, which was last updated in 2000 and is current with the AG lists of that time. This list defines biological agents, toxins, and dual-use equipment that require an export license from the Federal

²⁰ United Nations, Document S/2001/1274, Geneva, 2001

Office of Economics and Export Control. It is strictly forbidden to export a “biological weapon” as defined in the War Weapons Control Act.

Act to the Biological and Toxin Weapons Convention (1983)

This act implements the prohibitions of the BWC.

All of these acts are subject to German penal sanctions.

Japan

The Law for the Implementation of the Convention on the Prohibition on the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (1982)

This law implements the provisions included in Article I of the BWC and includes criminal penalties for those who transgress these prohibitions.

Infectious Disease Prevention Law (1999)

Physicians must report the occurrence of certain diseases to a network of health centers associated with Japan’s Infectious Disease Surveillance Center. Reportable diseases include, inter alia, AIDS, Anthrax, Crimean-Congo hemorrhagic fever, Ebola, Japanese encephalitis, Lassa, Marburg, and Polio. This law applies only to human diseases.

Latvia

Criminal Code of Latvia (1961), with amendments

The Criminal Code outlaws the production, development, stockpiling or acquiring of BW. Penalties include up to life imprisonment.

Regulation on the Control of Strategic Goods (1997)

The export of those biological goods listed in Annex 1 of the European Union Council Regulation (EC) No. 2432/2001 require a license granted by the Control Committee of Strategic Goods. Although no countries are automatically denied strategic goods, licenses to “countries in the process of acquiring or developing weapons of mass destruction or the means of their delivery, or which support international terrorism, practice violations of human rights or genocide...are denied.”²¹

²¹ “Export, Import and Transit Control of Strategic Goods in the Republic of Latvia,” 2002, <http://www.am.gov.lv/en/?id=58>

Lithuania

Law Concerning Control of Import, Transit and Export of Strategic Goods and Technologies (1995)

AG listed goods imported into, exported out of, or transported through Lithuanian territory must be licensed by the appropriate Ministerial authority prior to beginning the action. The accompanying *Law On Enforcement of the Law on Import, Transit and Export Control of Strategic Goods and Technologies (1995)* establishes criminal penalties for unauthorized imports, exports and transports.

Control lists associated with this law are in accordance with current AG regulations.

Constitution of the Republic of Lithuania (1992)

Article 13 of the Constitution prohibits any WMD, including BW, on Lithuanian territory.

Penal Code of Lithuania (1999, as amended)

It is illegal to produce, acquire or sell toxic or poisonous substances in Lithuania. Contravention of this law can result in up to three years incarceration or two years of penitentiary labor.

People's Republic of China

The Criminal Law as Amended (2001)

Following the September 11th attacks, China amended their Criminal Law to address and punish acts of terrorism. Amendments to Articles 114, 115, 125, and 127 punish the “dissemination... or illegal manufacturing, trading, transporting or storing... or the stealing or seizing or plundering...[of] contagious-disease pathogens.”²² Punishments include varying prison sentences or capital punishment.

Regulation of Export Control of Dual-Use Biological Agents and Related Equipment and Technologies (2002)

China's new export control regulations over WMD-related materials and equipment impose a licensing system over certain exports. Those items subject to export control include, but are not limited to items listed in the “Dual-Use Biological Agents and

²² “China's Anti-Terrorism Legislation and Repression in the Xinjiang Uighur Autonomous Region,” Amnesty International, 2002, ASA 17/010/2002

Related Equipment and Technologies Export Control List.” This list mirrors those of the Missile Technology Control Regime and the Australia Group despite the fact that China is not a member of either group.

Russian Federation

Decree of the President of the Russian Federation No. 390: On Insuring Fulfillment of International Obligations in the Field of Biological Weapons (1992)

Russian President Boris Yeltsin, in an official statement on January 29, 1992, made clear that: "We confirm all obligations on bilateral and multilateral agreements in the field of limitation of armaments and disarmament, that had been signed by the Soviet Union and is valid at present, that Russia is for strict implementation of the Convention of 1972, for creation of appropriate control mechanism on a multilateral basis, for realization of measures of trust and openness." This declaration led to amendments to the Criminal Code of the Russian Federation outlawing BW-related activities.

Criminal Code of the Russian Federation (as amended, 1996)

Russia’s Criminal Code established punishments for violations involving biological weapons including illegal export of biological materials and the use, production and stockpiling of BW. It also creates penalties for the “violation of sanitary and epidemiological rules which has resulted, through negligence, to mass disease or poisoning of people.”

Federal Law on Export Control (1999)

The establishment of export controls involving BW, their precursors, and means of delivery are drafted in the Federal Law on Export Control. Russia, although not a member, has unilaterally adopted Australia Group export controls and control lists.

Tajikistan

Criminal Code (1998)

Article 399 (Biocide) of the Criminal Code of Tajikistan punishes by long-term imprisonment or death the use of nuclear, neutron, chemical, bacteriological, climatic or any other type of weapon of mass destruction to cause harm to humans or the environment.

United Kingdom

Biological Weapons Act (1974)

The Biological Weapons Act fulfills Britain's obligation under Article IV of the BWC. This Act makes it a crime to "develop, produce, stockpile, acquire or retain...any biological agent or toxin" unless used for "peaceful purposes." Contravention of this Act is punishable of up to life in prison. The Act's jurisdiction does not reach British citizens who work outside the boundaries of the UK.

Export of Goods (Control) Order 1994 (as amended 2002)

This order brings into force the evolving export regulations formulated by the Australia Group and is up to date as of 2002.

Specified Animal Pathogens Order (1998)

The Specified Animal Pathogens Order prohibits any person to possess certain microorganisms harmful to the health of animals, including, *inter alia*, *Bacillus anthracis*, equine encephalomyelitis viruses, FMD, Newcastle, and Rinderpest. Possession of these diseases includes the possession of infected animals, their excreta and tissue, as well as cellular cultures. Laboratories may possess these pathogens if the appropriate Minister grants a license to that facility. Licenses may be revoked following an inspection of the facility if it is found that the pathogens are being stored or handled in an unsafe or improper fashion.

Anti-Terrorism, Crime and Security Act (2001)

The Anti-Terrorism, Crime and Security Act (2001) represents the most comprehensive legislation combating bioterrorism outside of the United States. Written in reaction to the September 11th attacks on New York and the Pentagon, this act provides powers to the UK to "counter the threat of terrorism." Part 6 of the act specifically addresses WMD, while Part 7 focuses on the physical security of pathogens and toxins.

Part 6 of the Act amends the Biological Weapons Act (1974) and the Chemical Weapons Act (1996) to prohibit the transfer of biological weapons and extends the Biological Weapons Act's reach to include all British nationals either at home or abroad.

Part 7 exclusively addresses the security of dangerous pathogens and toxins. These microorganisms are listed within the act under Schedule 5. Schedule 5 pathogens and toxins include 19 viruses, 5 rickettsiae, and 13 bacteria strains, along with 11 toxins. Any facility handling or storing listed agents must notify the Secretary of State that such organisms are located there and give the chief officer of police information on the

measures taken to secure the pathogens or toxins from theft or diversion. If security measures are not to the satisfaction of a constable, he or she may “give directions..to ensure the security of any dangerous substance kept or used there.”

Additionally, the act requires facilities that store or use Schedule 5 pathogens and toxins to notify the chief officer of police of all persons not only with access to the materials, but also of any person with access to any building associated with a facility that handles listed pathogens and toxins. Access to listed pathogens may be denied to any listed individual if it is believed that doing so is “necessary in the interests of national security.”

Not yet included in the Act, but drafted and awaiting vote, is a provision that allows the act to be extended to animal pathogens, plant pathogens, and pests if any of these cause “(a) widespread damage to property; (b) significant disruption to the public; or (c) significant alarm to the public.”

Animal Health Act (2002)

This act amends the Animal Health Act (1981) making it an offence to deliberately infect an animal with certain diseases. The maximum penalty for this crime is two years in prison and a disqualification of an individual in handling or keeping animals. The specified diseases are listed and include 15 diseases including FMD, Bluetongue, Newcastle, Rinderpest, and avian influenza.

United States of America

Biological Weapons Act (1989)

The Biological Weapons Act implements the prohibitions of the BWC, criminalizing production, development, transfer, acquisition, retention, or possession of any “biological agent, toxin, or delivery system for use as a weapon.” Penalties for contravention of this act include monetary fines and up to life imprisonment. There is extraterritorial Federal jurisdiction over an offence committed by or against a national of the U.S.

Antiterrorism and Effective Death Penalty Act (1996)

In response to a member of the Aryan Nations legally ordering and receiving three vials of the bacterium that causes bubonic plague from the American Type Culture Collection, Congress tightened the controls surrounding dangerous biological agents and toxins. One consequence of the Antiterrorism Act was to outlaw even the threat of BW use.

The most salient outcome of the act was to mandate the creation of a “Select Agent List”²³ by Health and Human Services (HHS). Agents on this list were subject to

²³ A current Select Agent List is available on line at: <http://www.cdc.gov/od/sap/docs/salist.pdf>

increased regulations due to their threat to the public health, but not necessarily on their ability to be used as a biological weapon. In accordance with this law, select agents were reported before and after transfer to ensure that they were registered and safely handled by professionals. This law did not restrict legitimate research in any way, and although select agents were regulated during transfer, they continued to be available to researchers and educators for scientific purposes.

Export Administration Act and Regulations (EAR) (as amended 2001)

The purpose of the Export Administration Act is to control the exports of certain items, including exports related to biological weapons. The Commerce Control List, created under the authority of the EAR, lists biological agents and dual-use equipment that requires an export license prior to shipment. This list is in accordance with similar lists published by the Australia Group.²⁴ Export regulations of listed items are based on the intentions of the end use and end user, and whether the item could lead to the proliferation of BW. The act also encourages U.S. participation in multilateral export control regimes, including the Australia Group.

Uniting and Strengthening America by Providing Appropriate Tools to Intercept and Obstruct Terrorism Act USA PATRIOT Act (2001)

In direct response to the terrorist attacks of September 11, the U.S. Congress passed the USA PATRIOT Act to increase the capabilities of intelligence and law enforcement to detect and deter terrorist activities. Included in the act are provisions that restrict access to select agents and other dangerous pathogens registered by the U.S. Department of Agriculture (USDA). Taken together, these two lists comprise the “regulated agents.”

The PATRIOT Act mandates that “restricted persons”²⁵ be prohibited from shipping, receiving, transporting, or possessing any regulated agent. In fact, any person attempting to secure a license to transport select agent materials may be subject to a background check conducted by the Attorney General. During this background check, the AG may investigate the individual’s immigration status, criminal history, and international standing.

Further, foreign students, including post-doctoral fellows and visiting scholars, inside the U.S. are strictly monitored throughout their stay, as required by the Illegal Immigration

²⁴ A comparison of the Australia Group, Commerce Control List, and US regulated pathogens and toxins is available on line at: <http://www.biosecurity.sandia.gov/>

²⁵ The USA PATRIOT Act defines “restricted persons” as: (1) individuals under indictment for a crime punishable by imprisonment for a term exceeding one year; (2) individuals who have been convicted in any court of a crime punishable by imprisonment for a term exceeding one year; (3) fugitives from justice; (4) unlawful users of a controlled substance; (5) individuals who have been adjudicated as mentally defective or have been committed to a mental institution; (6) illegal aliens; (7) foreign nationals (other than permanent resident aliens) who are citizens of a country that the Secretary of State has determined has repeatedly provided support for acts of international terrorism; and (8) individuals who have been discharged from the Armed Services of the United States under dishonorable conditions.

Reform and Immigrant Responsibility Act of 1996. The USA PATRIOT Act redoubled the level of surveillance mandated by the 1996 act, which had not been consistently implemented by universities prior to 2001.

Despite the restrictions implemented by the USA PATRIOT Act, it is important to note that this act neither prohibits microbiological research with any particular microbiological agent or toxin, nor does it restrict who may conduct research on certain agents. The objective of the act is not to restrict vital microbiological research, but rather to ensure only legitimate access to certain pathogens and toxins that, if misused, may be a danger to the public health.

Public Health Security and Bioterrorism Preparedness and Response Act (BPARA) (2002)

BPARA, which was passed in response to the anthrax attacks of 2001, provides statutes that address three main goals: (1) assessing and improving infrastructure integrity, (2) augmenting public health capabilities, and (3) improving pathogen and toxin security.

An important step in preparing for and responding to a BW attack is to increase the integrity and security of facilities, systems, and personnel who are vulnerable to attack. BPARA attempts to do this by calling for hospital preparedness reviews, water supply vulnerability assessments, and facility upgrades for the CDC and the U.S. Department of Agriculture laboratories. The aim of these actions is to ensure hospitals are capable of handling a bioterrorist incident, to secure vital U.S. water supplies, and to better prepare the CDC and USDA to respond to terrorist attacks by strengthening their capabilities to diagnose, track, and treat disease.

Effective response to a biological incident requires effective public health capabilities. To this end, BPARA awards grants to “improve state, local, and hospital preparedness for and response to bioterrorism and other public health emergencies.” Detection methods, such as syndromic surveillance systems and biosensors, are given research priority, and are countermeasures to treat incidents of disease outbreak. BPARA mandates the creation of a Strategic National Stockpile of vaccines and therapies. Quarantine procedures are to be streamlined to contain outbreaks, and actions to prevent public health emergencies are to be taken. All of these measures decrease the likelihood of a bioterrorist attack by mitigating the results of such an attack. Adversaries are less likely to strike if they know the results will not cause the desired affect.

Another important goal of BPARA is protecting pathogens and toxins against theft or diversion. Securing these materials is a fundamental component of preventing a bioterrorist attack. Although the Antiterrorism and Effective Death Penalty Act contained provisions for the security of pathogenic organisms, BPARA has expanded these standards considerably. BPARA mandates the creation of updated regulated agent lists and registration of all facilities and personnel who use, store, or transfer such agents.

These activities must be coordinated and enforced through the Secretaries of HHS and USDA.

As mandated by BPARA, researchers that work with any of the registered agents will have to register themselves and their facilities with HHS or USDA depending on the type of pathogens present in their laboratories. These laboratories are further mandated to establish “security measures to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose.” According to BPARA these security measures must also be implemented to pathogens during transfer and transport. These security measures must include policies of limited access to certain pathogens and toxins, and personnel reliability programs.

