Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

3 August 2012

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2012 Meeting
Geneva, 10–14 December 2012

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Item 7 of the agenda
Standing agenda item: Strengthening National Implementation

National Implementation of the BTWC Compliance Assessment

Submitted by Canada and Switzerland[1]

Background

1. Assessment of compliance is a common practice among regulators and standards-setting organizations on an international scale. The concepts utilized for compliance assessment can be as focussed as on-site inspections of facilities, warehouses, factories or specific end-product units, or it can be approached from a broader perspective of verifying compliance by examining and assessing the regulatory *program* in place, the program that has been implemented to ensure compliance with a regulatory/legislated requirement.

2. Development of an internationally-led on-site inspection regime has never reached consensus in the BTWC, though States Parties are encouraged to submit Compliance Reports every five years. However, a broader approach to assessing compliance may be feasible and acceptable if it is the national implementation program that is examined, and not individual facilities within a State Party's borders.

3. In December 2010, Canada proposed to work with interested State Parties to develop this broader concept, based on the following principles of compliance assessment. Under this proposal, each State Party would submit to the ISU (or other BTWC supported body), as an initial submission, a detailed description of national legislation and regulations supporting the national implementation of the BTWC, including those that cover the oversight of human, animal and plant pathogens. This detailed description could include

[1] This document was originally submitted to the Seventh Review Conference of the Biological Weapons Convention. Due to an oversight by the Secretariat, it was never processed and is now appearing as an official document of the 2012 Meeting of Experts.

very specific section-by-section analysis of how the legislation/regulations work, the scope of the legislation/regulations (e.g. any exceptions/exemptions from the law, is the legislation based on lists of organisms or broader categories of risk groups, etc.) and the penalties associated with contraventions.

4. In addition to the analysis of the national implementation legislation, each submitting State Party would also submit a detailed description of how the program was implemented on a national level. This could include process flow diagrams, organizational charts of the implementing program, showing clear lines of reporting, process and standard operating procedure descriptions, as well as clear indications of the inspection program, frequency of inspections and how major and minor non-compliances are handled. The submission could also include the yearly budget associated with running the program.

5. Because this submission would take significant effort on behalf of the State Party to assemble, this level of detail need only be submitted once initially, and then amended when programs are added, updated, or otherwise modified. However, a yearly submission that comprised the number of inspections conducted (on-site and remote verification), what biosafety levels were inspected, number of announced vs. unannounced inspections, number of major non-conformities and number of enforcement activities carried out, among other possible criteria, would be reported.

6. Information submitted in this manner would help demonstrate a State Party's commitment to implement the BTWC on a national level, by providing a clear analysis of national legislation and the program that implements the law. This process would demonstrate State Party's national compliance and enforcement as the relevant data would be available for examination, including inspection statistics, as well as enforcement activity statistics for the program itself. The end result could be an assessment of compliance of the national program to the BTWC.

7. At the 2010 Meeting of States Parties, Canada invited any interested States Parties to join in developing initial declarations as a pilot project, to demonstrate the effectiveness of compliance assessment. Switzerland joined the project, and both States Parties have prepared sample declarations, as Annex I (Canada) and Annex II (Switzerland) to this paper.

Annex I

Report on Compliance
Canada and BTWC

1. In accordance with the request of the Preparatory Committee of the Seventh Review Conference of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons for background information (BWC/CONF.VII/PC.2 paragraph 24 (b)), in particular the request for the Implementation Support Unit (ISU) to prepare "a background information document on compliance by States Parties with all their obligations under the Convention, to be compiled from information submitted by States Parties" Canada submits the following report to States Parties.

I. Introduction

2. This report covers the period January 2007 to August 2011. Canada has submitted a Compliance Report to the Seventh Review Conference2 . In accordance with the concept paper submitted by Canada in 2010 (BWC/MSP/2010/WP.3/Rev.1), this additional report is intended to fulfil two objectives:

(a) Fulfil the request of the Preparatory Committee for an information document on compliance with all obligations under the Convention; and

(b) provide States Parties with a detailed description of national legislation, regulations and operational details supporting the national implementation of the BTWC within Canada that is in addition to the information submitted annually by Canada in the Confidence Building Measures and in addition to the information submitted to the United Nations Security Council Committee of Resolution 1540 (2004).

A. General information

1. Canada's System of Government[3]

3. Canada is a democratic constitutional monarchy, with a Sovereign as head of State and an elected Prime Minister as head of Government. A federal system of parliamentary government exists where Government responsibilities and functions are shared between federal, provincial and territorial governments.

(a) It is generally agreed that the following characteristics are among those shared by states with a federal system of government[4] :

(b) At least two orders of government;

(c) Division of powers between the orders of government defined in the constitution;

[2] Number not yet available.

[3] Content for this section was extracted from the Government of Canada website where more detailed information can be found at: http://www.canada.gc.ca/aboutgov-ausujetgouv/menu-eng.html

[4] Ronald Watts, Comparing Federal Systems, Institute of Intergovernmental Relations, Queen's University, Kingston, Ontario, 1999, p.7

(d) Division of revenue sources to ensure each order of government certain areas of autonomy, also set out in the constitution;

(e) Written constitution that cannot be amended unilaterally.

4. Reasons for a state to adopt a federal system include the need to reflect linguistic, economic and cultural differences of a population, especially one that is concentrated geographically. Federal responsibilities are carried out by the Monarchy and the Executive, Legislative and Judicial branches of Government. The powers of the Parliament of Canada, enumerated in ss. 91 and 92 (10) of the Constitutions Acts, 1867 to 1982, concern matters of national interest and include the following, pertinent to Canada's compliance with the BTWC:

(a) Regulation of Trade and Commerce

(b) Defence

(c) Quarantine

(d) Criminal law, including Criminal Procedure

(e) Works connecting provinces; beyond boundaries of one province; within a province but to the advantage of Canada/or more than one province.

5. Exclusive powers of Provincial Legislatures enumerated in ss. 92, 92(A) and 93 of the Constitution Acts, 1867 to 1982, concern matters of a local nature and include the following, pertinent to Canada's compliance with the BTWC:

(a) Hospitals

(b) Administration of Civil/Criminal Justice

(c) Natural Resources

(d) Matters of a merely local or private nature (i.e., intra-Provincial Transport of Dangerous Goods).

6. Concurrent or shared powers are specified in ss. 94A and s. 95 of the *Constitution Acts*, 1867 to 1982 and include the following, pertinent to Canada's compliance with the BTWC:

(a) Agriculture.

7. Certain areas of government action are not specifically identified and assigned to one or both orders of governments in the Constitution Act, 1867, however, the courts have found that these areas come under various legislative powers, some federal, others provincial. Two such areas are the Environment and Health.

2. Legal System[5]

8. Canada's legal system derives from various European systems brought to this continent in the 17th and 18th centuries by explorers and colonists. Except for Quebec, where the civil law is based on the French Code Napoléon, Canada's criminal and civil law has its basis in English common and statutory law.

9. The common law is based on the decisions of judges and is based on "precedent." Whenever a judge makes a decision that is to be legally enforced, this decision becomes a

[5] Content for this section was extracted from the Government of Canada website where more detailed information can be found at: http://www.justice.gc.ca/eng/dept-min/pub/just/02.html

precedent: a rule that will guide judges in making subsequent decisions in similar cases. The common law is unique because it cannot be found in any code or body of legislation, but exists only in past decisions. At the same time, common law is flexible and adaptable to changing circumstances.

10. Civil law is quite different and is associated with a "civil code." Quebec's Civil Code, first enacted in 1866 just before Confederation and amended periodically, was recently thoroughly revised. It contains a comprehensive statement of rules, many of which are framed as broad, general principles, to deal with any dispute that may arise. Unlike common-law courts, courts in a civil-law system first look to the Code, and then refer to previous decisions for consistency.

11. Since Canada is a federation (a union of several provinces with a central government), it has both a federal parliament in Ottawa to make laws for all of Canada and a legislature in each province and territory to deal with local matters. Laws enacted at either level are called "statutes," "legislation," or "acts." When Parliament or a provincial or territorial legislature passes a statute, that statute takes the place of common law or precedents dealing with the same subject. In Quebec as well, much legislation has been passed to deal with specific problems not covered by the Civil Code.

B. General Situation in Canada relating to BTWC

12. Canada is in full compliance with the BTWC and its obligations. Compliance with the Convention is interpreted in Canada as fulfilment of the legally binding obligations established by the Convention and implementation of the politically binding obligations resulting from decisions and agreements reached by States Parties as included in Final Documents of previous review conferences of the BTWC.

1. Outbreaks of infectious diseases and similar occurrences caused by toxins

Human Health

Measles

13. Within the last 10 years, the number of measles cases reported globally has decreased significantly; however, there have been a number of large outbreaks recently, mostly in Africa but also in Europe. The Americas, including Canada, are also experiencing outbreaks of measles linked to importation of the measles virus from other regions. With total number of confirmed cases at 101, 61 and 15 for 2007, 2008 and 2009 respectively, the 2010 case number was 99 and the current 2011 case number is 770.

14. As of October 19, 2011, there have been 751 confirmed and probable measles cases associated with an outbreak in the province of Quebec[6]. The outbreak began on April 3, 2011 and in currently ongoing. There has been one secondary case in New Brunswick associated with this outbreak. Generally, PHAC would only become involved in the direct response to a provincial or territorial outbreak if requested by the province or territory, and Quebec has not requested assistance. PHAC has, however, submitted a publication in the Canadian Medical Association Journal (CMAJ) targeted at front line health professionals to assist in identification of measles cases and to remind them of the preferred specimens to collect for accurate diagnosis and molecular characterization, as many physicians

[6] For more information please visit Santé et services sociaux – Quebec at http://www.msss.gouv.qc.ca/sujets/prob_sante/rougeole/rougeole.php

experience with measles is dated. This outbreak constitutes the most significant outbreak in the Americas since 2002 when the region received its measles free status. As such, Quebec is taking steps to control the outbreak and in November 2011 the province launched a "catch-up" vaccination campaign in its schools.

Influenza H1N1[7]

15. In April 2009, the world saw the emergence of a novel influenza strain now formally called influenza A(H1N1)pdm09 that spread very quickly around the globe. In Canada, the first six cases of the pandemic H1N1 strain were reported on April 26th 2009 and marked the beginning of the first wave of the pandemic. Cases continued to increase across the country and the first wave peaked during the first three weeks of June 2009. Influenza activity declined throughout summer 2009 and began to increase again across the country starting in mid-September, marking the start of the second wave of the pandemic. The second wave peaked from late October to mid-November and decreased dramatically by mid-December. In comparing the differences in magnitude between the two pandemic waves, the second wave was substantially larger with four to five times more hospitalized and fatal cases than the first wave.

16. From April 12, 2009 to July 17, 2010 (encompassing the first and second waves), the number of laboratory-confirmed pandemic H1N1 cases was 40,204; however, an additional 12,363 cases were positive for un-subtyped influenza A, for which the large majority is considered to be due to influenza A(H1N1)pdm09 since only a small proportion of other influenza subtypes were circulating at the time of the pandemic. The per capita influenza testing rate for Canada during the pandemic period was 956 influenza tests per 100,000 population. The largest proportion of cases was observed in those aged 5-14 years (26%), 25-44 (22%) and 15-24 (18%).

17. While most illnesses caused by the virus were acute and self-limited, a number of severe outcomes were reported. There were a total of 8,678 hospital admissions (including 1473 ICU admissions) and 428 deaths related to pandemic (H1N1) influenza that were reported between April 12, 2009 to April 3, 2010. Hospitalization rates were highest for children under 5 years of age; however, the highest mortality rate occurred in adults aged 45 and older. These hospitalizations and deaths were only those that were laboratory confirmed, and the true number of hospitalizations and deaths due to influenza A(H1N1)pdm09 are considered to be much more.

18. Lessons learned from the pandemic include: the need to further strengthen federal/ provincial/territorial capacity to prepare for and respond to pandemic influenza; and the need for pre-existing Memorandums of Understanding for information sharing during public health emergencies between provinces, territories and the federal government.

Listeria

19. In August of 2008, a nation-wide outbreak of listeriosis led to the largest recall of contaminated food products in recent Canadian history. The health impact was significant: a total of 57 cases of illness were confirmed and 23 deaths were linked to the outbreak. Following the recall, reviews of Canadian public health and food safety protocols were conducted by the federal agencies involved in the response, a Senate Standing Committee and an independent investigator, Sheila Weatherill. Lessons learned documents were

[7] NACI Statement on Season Trivalent Inactivated Influenza Vaccine (TIV) for 2010-2011: http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/10vol36/acs-6/index-eng.php#toc2
Helferty M, et al. Incidence of hospital admissions and severe outcomes during the first and second waves of pandemic (H1N1) 2009. CMAJ Dec. 14, 2010 vol. 182 no. 18

compiled by the federal agencies and Weatherill completed her Report of the Independent Investigator into the 2008 Listeriosis Outbreak[8]in July of 2009.

20. Following these reviews, the Government of Canada committed to addressing the gaps that had been identified within the country's food safety systems. The federal agencies with jurisdiction over food safety and food-borne illness drafted Action Plans to guide their response to both Weatherill's Report and the federal agency Lessons Learned documents. Since the 2008 outbreak, a number of initiatives have been carried out to improve Canada's preparedness for dealing with a serious food-borne illness outbreak. One key item was the revision of Canada's Food-borne Illness Outbreak Response Protocol (FIORP) in 2010. This collaborative effort between federal, provincial and territorial (FPT) governments across the health and agriculture sectors resulted in a number of new roles, responsibilities and information exchange processes being incorporated into the Protocol. Following the completion of the 2010 revisions, the FIORP was then exercised in each of Canada's thirteen provinces and territories, allowing for relationship-building and increased knowledge related to collaborative investigation processes among FPT and local officials.

General Trends

21. Trends in the rates of sexually transmitted infections and hepatitis have been changing recently for a variety of reasons, outlined below.

22. Chlamydia: Reported rates of chlamydia have been increasing steadily since 1997, when more sensitive laboratory tests were introduced in Canada. Thus, part of the increase in rates can be attributed to improved detection of infections among those who are tested. Other postulated reasons for the increase in reported chlamydia rates include increased case finding (through contact tracing and improved screening), and an actual increase in incidence due to changes in behaviour at the population level. Data to support any of these theories are limited. However, there have been no recent reports of chlamydia outbreaks in any Canadian jurisdiction to explain the increase. The observed increase in reported chlamydia rates in 2008 is in line with the longer-term trend.

23. Hepatitis B: Recent increases in hepatitis B reported rates are probably attributable to changes in case counting and reporting to the Public Health Agency of Canada. The increase in 2008 seems to be largely driven by Alberta, where a change in reporting practices (from reporting only acute cases to including both acute and chronic) caused a dramatic increase in reported rates. In fact, data from enhanced hepatitis B surveillance indicate that the reported rate of acute hepatitis B infections is decreasing, from 0.97 per 100,000 in 2005 to 0.49 per 100,000 in 2010. Routine childhood immunization for hepatitis B in Canada has reduced the occurrence of large-scale outbreaks; occasional sporadic transmission of hepatitis B infections has been limited to small groups (e.g. a small 2006 outbreak limited to household transmission in several families in New Brunswick).

24. Hepatitis C: Reported rates of hepatitis C have decreased since 2005.

25. Infectious syphilis: The reported rate of infectious syphilis was maintained below 1.0 per 100,000 for several years prior to 2002, when rates started to increase due to outbreaks in several jurisdictions. In recent years, sustained high reported rates of infectious syphilis have been documented in British Columbia, Alberta, Ontario, and Québec, concentrated mainly in large urban centres, suggesting that syphilis is once again becoming endemic in much of Canada. More recent outbreaks have occurred or are in progress in the Northwest Territories, Saskatchewan, Nova Scotia, and New Brunswick.

[8] http://www.listeriosis-listeriose.investigation-enquete.gc.ca/index_e.php?s1=rpt&page=tab

Outbreaks are often associated with travel between jurisdictions in Canada or outside of the country. Men who have sex with men are one of the most affected groups; however, outbreaks have also been seen in heterosexual men and women, with resulting increases in congenital syphilis in infants. Injection drug use and involvement in the sex trade have been implicated in some jurisdictions. Public health response to the increase in infectious syphilis has included communication to health care providers to raise awareness and increase testing, internet-based awareness campaigns directed at the general population, and testing "blitzes" among the populations most affected.

2. Animal Health[9]

26. Beginning in 2009, the Canadian Food Inspection Agency (CFIA) began providing a more comprehensive view of Canada's animal health status by monthly posting to its website all detections of federally reportable diseases.

27. This reporting approach captures confirmed cases of federally reportable diseases, including scrapie, chronic wasting disease (CWD), anthrax, and bovine spongiform encephalopathy (BSE), in farmed animals. In addition to providing monthly reports, the CFIA immediately announces any detection of reportable, foreign, or newly emerging diseases which pose significant health or economic risks.

Reportable diseases

28. These diseases are outlined in the Health of Animals Act and Regulations and are usually of significant importance to human or animal health or to the Canadian economy. Animal owners, veterinarians and laboratories are required to immediately report the presence of an animal that is contaminated or suspected of being contaminated with one of these diseases to a CFIA district veterinarian. Control or eradication measures will be applied immediately.

Immediately notifiable diseases (for laboratories only)

29. In general, immediately notifiable diseases are diseases exotic to Canada for which there are no control or eradication programs.

30. The CFIA can undertake control measures for such diseases when notified of their presence in Canada. This category also includes some rare indigenous diseases. A herd or flock of origin must be certified as being free from these diseases in order to meet import requirements of trading partners.

Annually notifiable diseases (for laboratories only)

31. Annually notifiable diseases are diseases for which Canada must submit an annual report to the World Organisation for Animal Health (OIE) indicating their presence within Canada. In general, they are diseases that are present in Canada, but are not classified as reportable or immediately notifiable.

32. All veterinary laboratories are required to comment on Canada's report to the OIE, which is prepared each February by the CFIA's Epidemiology and Surveillance Unit.

[9] Information for this section was extracted from the following website where additional information on specific diseases can be found: http://www.inspection.gc.ca/english/anima/disemala/guidee.shtml

Exceptional epidemiological events[10]

33. Between 2007 and present, Canada has had 11 notifications to the OIE under this provision as follows:

(a) 2011 – Epizootic ulcerative syndrome and rabbit haemorrhagic disease (first occurrence for each)

(b) 2010 – Low pathogenic avian influenza in poultry (reoccurrence)

(c) 2009 – A/H1N1 influenza and Pandemic H1N1 (emerging disease); bovine anaplasmosis and low pathogenic avian influenza in poultry (reoccurrences); infectious salmon anaemia (first occurrence)

(d) 2008 – Bovine anaplasmosis and small hive beetle infestation (reoccurrence for each)

(e) 2007 – Highly pathogenic avian influenza (reoccurrence)

3. Report on any notification under international requirements

Exceptional epidemiological animal health events reported to the World Organisation for Animal Health (OIE) [11]

34. Please refer to Section 'Exceptional epidemiological events' above.

International Health Regulations (2005)

An Overview

35. The International Health Regulations (IHR) (2005) is an internationally legal binding agreement "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade." IHR (2005) broadens the scope of collective defence from previous iterations to encompass an all-hazards approach to outbreaks of emerging and epidemic-prone disease, outbreaks of food-borne disease, natural disasters, and biological, chemical or radiological-nuclear events, whether accidental or deliberate. This risk management strategy aims to detect possible areas of concern early and to stop them at source before becoming an international threat, thereby enabling WHO Member States to achieve maximum security against the international spread of disease and to reduce the impact of public health emergencies.

36. As per IHR (2005), a Public Health Emergency of International Concern (PHEIC) is defined as an extraordinary event which is determined to constitute a public health risk to other States Parties through the international spread of disease and/or an event which may potentially require a coordinated international response.

37. A decision instrument for events that may constitute a potential PHEIC is outlined in Annex 2 of the Regulations. This decision instrument establishes the necessary criteria for assessment and notification to WHO. States Parties are required to assess public health events arising in their territories utilizing this decision instrument.

[10] Information for this section extracted from OIE World Animal Health Information Database at: http://web.oie.int/wahis/public.php

[11] Information for this section extracted from OIE World Animal Health Information Database at: http://web.oie.int/wahis/public.php

Canadian Context

38. IHR (2005) specifies that each State Party must designate a National IHR Focal Point as a national centre which is accessible at all times (7/24/365) for communications with WHO IHR Contact Points.

39. Within Canada, the National IHR Focal Point (NFP) Office is located in the Public Health Agency of Canada's Centre for Emergency Preparedness and Response. This Office is the main point of contact between Canada and the WHO regional office for Canada – the Pan American Health Organization (PAHO).

40. The Canada IHR NFP Office provides an efficient mechanism for communicating with State Party NFPs and/or the relevant programme areas within countries. This method of communication can be used for IHR reportable events (i.e. potential PHEICs) as well as routine (non-PHEIC) public health events (i.e. notifiable diseases involving foreign nationals).

Proposed Monthly Report

41. The Canada IHR NFP is currently working to develop a monthly report for internal stakeholders which would show the volume and type of communications and activities that are being monitored by the office on a regular basis. The report would also likely contain a tally of public health risks / events and States Parties involved in bilateral information exchanges with Canada. Certain statistics from this report may be beneficial for the annual BTWC compliance report.

II. Legislation

42. Canada has several pieces of legislation in place to see to the non-proliferation of biological weapons as required by the BTWC and biosecurity and the non-proliferation of biological materials. Each law covers a piece of the biosafety/biosecurity landscape and, all together, allows Canada to meet its obligations under the Biological and Toxin Weapons Convention and the United Nations Security Council Resolution 1540. This legislation enforces biosafety, biosecurity, and non-proliferation of biological materials in Canada. Laws are separated into two sections: main relevant legislation, that have a more direct effect on biosecurity and non-proliferation, and other legislation of relevance, that have a limited impact on these issues.

43. Note that the reference in Canadian legislation to a "person" generally includes a corporation. Some Acts it can be even broader. For example, under the Human Pathogens and Toxins Act (HPTA) a person includes an "organization" as defined in section 2 of the Criminal where "organization" means:

(a) A public body, body corporate, society, company, firm, partnership, trade union or municipality, or

(b) An association of persons that

(i) Is created for a common purpose,

(ii) Has an operational structure, and

(iii) Holds itself out to the public as an association of persons.

44. In addition, where a corporation commits an offence, there are often provisions that directors, officers or agents of the corporation who directed, authorized, assented to, acquiesced in or participated in the commission of the offence may also be prosecuted whether or not the corporation is prosecuted.

1. Main Relevant Legislation

45. Main Relevant Legislation

(a) Human Pathogens and Toxins Act (partially in force)

(b) Human Pathogens Importation Regulations

(c) Health of Animals Act

(d) Plant Protection Act

(e) Export and Import Permits Act

2. Other Legislation of Relevance

46. Other Legislation of Relevance

(a) Canadian Environmental Protection Act

(b) Department of Public Safety and Emergency Preparedness Act / Emergency Management Act

(c) Feeds Act

(d) Pest Control Products Act

(e) Fertilizers Act

(f) Hazardous Products Act

(g) Quarantine Act

(h) Transportation of Dangerous Goods Act

(i) Chemical Weapons Convention Implementation Act

(j) Customs Act / Canada Border Services Agency Act

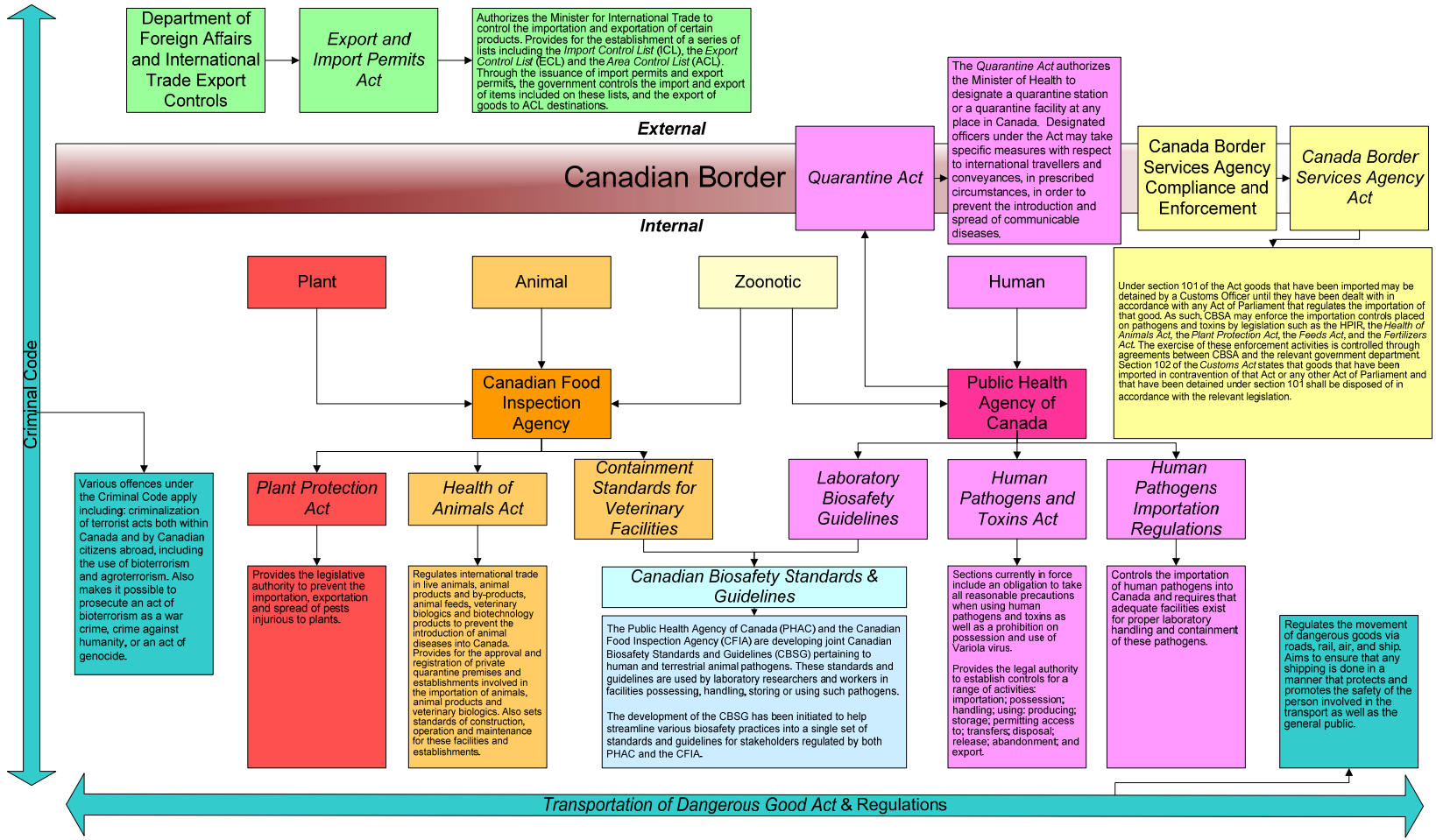
(k) Criminal Code of Canada

(l) Biological and Toxins Weapons Convention Implementation Act (not in force[12])

3. Overview of compliance architecture in Canada

47. Compliance with the BTWC requires action by Canada at the international and national level. To illustrate the breadth and depth of the compliance procedures and mechanisms in place within Canada Figure 2.1 presents a visual summary of the compliance architecture in place in 2011. Figure 2.1 is not intended to represent all aspects of the compliance architecture and further detail on the various legislation, regulations, and procedures is presented below.

[12] *Biological and Toxin Weapons Convention Implementation Act* is not in force.



Visual summary of Canadian BTWC compliance architecture as of 2011

III. BTWC Compliance

A. Article I

48. Canada is in full compliance with its obligations under Article I of the BTWC. Since its ratification of the Convention Canada has not developed, produced, stockpiled or otherwise acquired or retained microbial or other biological agents, or toxins, whatever their method of production or origin, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes. Since its ratification of the Convention Canada has not possessed or developed, produced, or stockpiled other otherwise acquired or retained any weapons, equipment, or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

49. In keeping with the politically binding obligation under the agreed annual information exchange – the confidence building measures – Canada has reported on the nature of the Canadian biological weapons program as it existed historically and as terminated long before the entry into force of the BTWC.

50. Canada holds biological or toxin agents of types and in quantities justified for prophylactic, protective or other peaceful purposes under appropriate supervision or control in accordance with Canadian national implementation measures under Article IV of the BTWC.

B. Article II

51. The provisions of Article II impose obligations only upon those States Parties which possess or have under their jurisdiction or control, microbial or other biological agents, or toxins, weapons, equipment, or means of delivery specific in Article I. At the time of its ratification of the Convention (18 September, 1972), Canada had already biologically disarmed. Canada's past offensive biological weapons program was shut down on 30 June 1958. There had been no large-scale production or weaponization, and all biological warfare agents were destroyed.

52. In its CBM Form F (1991) and in 2011 Canada reported to States Parties the destruction of biological warfare agents prior to the entry into force of the BTWC. The submission by Canada for 2010 (dated April 2011) is available on the Implementation Support Unit (ISU) website in both the public and restricted areas and in English and French.

C. Article III

53. Canada complies fully with the undertaking 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.

54. Canada's fulfilment of its obligations under Article III has evolved since the Convention entered into force through the adoption of legislation, regulations, and other arrangements and guidelines principally through the Export and Import Permits Act and related regulations, so that national authorities maintain the necessary oversight of transfers

and have the necessary legal authority to intervene should there be any uncertainty or suspicious activity that would warrant such intervention.

D. Article IV

55. In accordance with Article IV Canada has undertaken the necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of agents, toxins, weapons, equipment, and means of delivery specified in Article I of the BTWC.

56. The necessary measures required for national implementation have been reported to States Parties to the BTWC in previous compliance reports, in documents submitted to meetings of experts and meetings of States Parties since 2003 and to the Committee of United Nations Security Council Resolution 1540 (2004). In addition to these previous submissions the following information[13] is provided.

1. Human Pathogens and Toxins Act (HPTA, 2009)

Articles of the BTWC covered by HPTA (2009) legislation

57. Articles I, III, IV.

Purpose

58. The purpose of this Act is to establish a safety and security regime to protect the health and safety of the public against the risks posed by human pathogens and toxins.

59. Canada recognizes that human pathogens and toxins pose varying levels of risk to the health and safety of the public and that a lack of full scientific certainty regarding the risks posed by certain human pathogens and toxins is not to be used as a reason to postpone measures that protect the health and safety of the public. In addition, Canada recognizes that human pathogens and toxins evolve and can be altered and that new human pathogens and toxins appear continually, therefore creating unique challenges in meeting the objective of protecting the health and safety of the public.

60. The HPTA is in some respects broader than the BTWC since it provides a robust legislative framework that covers human pathogens and toxins even where they are intended for peaceful purposes.

61. The regulatory framework for HPTA is being developed and full publication of the regulations is expected by 2015. Until that time a dual system comprised of HPTA and the HPIR (1994) regulations remain in place. HPIR will, thus, remain in force until HPTA is fully developed and in place.

Scope

62. Over the past decade, many countries have developed more stringent controls over the possession, containment and movement of pathogens into and within their borders. In Canada, while imported human pathogens and toxins are subject to the Human Pathogens Importation Regulations (HPIR), the regulations under HPIR did not provide for

[13] The information for this section was compiled from a variety of sources including departmental experts, legal services units, and Government of Canada websites, including that of the Department of Foreign Affairs and International Trade at: http://www.international.gc.ca/arms-armes/non_nuclear-non_nucleaire/bio_legislation-bio_lois.aspx?view=d

comprehensive nationally consistent controls for non-imported human pathogens and toxins. As a result, there were no nationally consistent safety requirements (e.g. no comprehensive inventory of who has what pathogen and in what quantity, nor knowledge of how safely they are being handled). Since human pathogens and toxins pose a risk to human health and safety, either through accidental or deliberate release – whereby accidental release can result from inadequate and unsafe containment of a pathogen through unsafe possession, use, transfer or disposal and a deliberate release could result from having a lack of proper security measures in place – the HPTA addresses these concerns. The basis of the Act is primarily the criminal law power of the Parliament of Canada.

63. It is not the intent of the Act to apply to human pathogens and toxins that are found in an environment in which they naturally occur, and an exemption is provided for this situation. Some examples are provided including a person suffering from a disease caused by a human pathogen or toxin; a situation in which a human pathogen or toxins is expelled by a person suffering from such a disease; and a human pathogen or toxin that is in a cadaver, organ or other human remains. These examples highlight the fact that there is no intention to bring persons with diseases under the ambit of the bill simply because they possess a human pathogen or toxin as a consequence of having a disease. As well, there is no intent to bring persons under the purview of the bill owing to the fact that a human pathogen may be expelled by them, for example, when they sneeze. Finally, there is no intent to bring persons such a coroners who deal with human remains on a professional basis under the ambit of the bill simply because they interact with remains that may be infected with dangerous human pathogens or toxins.

64. Exemptions from application of the Act are also provided for drugs in dosage form whose sale is permitted or authorized under the Food and Drugs Act (1985). This exemption reflects the policy intent that these drugs should not come under the purview of the Act, so as to prevent unnecessary overlap between the two pieces of legislation. This concern to prevent overlap also underscores the exemption for controlled activities under the Assisted Human Reproduction Act.

Associated Penalties

65. Section 53 provides a general offence provision, outlining penalties from a fine of up to $250,000 and up to three months in prison on a first offence, to a fine of up to $500,000 and up to six months in prison on subsequent offences. The specific sections to which this section applies are 11(1), 11(2), 12(1), 12(2), 13, 14, 15, 18(6), 24(1), 27, 30(1), 30(2), 31, 32, 33, 36(1), 36(6), 38(3), 41(5), 43(2), 57(2), 70(1), 70(2), 70(3), and 71(1).

66. Additionally, failure to take all reasonable precautions to protect the health and safety of the public against the risks when knowingly conducting a controlled activity referred to in section 7 is prohibited (section 6). Penalties associated include a maximum sentence of two years in prison for an individual who knowingly breaches section 6 by not taking reasonable precautions to protect human life and health against the risks posed by human pathogens and toxins, and as a result creates a risk to public health or safety (section 54), a possible sentence of up to five years in prison for an individual who not only knowingly breach section 6 by not taking reasonable precautions, but in so doing show wanton and reckless disregard for the lives and safety of other persons (section 55).

67. Carrying out the controlled activities of section 7 is also prohibited without a licence (section 7(1), as per section 53 and 56 of the Act. Penalties range from a fine of up to $ 50,000 for a first offence relating to a human pathogen in Risk Group 2, to a maximum fine of $ 1,000,000 and up to 2 years in prison, or both, for a subsequent offence relating to a toxin or a human pathogen in Risk Group 3 or 4..

68. Section 8 prohibits any activities with human pathogens and toxins on Schedule 5 of the HPTA, i.e. the Variola virus. As detailed in section 57 punishments for violation of section 8 range to as high as $1 million and up to five years in prison.

69. Finally, section 58 of the HPTA provides for a prison sentence of up to 10 years for the intentional release of a human pathogen or toxin, or otherwise abandonment, in contravention of the Act.

2. Human Pathogens Importation Regulations (1994)

Articles of the BTWC covered by legislation

70. Article I, III, IV,

Purpose

71. The purpose of the Human Pathogen Importation Regulations (HPIR) is to place controls on the importation, and subsequent handling and containment, of human pathogens and toxins into Canada in order to mitigate the risks posed by these activities

Scope

72. The HPIR applies to all persons importing human pathogens and toxins into Canada. The HPIR excludes human pathogens that are a drug within the meaning of the Food and Drugs Act and animal pathogens, or toxins, which are incapable of causing human diseases.

73. The HPIR requires that every person importing a human pathogen in risk group 2, 3, and 4 or toxin must obtain an import permit. These regulations also make the Laboratory Biosafety Guidelines (LBGs) mandatory in all facilities dealing with imported human pathogens and toxins. Applicants wishing to import human pathogens or toxins must have facilities that comply with the operational practices and physical requirements for a containment laboratory detailed in the LBGs.

Associated Penalties

74. An individual who commits an offence under the HPIR is liable on summary conviction to a fine not exceeding $200 or to imprisonment for a term not exceeding three months. Offences include importing without a permit, failing to notify relevant authorities when an imported Risk Group 3 or 4 human pathogen, or toxin, is not received, failing to surrender an importation permit after it has been suspended or cancelled, breaching a term or condition of an importation permit, and submitting false or misleading information to relevant authorities.

3. Health of Animals Act (1991)

Articles of the BTWC covered by legislation

75. Articles I, III, IV

Purpose

76. The purpose of the Health of Animals Act and Regulations is to prevent the introduction of animal diseases into Canada and to protect the agricultural sectors and the economy.

Scope

77. The Health of Animals Act and its regulations give the Canadian Food Inspection Agency (CFIA) the legislative authority to deal with reportable animal diseases and prescribed toxic substances. Permits are required for the importation of all animal pathogens into Canada. For an agent brought into Canada under an import permit which restricts its distribution, further approval must be obtained before transferring the agent to another location.

78. With the Regulations, the Minister is empowered to exempt persons dealing with veterinary biologics from the requirements of the Regulations.

Associated Penalties

79. Every person who violates the provisions of the Health of Animals Act, other than section 15, is guilty of an offence punishable on summary conviction and liable to a fine not exceeding fifty thousand dollars or to imprisonment for a term not exceeding six months, or to both; or an indictable offence and liable to a fine not exceeding two hundred and fifty thousand dollars or to imprisonment for a term not exceeding two years, or to both.

80. For violations of section 15, prohibiting the wilful possession or disposition of an animal or thing imported in contravention of the Act, a person is guilty of an offence punishable on summary conviction and liable to a fine not exceeding fifty thousand dollars.

4. Plant Protection Act (1990)

Articles of the BTWC covered by legislation

81. Articles I, III, IV

Purpose

82. The purpose of this Act is to protect plant life and the agricultural and forestry sectors of the Canadian economy by preventing the importation, exportation and spread of pests and by controlling or eradicating pests in Canada.

Scope

83. The Act has controls over both importation and exportation of plant pests (i.e. plant pathogens, nematodes, insects etc). Importation of plant pests is prohibited without a valid import permit issued by CFIA. An export permit under the Export and Import Permits Act is required to export anything listed in Group 7 under the Export Control List [as a chemical or biological weapons agent] or anything infested with a listed agent.

Associated Penalties

84. Every person who violates the Plant Protection Act, other than section 9, is guilty of an offence punishable on summary conviction and liable to a fine not exceeding fifty thousand dollars or to imprisonment for a term not exceeding six months, or to both; or an indictable offence and liable to a fine not exceeding two hundred and fifty thousand dollars or to imprisonment for a term not exceeding two years, or to both.

85. For violations of section 9, prohibiting the possession or disposition of an animal they know was imported in contravention of the Act, a person is guilty of an offence punishable on summary conviction and liable to a fine not exceeding fifty thousand dollars.

5. Export and Import Permits Act (1947)

Articles of the BTWC covered by legislation

86. Articles I, III, IV

Purpose

87. The Export and Import Permits Act (EIPA) provides the Minister of Foreign Affairs wide discretionary powers to control the flow of goods contained in specified lists established by the Governor in Council including the Import Control List (ICL), the Export Control List (ECL), and the Area Control List (ACL). The controls provided by the EIPA have been judged essential for a variety of reasons, including:

(a) To regulate trade in military and strategic dual-use goods, and prevent the proliferation of weapons of mass destruction, as we are obliged to do under multilateral agreement;

(b) To prevent the supply of military goods to countries that threaten Canada's security, are under UN sanction, are threatened by internal or external conflict, and/or abuse the human rights of their citizens;

(c) To fulfil other international obligations; and

(d) To implement UN Security Council trade sanctions.

Scope

88. The Act sets out the purposes for including goods or countries on these lists. The ICL generally comprises a list of goods, some of which are only controlled for certain countries of origin; all goods contained in this list require an import permit. The ECL is a list of goods only; all goods contained on this list also require an export permit. The ACL is a list of countries for which export permits are required to export any and all goods.

89. In relation to biological non-proliferation, the most important piece of this legislation is the ECL. This list is divided into seven groups, Group 7 of which is the Chemical and Biological Weapons Non-Proliferation List. Sections 7-11 through 7-15 list the materials related to biological weapons, including dual-use biological test, inspection and production equipment (such as complete BSL3 and BSL4 laboratories, fermenters, centrifugal separators, tangential flow filtration systems, freeze-drying equipment, personal protective equipment, aerosol inhalation chambers and aerosol spraying systems), as well as a specific list of pathogens and toxins (separated by what they infect: humans, animals or plants, and their type: Virus, Rickettsiae, Bacteria, Toxins, Fungi and Genetic Elements). The common export controls on chemical substances and biological agents and related items that could be used in the production of chemical and biological weapons developed by the Australia Group have been implemented in Canada on the Export Control List as Group 7.

Associated Penalties

90. As described in section 19 of the EIPA, every person who contravenes any provision of this Act or the regulations is guilty of an offence punishable on summary conviction and liable to a fine not exceeding twenty-five thousand dollars or to imprisonment for a term not exceeding twelve months, or to both; or an indictable offence and liable to a fine in an amount that is in the discretion of the court or to imprisonment for a term not exceeding ten years, or to both.

E. Other Legislation of Relevance

1. Canadian Environmental Protection Act (1999)

Articles of the BTWC covered by legislation

91. Article I

Purpose

92. The primary purpose of the Canadian Environmental Protection Act (CEPA) is to contribute to sustainable development through pollution prevention. It does this through the prevention of pollution via control over toxic substances ("toxicity" referring to its effects on the environment and human health). Risk management of substances assessed under CEPA may also include export and import controls over toxic substances, to ensure that those substances will not be released into the environment in Canada or beyond our borders.

Scope

93. The CEPA and its regulations (specifically the New Substances Notification Regulations, or NSNR) apply to any new varieties of micro-organisms (some of which may be pathogenic), higher organisms (animals, including pests), as well as chemicals and polymers, unless that chemical or organism was previously assessed as falling under the jurisdiction of another Act. Also sections 2(3) and (4) exempt certain research and development micro-organisms and organisms. The NSNR play a 'safety net' role in the regulation of new chemicals and organisms in Canada. The NSNR mandates that Environment Canada must be notified of any new organism being imported into or manufactured within Canada. This is to ensure that organisms are appropriately assessed prior to their introduction into the environment, so as to protect both human health and the environment from any potentially adverse effects.

Associated Penalties

94. Every person who contravenes the CEPA is liable on conviction on indictment, to a fine of not more than $1,000,000 or to imprisonment for a term of not more than three years, or to both; and on summary conviction, to a fine of not more than $300,000 or to imprisonment for a term of not more than six months, or to both (section 272(2)).

95. Additionally, any individual who provides false and misleading information with respect to any matter covered by the CEPA or its regulations is liable on conviction on indictment, to a fine of not more than $1,000,000 or to imprisonment for a term of not more than three years, or to both, if the offence is committed knowingly; on summary conviction, to a fine of not more than $300,000 or to imprisonment for a term of not more than six months, or to both, if the offence is committed knowingly; on conviction on indictment, to a fine of not more than $500,000 or to imprisonment for a term of not more than three years, or to both, if the offence is committed negligently; and on summary conviction, to a fine of not more than $200,000 or to imprisonment for a term of not more than six months, or to both, if the offence is committed negligently.

96. As well, every individual who intentionally or recklessly causes a disaster that results in a loss of the use of the environment; or shows wanton or reckless disregard for the lives or safety of other persons and thereby causes a risk of death or harm to another person is guilty of an offence under the CEPA and may receive a jail term of not more than five years.

2. Department of Public Safety and Emergency Preparedness Act / Emergency Management Act

Articles of the BTWC covered by legislation

97. Complementary to main legislation.

Purpose

98. The purpose of the Department of Public Safety and Emergency Preparedness Act (DPSEPA) was to establish the Department of Public Safety and Emergency Preparedness and to amend or repeal certain Acts. The purpose of the *Emergency Management Act* (EMA) is to provide for emergency management.

Scope

99. When the DPSEPA came into force on April 4, 2005 it assigned to the Minister of Public Safety the responsibility to co-ordinate the activities of various entities for which the Minister is responsible, including the Royal Canadian Mounted Police, the Canadian Security Intelligence Service, the Canada Border Services Agency, the Canadian Firearms Centre, the Correctional Service of Canada and the National Parole Board, as well as three separate review bodies. It also assigned to the Minister of Public Safety responsibility for exercising leadership at the national level relating to public safety and emergency preparedness. The Act has contributed to fulfilling the fundamental role of government to secure the public's safety and security by improving emergency preparedness and responses to natural disaster and security emergencies, and improving connections to provincial and territorial emergency preparedness networks.

100. When the EMA came into force on August 3, 2007 it assigned to the Minister of Public Safety the responsibility for exercising leadership relating to emergency management in Canada by coordinating, among government institutions and in cooperation with the provinces and other entities, emergency management activities. The EMA has contributed to modernizing the federal government's approach to emergency management and to strengthening the readiness posture of the Government of Canada to mitigate the impact of, prevent or prepare for, and respond to all hazards in Canada. It recognizes that emergency management in an evolving risk environment requires a collective and concerted approach between all jurisdictions including the private sector and non-governmental organizations.

101. The EMA also authorized the Minister of Public Safety, in consultation with the Minister of Foreign Affairs, to develop joint emergency management plans with the relevant United States' authorities and, in accordance with those plans, to coordinate Canada's response to emergencies in the United States (which would include chemical, biological, radiological, nuclear, or explosives [CBRNE] incidents) and to provide assistance in response to those emergencies. To ensure a cohesive Canadian response, the Government of Canada has established Government Operations Centre, established to serve as the national focal point for emergency operations, will be used to coordinate efforts with the U.S. Department of Homeland Security and its Federal Emergency Management Agency.

102. In January 2007, Federal, Provincial, and Territorial Ministers responsible for Emergency Management approved an Emergency Management Framework for Canada. This is a cornerstone document for federal/provincial/territorial cooperation on all major functions and components of emergency management in Canada. Specifically with respect to CBRNE, the Chemical, Biological, Radiological, Nuclear and Explosives Resilience Strategy for Canada was released in January 2011 after extensive consultations. Once

implemented, this strategy and action plan will assist all jurisdictions in preventing/mitigating, preparing for, responding to and recovering from CBRNE events. This strategy is consistent with, and supports, the Emergency Management Act and the Emergency Management Framework for Canada.

Associated Penalties

103. Neither DPSEPA nor the EMA provide for any offences/penalties.

3. Feeds Act (1960)

Articles of the BTWC covered by legislation

104. Articles I & III

Purpose

105. The *Feeds Act* entered into force in 1960. It was designed to regulate and control the sale and distribution of animal feed for livestock. It makes it illegal to manufacture, sell or import feed for livestock unless it has been appropriately registered, packaged and labelled, and unless it conforms to prescribed standards. The Feeds Regulations, a set of regulations written in 1983 for this Act, provide details as to what feeds are regulated and how. Specific measures regulating products of biotechnology were added to the Feeds Regulations in 1997. The Feeds Act does not regulate export.

106. The regulation of the content of animal feeds is essential in the prevention of agro-terrorism. The strict regulations and testing done on animal feeds reduces the risk that feeds contaminated - either accidentally or intentionally - with biological contaminants (such Salmonella Enteritidis) or toxic chemicals will enter the feed supply.

Scope

107. The Act places controls on animal feed without Canada as well as the importation of feed. The Act does not regulate export. Specific measure regulating products of biotechnology were added to the Feeds Regulations in 1997.

108. The Act is key to the prevention of agro-terrorism in Canada. The system of regulation and testing done on animal feeds reduces the risk that feeds contaminated with biological containments or toxic chemicals will enter the feed supply.

Associated Penalties

109. Every person who, or whose employee or agent, contravenes any provision of this Act or the regulations is guilty of an offence punishable on summary conviction and liable to a fine not exceeding $50,000 or to imprisonment for a term not exceeding six months, or to both; or an indictable offence and liable to a fine not exceeding $250,000 or to imprisonment for a term not exceeding two years, or to both.

4. Pest Control Products Act (2006)

Articles of the BTWC covered by legislation

110. Articles I, III & IV

Purpose

111. The Pest Control Products Act originally entered into force November 25, 1972. It was designed to control products used to control pests of animals and plants, in both the

environment and in agriculture. The Act was replaced by a new Pest Control Products Act, which entered into force June 28, 2006 (this new act repealed the old one, which in turn repealed a previous one from 1939). Its purpose is to regulate products used for pest control to protect the environment and human health and safety.

112. The Pest Control Products Act's impact on biosecurity and non-proliferation is found in its regulations. Certain novel pest control products are based on live microbial agents. These products, while useful at selectively targeting certain pests while ignoring others, can theoretically be weaponized. The Pest Control Products Regulations clearly state that the use of microbial agents in pest control products is subject to the Act's prohibitions, especially when used in aerosol form and when the micro-organism is non-indigenous to the region. These controls are therefore important to the protection of public health and reducing the risk that dangerous pathogens are not released, either accidentally or as a biological weapon, in the form of a pesticide.

Scope

113. The Act applies to products within Canada used to control animal and plant pests. The act prohibits the possession, importation, exportation, and distribution of pest control products that are not registered with the Government of Canada and appropriately labelled.

114. Within the Act's regulations are controls on the use of live microbial agents in pest control products. Given that microbial agents can theoretically be weaponized, these controls help reduce the risk that dangerous pathogens are not released, either accidentally or as a biological weapon, in the form of a pesticide.

Associated Penalties

115. Section 68(1) states that any person who contravenes the Act or it's regulates is guilty of an offence if they cause a risk of imminent death or serious bodily harm to another person; a risk of substantial harm to the environment; or harm to the environment. Every person who commits an offence under section 68(1) is liable on summary conviction, to a fine of not more than $200,000 or to imprisonment for a term of not more than six months, or to both; and on conviction on indictment, to a fine of not more than $500,000 or to imprisonment for a term of not more than three years, or to both.

116. Separate from this, section 68(3) creates a separate offence for causing the same risks or harm where done wilfully or recklessly. Every person who commits an offence under section 68(3) is liable on summary conviction, to a fine of not more than $300,000 or to imprisonment for a term of not more than six months, or to both; and on conviction on indictment, to a fine of not more than $1,000,000 or to imprisonment for a term of not more than three years, or to both.

5. Fertilizers Act (1957)

Articles of the BTWC covered by legislation

117. Articles I, III & IV

Purpose

118. The purpose of the Fertilizers Act is to regulate fertilizers and supplements[14] that are imported into or sold in Canada. It was created in 1957.

[14] For use in the improvement of the physical condition of soils or to aid plant growth or crop yields.

Scope

119. Pursuant to the Act, most supplements and some fertilizers require registration from the Crop Inputs Division of the Canadian Food Inspection Agency. All regulated fertilizers and supplements, even if exempt from registration, must be safe (with respect to human, plant, animal health and the environment), efficacious for the intended purpose, and properly-labelled to avoid misrepresentation in the marketplace and fraud. Compliance of the regulated products with the prescribed safety, efficacy and labelling standards is verified through pre-market assessment or marketplace monitoring activities. The latter include product inspections, sampling, analysis (active ingredient guarantee verification, contaminant testing) and marketplace label verification. Non-compliant products are subject to enforcement actions including product detention and, in cases of repeated or severe cases of non-compliance, prosecution.

120. Microbial products represented to aid plant growth or improve the physical condition of soil are classified as supplements and require registration under the Fertilizers Act prior to sale in or importation into Canada. The registration process includes an in-depth safety assessment of the product including both its active and inert ingredients. In addition, microbial supplements must:

(a) Meet the minimum guarantee for the active organism,

(b) Not contain micro-organisms or other substances at levels that are likely detrimental or seriously injurious to plants, animals, human health or environment when the product is used as directed, and

(c) The micro-organisms other than those guaranteed must be present at levels that do not affect the viability or the performance of the active organisms.

121. Given the potential for microbial products to be used in biological weapons, the controls of the Act assist in protecting against bioterrorism acts through the use of regulated fertilizers and supplements.

Associated Penalties

122. Every person who, or whose employee or agent, contravenes any provision of this Act or any regulation made under paragraph 5(i) or (j) is guilty of an offence punishable on summary conviction and liable to a fine not exceeding $50,000 or to imprisonment for a term not exceeding six months, or to both; or an indictable offence and liable to a fine not exceeding $250,000 or to imprisonment for a term not exceeding two years, or to both.

6. Hazardous Products Act (1969)

Articles of the BTWC covered by legislation

123. Articles I, III & IV

Purpose

124. The Hazardous Products Act (HPA) was created in order to prohibit or regulate the advertisement, sale, or importation of materials, substances and products deemed to be hazardous. It entered into force in 1969 and has been amended several times since then, including amendments in 2010 that came into force in 2011,It specifically does not apply to the sale or importation of certain types of materials, substances and products, and including, among other things, explosive with in meaning of the Explosives Act; a cosmetic, devices, drug or food within the meaning of the Food and Drug Act, and consumer product as defined in section 2 of the Canada Consumer Product Safety Act.

Scope

125. The HPA applies to certain materials, substances and products intended to be used in a workplace in Canada. A “controlled product” or “hazardous product” is a product, material or substance specified by regulations to be included in certain classes – one of which is Poisonous and Infectious Material.

126. Part II of the Hazardous Products Act was enacted in 1987 to regulate the sale and importation of controlled products. The material safety data sheet (MSDS) and labelling requirements for controlled products are supplier/importer requirements under the Workplace Hazardous Materials Information System (WHMIS), a national system to provide information on certain products, materials or substances used in the workplace. The HPA requires the Canadian supplier of a WHMIS controlled product intended for use in a workplace in Canada to transmit a MSDS and apply a label disclosing prescribed information as a condition of sale. The supplier who imports a controlled product intended for use in a workplace in Canada must obtain or prepare a MSDS and ensure that the requisite label is applied as a condition of importation.

127. The Controlled Products Regulations (CPR), made under the authority of the HPA, set out criteria for the classification of certain products, materials or substances intended to be used in the workplace. The Regulations include criteria for biohazardous infectious material under Division 3 of Class D (Poisonous and Infectious Material). An organism and its toxins are considered to fall within the criteria for biohazardous infectious material if the organism is classified in WHO Risk Group II, III or IV.

128. The scope of the HPA and CPR in relation to biohazardous infectious materials is limited to regulating the sale and importation of these materials intended for use in a workplace in Canada. Materials that fall within the criteria for Class D, Division 3 are subject to WHMIS MSDS and labelling requirements. Subject to specified conditions, the CPR provides special provisions for laboratory samples that are less than 10 kg and intended solely to be tested in a laboratory. There is an allowance to disclose less information on the label than is normally required, provided that the label discloses, among other things, the statement "Hazardous laboratory sample. For hazard information or in an emergency, call [emergency telephone number]”. The Regulations also provide an exemption from the requirement to transmit, prepare or obtain a MSDS for laboratory samples that are labelled in accordance with the specified requirements. The MSDS exemption and special label provision for laboratory samples could be applicable to the sale/importation of biohazardous infectious material intended to be used in a workplace in Canada.

Associated Penalties

129. Every person who contravenes or fails to comply with any provision of this Act or of any regulation made under this Act is guilty of an offence punishable on summary conviction and liable to a fine not exceeding one hundred thousand dollars or to imprisonment for a term not exceeding six months or to both; or is guilty of an indictable offence and liable to a fine not exceeding one million dollars or to imprisonment for a term not exceeding two years or to both

7. Quarantine Act (2006)

Articles of the BTWC covered by legislation

130. Article I, III, IV

Purpose

131. An Act Respecting Quarantine first came into force in 1872. On December 12, 2006, a new Quarantine Act entered into force, which repealed and replaced the 1970 version. The purpose of the new Act is to "to protect public health by taking comprehensive measures to prevent the introduction and spread of communicable diseases."

Scope

132. The Act is applicable to persons and conveyances arriving in or in the process of departing from Canada. It provides the authority to designated officers, including quarantine officers and screening officers, to take specific measures with respect to travellers in certain circumstances where there is a communicable disease concern. The Schedule to the Act provides a non-exhaustive list of communicable diseases. Furthermore, in certain circumstances, the Act also provides the authority to take prescribed measures with respect to international conveyances, such as, disinfection and decontamination. Controls are placed on the importation and exportation of cadavers, body parts and other human remains. Measures can be taken under the Act with respect to cargo or any other thing on board an international conveyance in certain prescribed circumstances.

133. In short, the Quarantine Act aims to protect public health by focussing on communicable disease control at Canada's borders. Measures can be taken under this Act when the communicable disease concern occurs, due to a malicious act (e.g. a terrorist inoculated with smallpox) or, in a situation where there is no malicious intent (e.g. SARS). The application of the Quarantine Act to travellers departing from Canada helps protect public health outside Canada's borders.

Associated Penalties

134. The Quarantine Act prescribes prohibitions and penalties. For instance, according to section 67(1), every person is guilty of an offence if they cause a risk of imminent death or serious bodily harm to another person while wilfully or recklessly contravening this Act or regulations made under it. A person who is guilty of an offence under this provision may be may be fined up to $1,000,000 and/or imprisoned for a term of up to three years (section 67(2)).

8. Transportation of Dangerous Goods Act (2009, as amended)

Articles of the BTWC covered by legislation

135. Articles I, III & IV

Purpose

136. The purpose of the Transportation of Dangerous Goods Act is to promote public safety during the importation, handling, or transport of dangerous goods. The Act is criminal law and applies to all modes of transport (road, rail, sea, or air). The current Act came into force in 1992. On June 16, 2009, the TDG Act was amended to include a comprehensive security (terrorist) prevention and response program just like the one that currently exists for safety (accidental) incidents.

Scope

137. The Act enables Transport Canada to regulate the movement of dangerous goods in all[15] modes of transportation (road, rail, sea, or air). Through the Act the Canadian government is provided authority to develop policy, verify compliance, conduct research to enhance security and safety, guide emergency response, and develop regulations and standards to manage risk and promote public safety while mitigating the consequences of an incident during the transportation of dangerous goods.

138. In enforcement of the Act, Transport Canada maintains a team of inspectors who conduct inspections at dangerous goods sites and facilities on an ongoing basis.

139. The TDG Regulations associated with the Act divide dangerous goods into nine distinct classes. Relevant to the BTWC are Class 9 (non-pathogenic genetically modified organisms), Class 6.2 (all infectious substances), and Class 6.1 (all toxic chemicals, including biological toxins). Dangerous goods are required to be transported in accordance with the Act, and any incident involving the release of a micro-organism or toxin during transportation must be immediately reported.

140. Additionally, the Act was amended in June 2009 to provide for security requirements during the importation, handling, offering for transport and transportation of dangerous goods. The legislative provisions on which this new prevention and response security program will be based include:

(a) Requiring security plans and security training;

(b) Enabling the use of Security Measures and Interim Orders;

(c) Enabling regulations to be made to require that dangerous goods are tracked during transport or reported if lost or stolen;

(d) Reinforcing the existing Emergency Response Assistance Program to equally address responses to security incidents and accidents during the transportation of dangerous goods;

(e) Enabling the development of a program to require transportation security clearances for dangerous goods. (This section will come into effect at a later date)

141. Transport Canada's TDG program is based on the premise that properly classifying a dangerous good while ensuring that the dangerous good is transported in the required means of containment, along with other safety and security measures such as requirements for Emergency Response Assistance Plans, documentation, safety marks, reporting and training, are crucial elements in the safe transportation of dangerous goods.

Associated Penalties

142. Any person who commits an offence under the Act is liable on indictment to imprisonment for a term not exceeding two years; or is liable on summary conviction to a fine not exceeding $50,000 for a first offence, and not exceeding $100,000 for each subsequent offence.

143. Additionally, where a person is convicted of an offence, the court may make an order having any or all of the following effects:

[15] s 3(4):This Act does not apply in relation to (a) any activity or thing under the sole direction or control of the Minister of National Defence, including in circumstances in which the regulations provide that it is under that Minister's sole direction or control.

(a) Prohibiting the person for a period of not more than one year from engaging in any activity regulated under this Act;

(b) Requiring the person to provide compensation, whether monetary or otherwise, for any remedial action taken or damage suffered by another person arising out of the commission of the offence;

(c) Requiring the person to do anything that will assist in repairing any damage to the environment arising out of the commission of the offence; or

(d) Requiring the person to conduct programs of technical research and investigation into the development and improvement of safety marks, safety requirements and safety standards, or to pay an amount in accordance with the regulations to be used to conduct the research.

9. Chemical Weapons Convention Implementation Act (1997)

Article of the BTWC covered by legislation

144. Article IX

Purpose

145. The Chemical Weapons Convention Implementation Act (CWCIA) which entered into force in 1997, implements Canada's obligations under the Chemical Weapons Convention of 1993. It prohibits the development, production, acquisition, stockpiling, transfer and use of chemical weapons, including the biological toxins Ricin and Saxitoxin. The production, possession, consumption and transfer of toxic chemicals and precursors is also prohibited, except when done under authorization for industrial, agricultural, research, pharmaceutical, medical, and protective purposes and law enforcement, and is subject to an obligation to report to the National Authority (part of Foreign Affairs and International Trade Canada’s Non-Proliferation and Disarmament Division). It also guarantees the right of international inspectors to access and inspect facilities in a manner consistent with the Convention.

Scope

146. The provisions of the CWCIA apply throughout Canada to anyone undertaking activities with regulated goods.

Associated Penalties

147. The Act creates related penal offences in case of breach and extends jurisdiction to acts committed outside Canada by Canadian citizens and permanent residents.

10. Customs Act / Canada Border Services Agency Act

Articles of the BTWC covered by legislation

148. Articles I, III & IV

Purpose

149. The Customs Act was enacted in part to control the movement of people and goods into and out of Canada, which would include the import and export of pathogens and toxins.

Scope

150. It requires all persons arriving in Canada to present themselves at a customs office and answer any questions truthfully. Subject to certain exceptions, all imported goods must also be presented to a customs office, which would include any goods imported by mail. Any person who finds or has in his possession goods that have been imported and who believes on reasonable grounds that the Customs Act or any other Act of Parliament has not been complied with must report to an officer that he has found the goods or has them in his possession.

151. The Customs Act prohibits any person, without lawful authority or excuse, to have in his possession, purchase, sell, exchange or otherwise acquire or dispose of any imported goods in respect of which the provisions of the Customs Act or any other Act of have been contravened.

152. The Customs Act also regulates exports, and requires all goods that are exported to be reported, subject to those exempted by regulation.

153. The Customs Act was enhanced on December 12, 2005, when the Canada Border Services Agency Act entered into force. The Canada Border Services Agency (CBSA) formed by this Act has a mandate to ensure public safety and national security while also facilitating importation and exportation of all things that meet the legislation's requirements. The CBSA enforces the Customs Act, and also enforces importation and exportation laws related to many other pieces of legislation, including (but not limited to) the Health of Animals Act, the Human Pathogens Importation Regulations, the Plant Protection Act, the Feeds Act, and the Fertilizers Act. CBSA-designated inspectors may also act as inspectors regarding these other acts with respect to importation or exportation. As a result, all biological materials imported into or exported from Canada are checked at the border, ensuring that any controls imposed by all other pertinent pieces of legislation are in place. If a pathogen or something that may contain a pathogen arrives at the border without meeting the appropriate legislative and regulatory requirements, the CBSA can detain it until all legislation and regulatory requirements are met.

154. Under section 101 of the Customs Act, goods that have been imported may be detained by a Customs Officer until they have been dealt with in accordance with any Act of Parliament that regulates the importation of that good. In a situation involving a regulated item that has been imported in contravention of the law, the CBSA would have the power to detain the item until regulating department could be contacted to deal with the matter. Section 102 of the Customs Act states that goods that have been imported in contravention of that Act or any other Act of Parliament and that have been detained under section 101 shall be disposed of in accordance with the relevant legislation. Where there is no legislative provision for the disposition of the goods, there are two options under the Customs Act: the importer may abandon the goods to the Crown or export the goods. Federal regulators with oversight for import and/or export often have administrative agreements with CBSA, to make best use of these provisions with regards to import and export compliance and enforcement.

Associated Penalties

155. The penalties for most of the offences under the Customs Act, including failing to report goods being imported and answering any questions truthfully, or failing to report exported goods, are set out in section 160. On summary conviction, the maximum penalty is a fine of fifty thousand dollars or to imprisonment for a term not exceeding six months or both. If convicted of an indictable offence, the maximum fine is five hundred thousand dollars or imprisonment for a term not exceeding five years or both.

11. Criminal Code of Canada

Articles of the BTWC covered by legislation

156. Article I, III, IV

Purpose

157. The Criminal Code of Canada is federal legislation that defines a range of illegal activities, setting out most Canadian criminal law and procedure.

Scope

158. The provisions of the Criminal Code of Canada apply throughout Canada and some provisions deal with certain offences committed outside Canada.

159. Several sections within the Criminal Code are relevant to the BTWC. Part II.1, starting at section 83.01 deals specifically with terrorist activity. A core provision is the definition of “terrorist activity”. The definition, which has two components, applies to activities inside or outside Canada. Satisfying either component constitutes a "terrorist activity". The first component of the definition is defined in part as an act or omission committed in or outside Canada that would be an offence resulting from implementing certain UN counterterrorism conventions and protocols, dealing with such matters as hijacking and terrorist bombing.

160. In the second part, a general definition of "terrorist activity" is provided. Under this general definition, "terrorist activity" is defined as an act or omission undertaken, inside or outside Canada, for a political, religious or ideological purpose that is intended to intimidate the public with respect to its security, including its economic security, or to compel a person, government or organization (whether inside or outside Canada) from doing or refraining to do any act, and that intentionally causes one of a number of specified forms of serious harm. These harms include causing death or serious bodily harm, endangering life, causing a serious risk to health or safety, causing substantial property damage where it would also cause one of the other harms listed above, and, in certain circumstances, causing serious interference or disruption of an essential service, facility or system, whether public or private. As well, that aspect of the definition that relates to seriously interfering with or disrupting an essential service contains an exception for advocacy, protest, dissent and stoppage of work, providing this is not intended to cause most of the other forms of harm referred to in the definition. This exception recognizes that even unlawful protests and strikes that could lead to the disruption of an essential service are not the same thing as terrorist activity under the Code.

161. The Criminal Code also has a procedure for the listing of entities where it is reasonably believed that they have knowingly carried out, attempted to carry out, participated in, or facilitated a terrorist activity or knowingly acted on behalf of, at the direction of, or in association with such entities. The list supports the application of other provisions in the Code and elsewhere, including:

(a) Terrorism offences;

(b) Crimes related to the financing of terrorism;

(c) Requirements to freeze terrorist property and procedures for the court to order seizure and forfeiture of that property; and

(d) The removal or denial of the charitable status of organizations that engage in or support terrorism.

(e) Comprehensive terrorism offences in the Criminal Code include:

(f) Knowingly participating in, contributing to, any activity of a terrorist group for the purpose of enhancing the ability of any terrorist group to facilitate or carry out a terrorist activity;

(g) Knowingly facilitating a terrorist activity;

(h) Commission of a serious (i.e. indictable) offence for the benefit of, at the direction of or in association with a terrorist group;

(i) Knowingly instructing anyone to carry out a terrorist activity for a terrorist group; and

(j) Knowingly harbouring or concealing any person who has carried out or is likely to carry out a terrorist activity for the purpose of enabling the person to facilitate or carry out any terrorist activity.

162. Offences such as knowingly instructing the carrying out of any activity for a terrorist group or knowingly facilitating a terrorist group are specifically defined to be offences regardless of whether the ultimate terrorist activity is carried out and regardless of whether the accused knows the specific nature of the terrorist activity being contemplated. By creating such offences, the law takes into account both the manner in which terrorist groups actually operate and the fundamental need for prevention. Moreover, unlike the general concept of accessory after the fact, the harbouring or concealing can occur before the commission of any terrorist activity.

163. Obviously, acts of bioterrorism or agroterrorism could fall within the definition of "terrorist activity" or within the various "terrorism offences", or could trigger the procedure for listing entities, as described above.

164. There are also a number of other offences in the Criminal Code which could apply to situations of bioterrorism. These offences include:

(a) The possession and use of a "weapon" as defined under section 2 of the Criminal Code - namely, any thing used, designed to be used or intended for use in causing death or injury to any person or for the purpose of threatening or intimidating.

(b) Sending to a person or causing a person to take or receive a dangerous substance or thing with the intent to cause bodily harm pursuant to section 81.

(c) Intending to cause any person to fear death, bodily harm, substantial damage to property, or serious interference with use or operation of property and causes information to be conveyed, without believing the information to be true, or commits an act that in all the circumstances is likely to cause a reasonable apprehension that terrorist activity is occurring or will occur pursuant to section 83.231.

165. Depending on the particular facts of the incident, participating in bio-terrorism could be prosecuted for the offences of murder (s. 229); attempted murder (s. 239); aggravated assault (s. 268); assault with a weapon (s. 267(a)) and causing bodily harm (s. 267(b)); administering a noxious thing (s. 245), each with specific offence elements and punishments.

166. Outside of the Criminal Code, where all essential elements of the offence (chapeau and core offence) are present, it is also possible that an act of bioterrorism be prosecuted as an act of genocide, crime against humanity or war crime under the Crimes Against Humanity and War Crimes Act. In addition, there are offences under the Security of Information Act that could apply.

Associated Penalties

167. The penalties for terrorism related offences range from a maximum of 10 years imprisonment for crimes related to the financing of terrorism, to life imprisonment for the commission of a serious offence for the benefit of or at the direction of a terrorist group. The penalties that may apply under the Criminal Code general offence provisions also vary. For example, the penalty for a conviction of the indictable offence of possessing a weapon for a dangerous purpose is a maximum of 10 years imprisonment, the penalty for administering or causing to be administered a noxious thing is a maximum of 14 years imprisonment, and the penalty for murder is a sentence of life imprisonment.

12. The Biological and Toxin Weapons Convention Implementation Act

168. This Act is not in force

F. Article V

169. Canada has not invoked the provisions of Article V of the BTWC. Canada supports fully the decisions recorded in the final declarations of previous review conferences with regard to consultation and cooperation mechanisms. Canada does not interpret the provisions as being a required prior stage that needs to be invoked before proceeding to Article VI of the Convention, should circumstances so warrant.

170. Canada supports fully the commitments reached at the second and third review conferences with regard to the annual exchange of information – the confidence building measures. Canada has submitted its annual return each year as requested. The information submitted for calendar year 2010, submitted in April 2011, is available online to States Parties and publicly. Canada intends to make future submissions available to States Parties and the public via the Implementation Support Unit.

G. Article VI

171. Canada has not invoked Article VI of the BTWC.

172. Canada supports the United Nations Secretary-General's investigation mechanism, set out in A/44/561 and endorsed by the General Assembly in its resolution 45/57, and is of the view that the mechanism is appropriate for investigating cases of alleged use of biological or toxin weapons. In accordance with General Assembly resolution 60/288 (2006) Canada has:

173. Informed the United Nations Office for Disarmament Affairs of laboratory or other assistance that is available from Canada upon request; no experts or laboratories are currently on the Roster.

174. Initiated a proposal to provide approximately $300,000.00 to the United Nations Secretary-General's investigation mechanism.

H. Article VII

175. Canada has not requested any assistance under Article VII of the BTWC, nor has Canada received any requests for assistance under Article VII of the BTWC.

176. Canada reaffirms its undertaking to provide or support assistance to any State Party which so requests, if that State Party has been exposed to danger as a result of a violation of the Convention, as per the commitment made at the Sixth Review Conference. In addition,

Canada confirms its willingness, where appropriate, to provide or support assistance to any State Party which so requests, when that State Party has been exposed to danger or damage as a result of the use of bacteriological (biological) agents and toxins as weapons.

I. Article VIII

177. Canada supports very strongly the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare and is in full compliance with the Protocol. As reported in 2001, Canada withdrew its last reservation to the Protocol on 19 October, 1999.

J. Article IX

178. As a State Party to the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction (CWC), Canada fully implements the CWC and its obligations. National implementation legislation is in place – The *Chemical Weapons Convention Implementation Act* – and regulations under the Exports and Imports Permit Act were revised to reflect the obligations undertaken upon ratification of the CWC. The National Authority is located in the Department of Foreign Affairs and International Trade.

179. Canada participates actively in the Organisation for the Prohibition of Chemical Weapons (OPCW) and supports the disarmament and non-proliferation objectives of the CWC through a number of activities, including the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction.

K. Article X

180. Canada is a significant contributor to a wide range of peaceful cooperation mechanisms related to the life sciences and public and international health. To illustrate the range of activities undertaken, supported, and facilitated by Canada that are relevant to the objectives of Article X of the BTWC, Canada offers information on the following projects and data.

Project Title	Caribbean Public Health Agency (CARPHA)
Relevance to Theme	Disease detection and diagnosis
Canadian Department/ Agency Responsible	Strategic Policy and International Affairs Directorate of the Public Health Agency of Canada
Other Partners	Pan-American Health Organization (PAHO)
Project Value	$800,000 CAD
Project Duration	2008-2014
Area Affected	Caribbean Community (CARICOM)

181. To ensure the safety and health security of Canadians at home and in the Region, the Public Health Agency of Canada (PHAC) is supporting the Caribbean Community (CARICOM) in the creation of a pan-Caribbean Public Health Agency (CARPHA), which would enhance the overall capacity of Caribbean regional health institutions to improve their governance in addressing public health issues. CARPHA will provide an opportunity to address existing gaps in responding to common public health challenges (e.g. pandemics

such as H1N1) and strengthening public health capacity in its member-states. On July 2. 2011, CARICOM Heads of Government signed the Inter-Governmental Agreement (IGA) amongst CARICOM Member States that formally established CARPHA as a legal entity. On January 1, 2012, the five regional health institutes will merge, and CARPHA will begin it's implementation phase, anticipated to be complete in 2014. The organization will be located in Trinidad and Tobago, save for one regional health institute (Caribbean Drug Testing Laboratory) which will remain in Jamaica.

Project Title	Contract for an OIE Laboratory (or Collaborating Centre) Twinning Project Technical Support to the LNDV for the Diagnosis and Control of Avian Influenza and Newcastle Disease
Relevance to Theme	Disease surveillance, detection, and diagnosis
Canadian Department/ Agency Responsible	Canadian Food Inspection Agency, National Centres for Animal Disease, National Centre for Foreign Animal Disease, Winnipeg
Other Partners	The World Organisation for Animal Health (OIE) Paris, France National Veterinary Diagnostic Laboratory (LNDV-ICA-Colombia)
Project Value	€ 99,092
Project Duration	Ongoing
Area Affected	Colombia

182. The Canadian Food Inspection Agency (CFIA) started this project, aiming to implement laboratory diagnostic methods at the National Veterinary Diagnostic Laboratory of the Colombian Agriculture Institute (ICA) in Bogotá, Colombia for the surveillance, identification and characterization of Avian Influenza and Newcastle Disease viruses. This will be based on the standards of the World Organization for Animal Health (OIE) and will be accomplished with the support of the parent laboratory, the National Centre for Foreign Animal Disease (NCFAD) located in Winnipeg, Canada. The three-year project will involve direct interactions between scientists and technicians of candidate and parent laboratories. Workshops and hands-on training in select diagnostic test methods and test result evaluation, as well as trouble-shooting, quality assurance, inter-laboratory comparison testing through the exchange of proficiency panels, and reagent preparation will form the basis of the twinning project.

Project Title	Improvement of Foot-and-Mouth Disease (FMD) preparedness and response in South America
Relevance to Theme	Disease surveillance, detection, diagnosis, and containment
Canadian Department/ Agency Responsible	Counter-Terrorism Capacity Building Program of Foreign Affairs & International Trade Canada
Other Partners	Canadian Food Inspection Agency
Project Value	$778,000 CAD
Project Duration	2007-2011
Area Affected	Bolivia, Colombia, Ecuador, Venezuela, Peru (principals) + Latin America

183. The CTCBP and the Canadian Food Inspection Agency (CFIA) worked at improving South America's ability to rapidly diagnose Foot-and-Mouth Disease (FMD) and apply control measures to restrict the FMD Virus's spread via computer modelling. Technology and training were given to several South American countries to improve virus detection, isolation, and typing. The model used to plot the spread of animal diseases in North America was adapted to South America and as of 2010 is able to show proper response strategies for both FMD-free and endemic countries.

Project Title	Occupational Health and Infection Prevention in Healthcare Facilities: Preparing for biological and bioterrorism events in Trinidad and Tobago
Relevance to Theme	Disease surveillance, detection, and diagnosis
Canadian Department/ Agency Responsible	Counter-Terrorism Capacity Building Program of Foreign Affairs & International Trade Canada
Other Partners	PAHO (Pan American Health Organization)
Project Value	$499,000 CAD
Project Duration	2008-2010
Area Affected	Trinidad and Tobago (TRT; principal), selected Caribbean Basin states.

184. In light of the threat of highly infectious biological agents to public health, trade, and travel, the CTCBP worked in Trinidad and Tobago to improve their capacity to respond efficiently to biological outbreaks and bioterrorism events. This contributed to an improvement of the overall health and safety of healthcare workers, the community at large, and government officials attending major events in Port-of-Spain, including the 2009 Summit of the Americas, the Commonwealth Heads of Government meeting, and the Caribbean Games.

Project Title	Support to PAHO Health Program
Relevance to Theme	Capacity building
Canadian Department/ Agency Responsible	Canadian International Development Agency (CIDA)
Other Partners	Pan-American Health Organization (PAHO)
Project Value	$3,758,400 CAD (of larger $18,000,000 CAD program)
Project Duration	2006-2011
Area Affected	PAHO member states

185. The Canadian International Development Agency (CIDA) is ensuring that PAHO and its member-states have National Influenza Pandemic Preparedness Plans (NIPPPs). The project also intends to build an Emergency Operations Centre in PAHO's headquarters in Washington, DC and to establish regional multidisciplinary pandemic response teams.

Project Title	Avian Influenza Prevention and Control
Relevance to Theme	Disease surveillance, diagnosis, and containment
Canadian Department/ Agency Responsible	Canadian International Development Agency (CIDA)
Other Partners	United Nations Development Program (UNDP)

Project Value	$2,200,000 CAD
Project Duration	2005-2011
Area Affected	Vietnam

186. A series of projects by CIDA from 2005 to 2011 involves the development of action plans on human and animal outbreaks of avian influenza in Vietnam. With the help of the United Nations Development Program (UNDP), capacity is being enhanced in veterinary laboratories throughout the country and a national reporting system is being put in place to ensure that early warning systems will function. Training programs on safe poultry-rearing and processing were also being developed. Furthermore, the efficacy of new vaccines and the mass vaccination of poultry in Vietnam were being done.

Project Title	Avian Influenza Social Mobilization
Relevance to Theme	Disease surveillance
Canadian Department/ Agency Responsible	Canadian International Development Agency (CIDA)
Other Partners	United Nations Children's Fund (UNICEF); Japanese International Cooperation Agency
Project Value	$7,600,000 CAD
Project Duration	2006-2009
Area Affected	Indonesia

187. In several projects running from 2006 to 2009, CIDA, the United Nations Children's Fund (UNICEF), and the Japanese International Cooperation Agency involve the development of a communication system of Indonesia's National Pandemic Plan and to implement it to hundreds of villages in Sumatra. The project also involves supporting media centres for holding media conferences on avian influenza and other awareness-raising, pandemic preparedness, and risk management activities.

Project Title	Canada-Asia Regional Emerging Infectious Disease (CAREID) project
Relevance to Theme	Disease surveillance, detection, and containment
Canadian Department/ Agency Responsible	Canadian International Development Agency (CIDA) Public Health Agency of Canada (PHAC)
Other Partners	
Project Value	$4.3 million CAD
Project Duration	2004-2012
Area Affected	Vietnam, Philippines, Laos and Cambodia

188. The Canada-Asia Regional Emerging Infectious Disease (CAREID) is led by the Public Health Agency of Canada and funded by CIDA. It focuses on reducing the threat of emerging infectious disease in South East Asia, by capacity building and training in the areas of surveillance, outbreak investigation and response, laboratory systems and risk communications.

Project Title	Rapid Triage Management Workbench (RTMW) for Southeast Asia – Malaysia, Indonesia,

	Philippines & Thailand Deployment
Relevance to Theme	Disease containment
Canadian Department/ Agency Responsible	Counter-Terrorism Capacity Building Program of Foreign Affairs & International Trade Canada
Other Partners	AMITA Corp.
Project Value	$584,000 CAD
Project Duration	2008-2010
Area Affected	Philippines, Malaysia, Thailand and Indonesia.

189. The CTCBP, with the help of the AMITA Corporation, is providing the Philippines, Malaysia, Thailand, and Indonesia with software called Rapid Triage Management Workbench (RTMW) and related training. This software is an information management system for mass casualty treatment, and will enhance triage operations in beneficiary states who suffer from a disease outbreak or a bioterrorist attack.

Project Title	Response Capacity for Avian Influenza
Relevance to Theme	Disease diagnosis and containment
Canadian Department/ Agency Responsible	Canadian International Development Agency (CIDA)
Other Partners	United Nations Development Program (UNDP)
Project Value	$5,000,000 CAD
Project Duration	2005-2007
Area Affected	Indonesia

190. From 2005 to 2007, CIDA and UNDP provided Indonesia's Ministry of Health with assistance in developing training modules, infectious disease control procedures, and helped to develop the country's national pandemic response plan. These agencies also provided medical and diagnostic equipment and reagents to avian influenza referral hospitals throughout Indonesia.

Project Title	Biological Non-proliferation Policy Programming in the Former Soviet Union
Relevance to Theme	Non-proliferation
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$348,000 CAD
Project Duration	2007-2013
Area Affected	Afghanistan, Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyz Republic, Tajikistan, Turkmenistan, Ukraine, Uzbekistan

191. Canada's Global Partnership Program (GPP) is funding various biological non-proliferation activities within the Former Soviet Union (FSU), such as funding certain delegations for the 2008, 2009, and 2010 BTWC intersessional meetings, and funding/preparing workshops on export controls in Bishkek, Kyrgyz Republic (March 2009), BTWC national implementation in Astana, Kazakhstan (September 2009), and

funding representatives from Central Asia (among others) to the BTWC Review Conference workshop in Beijing, China (November 2010).

Project Title	Biosciences Eastern and Central Africa (BECA) in Kenya
Relevance to Theme	Containment laboratory construction and renovations
Canadian Department/ Agency Responsible	Pathogen Regulation Directorate, Emergency Management and Corporate Affairs Branch of the Public Health Agency of Canada (PHAC), Canadian International Development Agency (CIDA) collaboration project
Other Partners	Canadian Food Inspection Agency (CFIA)
Project Value	2009: $10,000,000 (Buildings) / $1,400,000 (Infrastructure) / $3,500,000 (Equipment)
Project Duration	Completed in 2011
Area Affected	Nairobi, Kenya

192. CIDA's Health and Nutrition Directorate is managing a variety of projects to help enhance the health care system in Africa. This directorate has announced that it will be spending $450 million from 2006 to 2016 on the Africa Health Systems Initiative. Many of CIDA's projects in Africa have elements that relate back to this year's BTWC theme. In 2003, Canada announced a multi-million dollar contribution to establish a regional network of bioscience centres of excellence to offer the potential to address some previously intractable problems constraining Africa's development related to health, agriculture and sustainable development. A great portion of this contribution was used to construct and refurbish biocontainment level 3 and level 2 laboratory facilities in Nairobi, Kenya. In order to meet Canadian and international standards where comparable Kenyan standards do not exist, Canadian authorities led by PHAC, will review design plans, inspect microbiological containment laboratories at BECA before and after commissioning. PHAC will also provide further assistance where possible and linkages to laboratory safety tools and resources that have already been developed and applied throughout On June 1, 2009, the Public Health Agency of Canada (PHAC) and the Canadian International Development Agency (CIDA) signed an Administrative Arrangement (AA). PHAC was designated to provide technical expertise to CIDA on biosafety/biocontainment issues for the Biosciences in Eastern and Central Africa (BECA) project in Kenya.

Project Title	Canadian Biosafety Symposium
Relevance to Theme	N/A
Canadian Department/ Agency Responsible	Office of Biohazard Containment & Safety of the Canadian Food Inspection Agency; Pathogen Regulation Directorate and National Microbiology Laboratory of the Public Health Agency of Canada
Other Partners	International Centre for Infectious Diseases (ICID), Canadian Biological Safety Association (CABS),
Project Value	N.A.
Project Duration	Symposium last two days, pre-course last two days, annually.
Area Affected	International event, Winnipeg Canada in 2010 and Toronto, Canada in 2011

193. The CFIA, PHAC, the Canadian Biological Safety Association (CABS), and the International Centre for Infectious Disease (ICID) work together to host the Annual Canadian Biosafety Symposium. The 4th Canadian Biosafety Symposium was held in Winnipeg, Canada, from June 6-9th, 2010. The 5th Canadian Biosafety Symposium was held in Toronto, Canada from June 6-9th, 2011 and included a panel on International Biosafety Initiatives, as well as pre-Symposium courses on high containment laboratory certification and the investigation and analysis of hazardous occurrences. Over the last several years, GPP funded delegates from Russia, Kazakhstan, the Kyrgyz Republic, Ukraine, and Mongolia to attend and learn about Canadian activities in biosafety and biosecurity.

Project Title	Field Epidemiology
Relevance to Theme	Disease surveillance and detection
Canadian Department/ Agency Responsible	Public Health Agency of Canada
Other Partners	N/A
Project Value	N.A.
Project Duration	Ongoing
Area Affected	Member-countries of Training Programs in Epidemiology and Public Health Interventions Network (TEPHINET), the World Health Organization (WHO), and Pan American Health Organization (PAHO).

194. PHAC supports global public health capacity building through the development, delivery, and participation in various field epidemiology initiatives. These include the Canadian Field Epidemiology Program, a two-year program in applied epidemiology, and the Training Programs in Epidemiology and Public Health (TEPHINET) network, a global network of over 40 field epidemiology programs. PHAC further supports field epidemiology initiatives through its support of WHO global initiatives, including delivery and development of training, provision of technical expertise and response to global health events, including international mobilisations. For example, in the period 2009-2011, PHAC mobilised field staff for the WHO/PAHO H1N1 Caribbean response, the Haiti cholera response, the Mexico-Canada-US H1N1 investigation, surveillance activities for the Vancouver Olympics and the WHO-CDC Stop Transmission of Polio missions.

Project Title	PulseNet
Relevance to Theme	Disease surveillance and detection
Canadian Department/ Agency Responsible	Infectious Disease Prevention and Control Branch of the Public Health Agency of Canada
Other Partners	Other countries using PulseNet
Project Value	N.A.
Project Duration	Ongoing
Area Affected	Other countries using PulseNet

195. PulseNet: PHAC operates PulseNet Canada, a network that centralizes the data from diseases surveillance networks throughout the country involving food-borne and waterborne pathogens. This data is then shared with PulseNet USA and other countries that use the PulseNet program for disease surveillance, allowing easy tracking of disease outbreaks caused by food-borne and waterborne agents. Data are also shared across international jurisdictions through the PulseNet International network, which is comprised

of 80 countries spanning Central and South America, Europe, the Middle East, Sub-Saharan Africa, and the Asia-Pacific region; this facilitates the identification of emerging regional and global trends. The communication platform for all PulseNet International participants is also housed on CNPHI. Additionally, Canada and the United States participate in a bilateral Memorandum of Understanding that enables real-time sharing and direct access to national-level food-borne disease data, ensuring that outbreaks and emergencies that span (or potentially span) both sides of the border can be identified and investigated without delay. This MOU was initially signed in 2005 and was renewed in 2010.

IV. Administration and Enforcement of Primary Legislation

A. Department of Foreign Affairs and International Trade (DFAIT) - Trade Controls and Technical Barriers Bureau

1. Legislative Authority

196. Export and import permits are issued under the authority of the Export and Import Permits Act. The Act authorizes the government to control the import and export of certain goods as defined in various intergovernmental arrangements, as well as the export of natural resources and other goods for the purpose of ensuring both adequate supply and for the security of Canada.

2. Relevant Articles of the BTWC

197. Article III - Not to transfer, or in any way assist, encourage or induce anyone else to acquire or retain biological weapons.

3. Overview of the Program

198. An export permit is required before an item included in the Export Control List (ECL) may be exported from Canada to any destination, with the exception (in most cases) of the United States. Nuclear material and equipment, automatic firearms, logs, softwood lumber, pulpwood, roe herring and red cedar bolts and blocks are among the items requiring permits for export to the United States. This requirement enables Canada to meet international commitments, such as preventing the proliferation of missile technology and biological, chemical and nuclear weapons. Permits are also required to export any items to countries on the Area Control List (ACL). At present only Belarus and Burma (Myanmar), and North Korea are on the ACL.

199. Responsibility for the issuance or denial of export permits for most of the items on the ECL lies with Export Controls Division of the Trade Controls and Technical Affairs Bureau (TCTBB). Group 7 of the ECL provides a Chemical and Biological Weapons Non-Proliferation List which outlines goods whose export is controlled in accordance with the BTWC. This list is identical to the Australia Group Common Control List.

4. Program Compliance Monitoring and Enforcement Metrics

200. Canada has issued a total of 220 export permit of Australia Group-controlled goods since January 1st, 2007.

Year	*Number of Export Permits for AG-controlled goods*	*Number of Export Permits for Biological Agents*	*Number of Permits currently active (Nov. 3, 2011)*
2007	48	2	0
2008	37	5	0
2009	40	2	10
2010	57	4	42
2011	38	0	37

B. Canadian Food Inspection Agency

1. Office of Biohazard Containment and Safety (OBCS) - CFIA

Legislative Authority and Mandate

201. The Canadian Food Inspection Agency (CFIA) has a broad mandate to protect the health of Canada's animal population. The Office of Biohazard Containment and Safety (OBCS) is committed to enhancing the security of animal pathogen biocontainment facilities in Canada and ensuring that safe work practices are used in those facilities through the provision of standards, advice, and training. The Health of Animals Act, 1990 and its Regulations give the CFIA the legislative authority to control the use of imported animal pathogens and pathogens associated with reportable animal diseases.

202. As part of its mandate, OBCS ensures that facilities wishing to import animal pathogens meet the necessary containment requirement(s) to work safely with the pathogen(s) requested. To assist with compliance OBCS publishes the following standards outlining necessary and voluntary biosafety and biocontainment requirements:

(a) Containment Standards for Veterinary Facilities, 1996

(b) Containment Standards for Facilities Handling Prion Disease Agents, 2005

(c) Containment Standards for Facilities Handling Plant Pests, 2007

(d) Containment Standards for Facilities Handling Aquatic Animal Pathogens, 2010.

Relevant Articles of the BTWC

203. Articles III & IV

Overview of the Program(s)

204. The CFIA OBCS and the Public Health Agency of Canada (PHAC) Pathogen Regulation Directorate (PRD) collaborate extensively for zoonotic pathogens which are regulated by each Agency respectively. Processes for import as well as inspection and high biocontainment certification are aligned to the extent reasonably possible and in an effort to reduce burden on stakeholders. To this end, some of the procedures outlined below will apply to those for PHAC and this will be noted in section 4.3.

Importation of Animal Pathogens

205. Animal pathogens fall into four risk groups, of ascending level of risk. Risk groups 2 through 4 are covered under the Health of Animals Act and Regulations. Although exceptions exist, risk group 2 is generally permitted to be used in a containment level (CL) 2 laboratory, risk group 3 in a containment level 3 and so on.

206. Activities undertaken to administer and enforce the Health of Animals Act and Regulations include permit issuance, inspections, the performance of risk assessments to ascertain risk group of animal and zoonotic pathogens and the maintenance of databases of relevant administrative information.

207. The Animal Pathogen Import Program (APIP) within OBSC is responsible for assessing compliance of, and inspecting, containment level 2 (CL2) zones (i.e. laboratories, small animal, large animal, etc).

208. For the most part, Containment Level 2[16] compliance is assessed by APIP using a self-certification inspection checklist which is completed by a laboratory representative (e.g. director, manager, supervisor) and the institutional biological safety officer (BSO). The inspection checklist used is adapted from the Containment Standards for Veterinary Facilities and evaluates the facility's compliance with the physical and operational requirements for Containment Level 2 zones.

209. It is the intent of the APIP to conduct on-site inspections of 2 - 3 institutions each month to confirm compliance which was already evaluated through the self-assessment process (i.e. inspection checklist). All inspections are announced.

Biocontainment and Certification Program

210. OBCS also certifies and performs inspections of high containment terrestrial animal pathogen facilities (CL3, CL4 and TSE), aquatic animal pathogen facilities (AQC2 and AQC3) and plant pest facilities (PPC2 and PPC3). Continuity is enhanced by the performance of annual re-certification for CL3, CL4, AQC2, AQC3 and PPC3 facilities and re-certification every 2 years for TSE, and PPC2 facilities. These biocontainment experts also advise containment facilities on the appropriate handling and containment of terrestrial animal pathogens, aquatic animal pathogens and plant pests as well as on the planning, development, operation and certification of containment facilities.

211. For the initial certification process, OBCS determines the applicable Standard based on the program intent and pathogen list provided by the Facility. Compliance to the Standard is assessed via review of the following documentation:

(a) Construction drawings of all architectural, mechanical, electrical and plumbing specifications.

(b) Complete Biosafety Manual compiling all standard operating procedures for the facility

(c) Performance and Verification Test Reports for all critical containment components:

(i) Room Integrity

(ii) Communication Devices

[16] Containment level 3 and 4 laboratories, as well as those for aquatic and plant pest facilities will be addressed in section 4.2.1.3.2.

(iii) Door Interlocks

(iv) Access Control and Security Devices

(v) Inward Directional Airflow

(vi) Autoclaves and Disinfection Systems

(vii) Backflow preventers

(viii) Emergency Generator

(ix) Effluent Treatment Systems

(x) Biological Safety Cabinets

(xi) HEPA Filters

(xii) HEPA Filter Housings

(xiii) Supply and Exhaust Ductwork

(xiv) Control Systems/ Fail Safe Operations

212. Once the documentation review component is complete and satisfactory, an on-site inspection is performed. A typical inspection is as follows:

(a) Introductions and discussion of applicable Act and Regulations

(b) Review of Entry and Exit SOPs

(c) Visual inspection of the facility

(i) Verify room integrity, sealed surfaces, cabinetry, etc

(ii) Verify door interlocks

(iii) Verify communication systems

(iv) Verify inward directional airflow

(v) Verify certification of biosafety cabinets

(vi) Verify autoclave and disinfection systems complete with bioseal

(vii) Verify effluent treatment system, if applicable[17]

(viii) Other verifications specific to the facility

(d) Failure Scenario Verifications

(i) Verification of the HVAC system's response to various fan failures

(ii) Ensure inward directional airflow is maintained during failure

(e) Discussion of findings

(i) Major vs minor deficiencies

213. A formal report is generated and the facility must respond to the deficiencies and any other outstanding requests within a designated timeframe. Once all requirements are satisfied the facility achieves certification, which is valid for one year.

[17] This is not a PHAC requirement for CL3.

214. Compliance thereafter is assessed annually via a paperwork approval process. The facility must submit all required test reports and any and all updates/ modifications to the Biosafety Manual or SOPs. The following is reviewed:

(a) Changes or updates made to the Biosafety Manual or standard operating procedures for the facility

(b) Performance and Verification Test Reports for all critical containment components:

(i) Room Integrity

(ii) Communication Devices

(iii) Door Interlocks

(iv) Access Control and Security Devices

(v) Inward Directional Airflow

(vi) Autoclaves and Disinfection Systems

(vii) Backflow preventers

(viii) Emergency Generator

(ix) Effluent Treatment Systems[18]

(x) Biological Safety Cabinets

(xi) HEPA Filters

(c) Note that the following are not required to be verified annually unless modifications were made:

(i) HEPA Filter Housings

(ii) Supply and Exhaust Ductwork

(iii) Control Systems/ Fail Safe Operations

Compliance and Enforcement

215. The tool used to enforce compliance varies depending on the gravity, severity, the intent and repeatability of the infraction. CFIA has a Compliance and Enforcement (E&C) Operational Policy and APIP has the following possible tools available to them:

(a) Warning Letter

(b) Seize / Detain

(c) Withhold / Cancel Import Permit

(d) Deny importation

(e) Disposal

(f) Notice of Violation with warning letter*

(g) Notice of Violation with monetary penalties, etc.[19]

[18] This is not a PHAC requirement for CL3.

[19] For Options F and G: the activity will be handled by CFIA's Regional Enforcement and Compliance

Program Compliance Monitoring and Enforcement Metrics

Summary of Import and Certification Activity between January 1 - July 28, 2011	
Permits and letters	
424	Permits issued (0 for risk group 4)
15	Transfer requests granted (1 for risk group 4)
39	"Non-pathogenic" courtesy letters issued for risk group 1
0	Refusal / denial letters
Laboratory Compliance (CL2)	
416	Areas deemed Compliant through self-certification (completion of an inspection checklist)
3	Areas deemed Non-compliant through the self-certification process
6*	CL2 On-site Inspections (*11 areas within 6 institutions between January - February)
Laboratory Compliance (CL3 and Prion; CL4; AQC2; AQC3; PPC2A; PPC3)	
30	High containment on site inspections
150	Remote verifications
Other	
0	Enforcement activities for e.g. importation without valid permit, transferring imported material without approval, etc.
N/A	Accidents and incidents (APIP does not require that Regulated Parties report incidents and accidents which may occur within their facility.)

2. Plant Health and Biosecurity Directorate - Import Control and Export Market Information

Legislative Authority

216. As Canada's national plant protection organization, the CFIA has the mandate to protect plant life and the agricultural and forestry sectors of the Canadian economy by preventing the importation, exportation and spread of plant pests (e.g. insects, weeds, nematodes, pathogens, etc.) and by controlling or eradicating plant pests in Canada. The CFIA derives its legal authority to carry out this mandate under the Plant Protection Act, the Seeds Act, and their respective regulations.

Relevant Articles of the BTWC

Articles III & IV

Overview of the Plant Protection Import Control Program

217. As Canada's national plant protection organization (NPPO), the CFIA prevents the introduction and spread of harmful plant pests in Canada by developing and enforcing a plant protection import control program for articles, which could either act as:

(a) A plant pest themselves

(b) As a biological obstacle to the control of a plant pest in Canada

(c) As a pathway for the entry of a harmful plant pest in Canada

Intentional importation of prohibited articles

218. The importation of some articles is prohibited as they carry an unacceptable and unmanageable phytosanitary risk to Canada plant resources. However, there is a provision under Section 43 of the Plant Protection Regulations which allows the importation of prohibited articles, such as harmful plant pests, for special purposes – more specifically, for the purpose of scientific research, education, exhibition and/or industrial processing.

219. Importers wishing to import a prohibited article are required to apply to the CFIA for a special plant protection import permit. The CFIA will only issue such a permit once it has confirmed the importer's ability to comply with the containment requirement(s) and any other conditions established by the CFIA for these high risk importations.

Intentional importation of harmful plant pests

220. The intentional importation of plant pests deemed harmful to Canada is prohibited, and consequently, any facility wanting to import such a plant pest requires a special plant protection import permit and may only import them for a permitted special purpose (i.e., research, exhibition, education, and/or industrial processing).

221. A condition for the importing facility is to be certified under the Containment Standards for Facilities Handling Plant Pests. The required containment level under these standards is dependent on the pest itself and the risk it represents to Canada. Furthermore, the plant pests may not be used for any other end use than what is indicated on the permit and the facility may not sell or otherwise further distribute the plant pests without prior written authorization from the CFIA.

Compliance Verification and Enforcement

222. As mentioned in Section 4.2.2.3.2, a facility's ability to comply with the containment conditions as well as any other import condition required for the safe importation of a harmful plant pest is assessed prior to CFIA issuing the facility a special plant protection import permit.

223. In addition, importing facilities may be subject to ad hoc CFIA inspections to verify that the facility continues to comply with the import conditions listed on their special mport permit and a certain percentage of special permits are also audited in any given year.

224. Where a non-compliance occurs, there may be a number of enforcement or regulatory actions that may be taken by the CFIA. Regulatory actions taken are dependent on the severity of the non-compliance and include, but are not limited to:

(a) A letter informing the facility of the non-compliance and the remedial actions which must be taken to bring the facility back into compliance

(b) Higher frequency of ad hoc facility inspections

(c) Revoking facility certification

(d) Destruction of imported plant pests

(e) Denying future requests from facility for special permits

C. Public Health Agency of Canada (PHAC) – Pathogen Regulation Directorate

1. Legislative Authority and Mandate

225. The Human Pathogens Importation Regulations (HPIR) provides PHAC with the authority to regulate the import of risk group 2, 3 and 4 human pathogens and toxins of infectious substances. Upon Royal Assent (June 23, 2009), the Human Pathogens and Toxins Act (HPTA) came partially into force to provide PHAC with the authority to regulate the possession and use of human pathogens and scheduled toxins, in Canada. The regulatory framework for HPTA is being developed and full publication of the regulations is expected by 2015. The intention is that the HPIR would then be repealed. This will authorize the regulation of controlled activities with human pathogens and scheduled toxins including: possessing, handling or using, producing, storing, permitting any person access to, transferring, importing or exporting, releasing or otherwise abandoning, and, disposing. Until that time a dual system comprised of HPTA and the HPIR (1994) regulations remain in place.

226. The Mission of the Public Health Agency of Canada is to promote and protect the health of Canadians through leadership, partnership, innovation and action in public health. The Pathogen Regulation Directorate supports this ultimate goal with a Mission to establish and maintain a strong and comprehensive safety and security regime to mitigate the risks posed by the unsafe use of human pathogens and toxins.

2. Relevant Articles of the BTWC

Article III, Article IV, Article VII

Overview of the Program

227. The Pathogen Regulation Directorate within PHAC administers and enforces the HPTA and the HPIR, and provides training and tools to promote safer biosafety practices and more secure laboratory environments. PRD consists of five (5) main offices, supported by a Business Integration and Planning Office and the Director General's Office. As noted above in section 4.2.1.3, the CFIA OBCS and PHAC PRD collaborate extensively in an effort to reduce regulatory burden for regulated parties, as well as increase efficiencies in government oversight of pathogen usage in Canada. For this reason, there is some reference to the procedures outlined above in Section 4.2.1.

The Office of Regulatory Policy and Affairs (ORPA)

228. ORPA is responsible for development of regulations under the HPTA to promote biosafety and biosecurity; other regulatory policy as well as the implementation and maintenance of the Cabinet Directive on Streamlining Regulation within PRD.

The Office of Outreach and Stakeholder Engagement (OOSE)

229. OOSE is responsible for the management of cross-Canada consultations to inform the Human Pathogens and Toxins Act program and regulatory framework; the development of strong and sustainable relationships with stakeholders to promote shared knowledge of best practices and the management of a WHO collaborating centre.

The Office of Biosafety and Biocontainment Operations (OBBO)

230. OBBO is responsible for the day to day administration and enforcement of the Human Pathogens and Toxins Act and Human Pathogens Importation Regulations

including the issuance of import permits, high containment laboratory commissioning and certification, compliance monitoring (laboratory inspection and liaison with CBSA regarding imports), and regulatory enforcement.

231. The OBBO regulated parties include 2 CL4 laboratories, 129 other higher containment laboratories (CL3, prion and CL2 with CL3 operational procedures) and approximately 1000 entities[20] with laboratories at CL2.

232. The Laboratory Biosafety Guidelines (LBGs) provide technical information, recommendations and guidance to those who design, construct or use laboratories where human pathogens and toxins are manipulated for purposes such as diagnostics, research or development. The LBGs outline the physical and operational requirements for laboratories in order to mitigate the inherent risks posed by human pathogens and toxins. They have been through a number of editions since their inception in 1990, and institutions have been incorporating these requirements into training, education and practice for many years. The Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) are developing joint Canadian Biosafety Standards and Guidelines (CBSG) pertaining to human and terrestrial animal pathogens. These standards and guidelines are used by laboratory researchers and workers in facilities possessing, handling, storing or using such pathogens. The development of the CBSG has been initiated to help streamline various biosafety practices into a single set of standards and guidelines for stakeholders regulated by both PHAC and the CFIA. The CBSG will combine and update the following documents:

(a) Laboratory Biosafety Guidelines 3rd Edition, 2004 (PHAC)

(b) Containment Standards for Veterinary Facilities 1st Edition, 1996 (CFIA)

(c) Containment Standards for Laboratories, Animal Facilities and Post Mortem Rooms Handling Prion Disease Agents, 2005 (CFIA)

HPIR Import Permit Issuance and Registration under the HPTA

233. As per the HPIR, an import permit is required to import a human pathogen that belongs to risk group 2, 3 or 4, and this includes the toxins of an infectious substance. Importation of risk group 1 organisms or material that is reasonably believed by its importer not to contain infectious organisms does not require an import permit (e.g., blood or tissue samples from healthy donors; purified DNA, cytological slides for microscopy). "Notices" may be issued in these circumstances for non-pathogenic material, to assist with customs clearance.

234. The issuance of an import permit begins with the submission of an application[21] detailing information in regards to the applicant, supplier, material to be imported, intended use of the material and facility in which the material will be used. For risk group 2 human pathogens, this application must be supported by a self-audit assessing compliance of the applicant's facility with requirements of the Laboratory Biosafety Guidelines which will be reviewed by the permit regulatory technologist. For risk group 3 and 4 imports, a certification is required, as described in Section 4.3.2.1.3.2 directly below. For zoonotic agents a cross-check is done with OBCS, CFIA and the permit always references a CFIA requirement if applicable. For toxin imports, the quantity requested is always verified as

[20] Entities refer to the consolidation of laboratories within an institution, i.e., the consolidation of an academic institution's laboratories captured by the HPTA and/or HPIR, which may be numerous. These are captured by one "entity".

[21] The application to import human pathogens can be found at: http://www.phac-aspc.gc.ca/lab-bio/permits/imp-permit/index-eng.php

necessary against the protocol submitted by the applicant. If a risk assessment is required, OBBO will request a formal risk assessment from the Office of Biosafety Programs and Planning (OBBO). Once all information is deemed acceptable, an import permit is issued. The permit is valid for multiple entries over one year for risk group 2 human pathogens and for one entry within a three month period for risk group 3 and 4 human pathogens.

235. When the HPTA received Royal Assent on June 23, 2009, Sections 70 and 71, along with a number of other sections, came into force. Section 70 requires that anyone responsible for activities involving human pathogens in Risk Group 2, 3 or 4, or toxins on Schedule 1 of the Act to "Register" by providing the following information:

(a) A confirmation that they are responsible for human pathogens or toxins;

(b) The risk groups to which the human pathogens belong;

(c) The location where activities involving human pathogens or toxins are conducted;

(d) The name of a contact person with appropriate safety training or relevant work experience relating to human pathogens and toxins.

236. Registrants are issued an HPTA registration number and letter, and receive information about the HPIR and the HPTA upon registration, as part of compliance promotion efforts. Registration will remain in effect until the licensing regime is operational under the HPTA. To date, just over 1000 entities or individuals have registered under the HPTA. An entity or an individual may be responsible for multiple laboratories.

Inspections under the HPIR and HPTA

237. Containment Level 2 laboratory inspections are an extension of the self-audit which laboratories can perform[22] whereby inspectors assess compliance with the Laboratory Biosafety Guidelines and other aspects of the HPIR and HPTA. These self-audits are submitted to OBBO and if all information is found acceptable a "Compliance Letter" valid for two years will be issued. A Compliance Letter supports the application to import human pathogens.

238. Preparation for CL2 inspection is minimal and includes review of documentation (self attestations, previous permit requests, and permits and correspondence). When on-site, inspectors focus on compliance promotion and verify documentation provided via the self-audit. Major non-compliance posing a serious and imminent danger to public health and safety is addressed immediately and minor non-compliance is noted in the inspection report with direction on when compliance is expected. Verification is done remotely via a paper process unless a second inspection is necessary.

239. High Biocontainment (CL3, CL4, Prion, Large Scale CL2 and CL2 with CL3 operational) inspection processes occur prior to import permit issuance for pathogens that require this type of containment, therefore, successful completion of this process is required prior to permit issuance.

240. Specific compliance to requirements (Laboratory Biosafety Guidelines) is assessed by the process outlined in 4.2.1.3.2. The general preparation and execution process for these inspections is as follows, and a visual depiction is found below:

[22] The "CL2 Checklist" which laboratories can use to audit themselves against the requirements in the Laboratory Biosafety Guidelines can be found at: http://www.phac-aspc.gc.ca/lab-bio/permits/imp-permit/index-eng.php

(a) Engineering and Biocontainment group review drawings, SOPs, specifications, and performance verification test reports (PVTR)

(b) Responsible group (OBBO or ESS) issue reports to regulated party identifying any deficiencies or missing information

(c) Inspection scheduled once all information has been provided and deficiencies repaired

(d) HBI and ESS meet to develop agenda and inspection checklist

(i) Engineering focus on failure testing

(ii) Biocontainment focus on SOP review

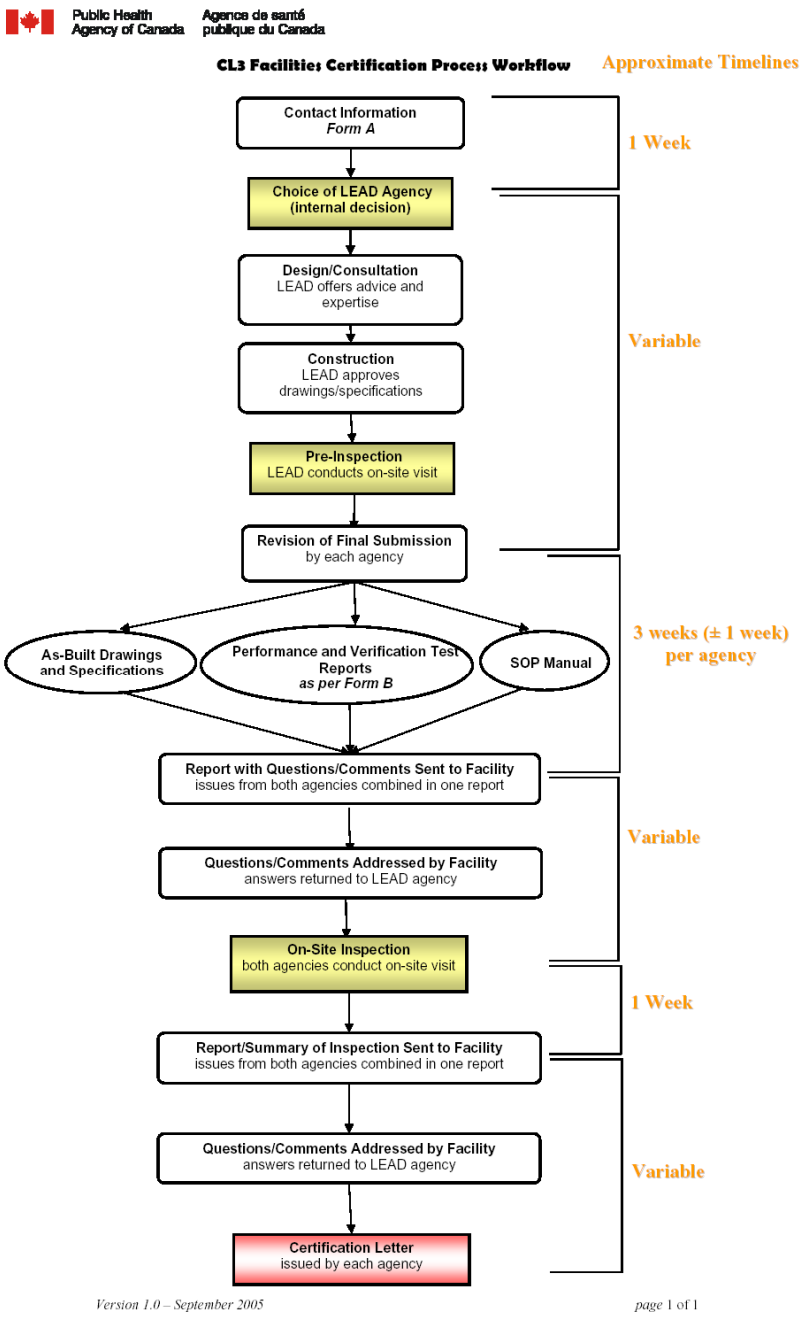
(e) Inspection performed and any additional major and minor deficiencies are reported to the regulated party (inspection report)

(i) Laboratories will not receive certification until major deficiencies are repaired and retested

(ii) Minor deficiencies will not delay certification, however information shall be required to be submitted within a specific timeframe as requested in the inspection report

241. Approximately 60% of these laboratories are completely compliant upon inspection. When there is non-compliance PRD generally works with the regulated party, to the extent reasonably possible, to achieve compliance.

PHAC high containment facilities certification process workflow[23]



[23] Reference to "each agency" or "LEAD agency" reflects the collaborative approach taken by PHAC and CFIA for regulated parties falling under both regimes.

The Office of Engineering and Science Support (ESS)

242. ESS assists OBBO in the provision of expert biocontainment engineering assistance, as well as fostering evidence based decision making with regards to biosafety standard and guideline development, in the identification and resolution of science gaps. ESS also provides expert biocontainment engineering advice to international partners and as in kind contribution.

The Office of Biosafety Programs and Planning (OBPP)

243. OBPP provides technical assistance and training to domestic and international stakeholders to promote safe biosafety practices; provides Pathogen Safety Data Sheets (formerly Material Safety Data Sheets) in both English and French; promotes the use of the Laboratory Biosafety Guidelines and the future Canadian Biosafety Standards and Guidelines; provides biosafety advisories and notifications and develops policies to support compliance and enforcement under the HPTA and HPIR and the penal enforcement (investigation/prosecution) aspects of enforcement.

Compliance and Enforcement

244. From a compliance and enforcement standpoint, PRD starts from the premise that the majority of the regulated community will comply with legislative and regulatory requirements if they understand the requirements and have the proper tools to comply with them. In keeping with this premise, PRD actively works with its regulated parties to encourage, promote, monitor and verify compliance.

245. Compliance is normally achieved through a co-operative approach between the regulated party and PRD. Correcting non-conformities can often be achieved through the development of appropriate corrective measures or other methods. However, when this co-operative approach does not lead to compliance, or when the regulated party is incapable of correcting non-compliance, enforcement actions may be used. In some cases, enforcement actions may be the appropriate initial tool to correct or prevent non-compliance.

246. The range of compliance and enforcement activities undertaken and tools available to PRD are outlined below.

PRD **compliance activities and enforcement**

Program Compliance Monitoring and Enforcement Metrics

Summary of Import and Certification Activity – Average Annual Numbers [24]	
Permits and letters	
1220	Permits issued (0 for risk group 4)
44	Transfer requests granted (1 for risk group 4)
236	"Non-pathogenic" courtesy letters issued for risk group 1
0	Refusal / denial letters
Laboratory Compliance (CL2)	
912	Areas deem Compliant through self-certification (completion of an inspection checklist)
0	Areas deemed Non-compliant through the self-certification process (work with regulated party to achieve compliance has always been successful)
3	CL2 On-site Inspections (will increase substantially beginning 2012)
Laboratory Compliance (CL4, CL3, Prion, large scale and CL2 with CL3 operational procedures)	
12	High containment on site inspections
80	Remote verifications (re-certification of CL3 laboratories)
80	Pre-certification clients (review of architectural drawings, performance and verification testing reports and standard operating procedures)
Other	
3	Enforcement activities for e.g. importation without valid permit, transferring imported material without approval, etc. (For fiscal year 2010-2011)
225	Accidents and incidents reported (Not yet a requirement under the HPTA)

V. International Efforts related to BTWC Compliance

247. The Government of Canada funds and provides technical assistance to several international assistance projects related to capacity building in disease surveillance, detection, diagnosis, and containment. The Non-Proliferation and Disarmament Division of Foreign Affairs and International Trade Canada has compiled a list of related ongoing and recent international activities performed by other divisions within Foreign Affairs and International Trade Canada (Global Partnership Program and Counter-Terrorism Capacity Building Program), Public Health Agency of Canada, Canadian Food Inspection Agency, Canadian International Development Agency, and Royal Canadian Mounted Police.

[24] Unless otherwise noted.
[25] Potential laboratory acquired infections with Salmonella.

A. International Conferences, symposia, and seminars

Project Title	Counter Terrorism Simulation Exercise: Response to a bioterrorist attack
Relevance to Theme	Disease detection and containment
Canadian Department/ Agency Responsible	Counter-Terrorism Capacity Building Program of Foreign Affairs & International Trade Canada
Other Partners	Secretariat of the Inter-American Committee against Terrorism (CICTE) of the Organization of American States (OAS)
Project Value	$475,000 CAD
Project Duration	2008-2010
Area Affected	Phase I : Mexico (host country), Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, and Panama; Phase II: Barbados (host country), Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Guyana, Jamaica, Haiti, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, Trinidad and Tobago

248. The Counter-Terrorism Capacity Building Program (CTCBP) of Foreign Affairs and International Trade Canada is performing table-top training exercises with the members of the Organization of American States on the response to a theoretical bioterrorist attack. The exercises will have two phases; the first exercise will involve an attack on a Mexican international airport, and the second will involve an attack on a Caribbean international airport. The goal is to help prepare and/or improve anti-terrorist contingency plans and interagency cooperation (including with disease surveillance/detection agencies).

Project Title	INTERPOL Train the Trainer course
Relevance to Theme	CBRNE training
Canadian Department/ Agency Responsible	Royal Canadian Mounted Police
Other Partners	INTERPOL
Project Value	N.A.
Project Duration	2008
Area Affected	International course, held in Lima, Peru
Project Description	The RCMP attended as a facilitator to the INTERPOL Train the Trainer course that was delivered in Lima, Peru during April 2008.

249. In 2008, the Royal Canadian Mounted Police (RCMP) helped the International Criminal Police Organization (INTERPOL) host a CBRNE training course in Lima, Peru. Parts of this course included disease surveillance and containment, in light of a biological attack.

Project Title	Tabletop Simulation Exercise: Response to a bio-terrorist attack (Agricultural Sector)
Relevance to Theme	Disease detection and containment
Canadian Department/ Agency Responsible	Counter-Terrorism Capacity Building Program of Foreign Affairs & International Trade Canada
Other Partners	Secretariat of the Inter-American Committee against Terrorism

	(CICTE) of the Organization of American States (OAS)
Project Value	$271,000 CAD
Project Duration	2007-2008
Area Affected	Scenario A: Fruit/Vegetable producing countries: Bolivia, Chile, Colombia, Ecuador, Guyana, Paraguay, Peru, Suriname, and Venezuela; Scenario B: Beef producing countries: Argentina, Brazil, and Uruguay

250. The CTCBP, with help from the Organization of American States, organized in 2007-2008 table-top simulations on agro-terrorism issues for countries with large produce and beef industries and with endemic plant and animal diseases. Government officials could identify vulnerabilities in their systems and improve interdepartmental operations. One of the items addressed was the ability for a country's international trade to recover after its major export was contaminated with a bio-terrorist agent.

Project Title	Operational deployment of biodetection capability in support of the CBRN IFRTP (International First Responder Training Program) in SEA: Delivery of intermediate training and detector test, evaluation, and feasibility study.
Relevance to Theme	Disease surveillance and detection
Canadian Department/ Agency Responsible	Counter-Terrorism Capacity Building Program of Foreign Affairs & International Trade Canada
Other Partners	Counter-Terrorism Technology Centre of Defence Research & Development Canada (DRDC)
Project Value	$33,000 CAD
Project Duration	2008-2009
Area Affected	Philippines, Malaysia, Thailand and Indonesia

251. The CTCBP and DRDC are assessing the feasibility of deploying biological detection technology in South-East Asia from 2008 to 2009. The project will result in improved risk and threat assessment, emergency planning, and information management capacity in the Philippines, Malaysia, Thailand, and Indonesia. The project will also evaluate the effectiveness of biodetection options in these beneficiary states.

Project Title	Workshop on the Prevention of BioTerrorism
Relevance to Theme	CBRNE training
Canadian Department/ Agency Responsible	CBRNE Response of Royal Canadian Mounted Police
Other Partners	INTERPOL
Project Value	N.A.
Project Duration	2006
Area Affected	International event, took place in Kiev, Ukraine
Project description	The RCMP's National CBRNE Response participated in the INTERPOL Eastern Europe Workshop on the Prevention of BioTerrorism held in Kiev in November 2006.

252. The RCMP participated in the INTERPOL Eastern Europe Workshop on the Prevention of Bioterrorism in November, 2006. It was held in Kiev, Ukraine.

Project Title	Train the Trainer program for the Prevention of BioTerrorism
Relevance to Theme	CBRNE training
Canadian Department/ Agency Responsible	Royal Canadian Mounted Police
Other Partners	INTERPOL
Project Value	N.A.
Project Duration	2007
Area Affected	International event, took place in Lyon, France
Project Description	The RCMP attended an INTERPOL planning meeting held in Lyon in February 2007 as part of a development team to design a Train the Trainer program for the Prevention of BioTerrorism. This led to five one-week sessions to be delivered internationally through INTEPOL.

253. In February, 2007, INTERPOL held a planning meeting which would develop a Train the Trainer program on the subject of the prevention of bioterrorism. The RCMP attended this planning meeting in Lyon, France. This meeting led to the creating of five one-week training courses, to be delivered internationally by INTERPOL.

Project Title	Global Human Pathogens Biosafety and Biosecurity Group (GHPBBG)
Relevance to Theme	Capacity Building
Canadian Department/ Agency Responsible	Pathogen Regulation Directorate – Emergency Management and Corporate Affairs Branch of the Public Health Agency of Canada
Other Partners	International partners
Project Value	N/A
Project Duration	Ongoing
Area Affected	Global

254. The third biennial meeting of this group took place in Singapore in February of 2011 with 20 participants from 12 Countries, including Canada, and the World Health Organization and saw the participation of 7 new countries. Meeting participants are mainly regulatory personnel representing competent authorities, as well as personnel involved in promoting biosafety and biosecurity standards and culture in their country. The meetings provide an opportunity for United Nations members to network, cooperate, and develop expertise to promote a more global or mutual response to emerging biosafety and biosecurity issues and threats.

Project Title	Procinorte – Animal Health Task Force
Relevance to Theme	Disease surveillance, diagnosis, risk assessment, preparedness
Canadian Department/ Agency Responsible	Canadian Food Inspection Agency
Other Partners	USDA's Agricultural Research Service & Mexico's INIFAP and SENASICA
Project Value	N.A.
Project Duration	Ongoing
Area Affected	Mexico -Canada -US

255. Procinorte is a mechanism to promote the cooperation in research and technology transfer between Canada, the United States, and Mexico for competitive and sustainable agricultural development. The objectives of Procinorte are the promotion of dialogue to identify priority research issues common to the three countries and to influence the regional, hemispheric and global agendas, the facilitation of the exchange of experiences, information and training through building linkages among public and private country institutions of the Northern Region and with the major research and technology transfer actors in the region, the hemisphere and the world, and the facilitation of collaboration among the countries to solve problems of mutual interest. Procinorte task forces include: Animal Health, Agricultural Libraries and Information Services, Genetic Resources, Tropical and Subtropical Fruits, Plant Health. Current activities of the Animal Health Task Force are focussed on animal influenzas, with a wet workshop being planned for November 2011 to be held at the NCFAD in Winnipeg. A web-based share point serves as a central communication tool for the task force members.

Project Title	CAPEX
Relevance to Theme	CBRNE training and capability exercise
Canadian Department/ Agency Responsible	Royal Canadian Mounted Police
Other Partners	Canada: Public Safety Canada, Royal Canadian Mounted Police – National CBRNE Response Team (ED&TS and NFISS CBRNE) Canadian Forces – Canadian Joint Incident Response Unit (CJIRU), Public Health Agency of Canada (PHAC - NML / MERT), Chemical Support - (DRDC Suffield and Environment Canada), Radiological Support - Federal Radiological Response Team (FRAT), Defence Research & Development Canada-Ottawa, Health Canada, Natural Resources Canada United States: US Department of State, US Department of Defence (20th Support Command CBRN) Technical Support Working Group (TSWG), US Department of Justice (FBI HazMat Operations Unit, Hazardous Materials Response Team Unit, Hazardous Materials Science Response Unit and Chemical Radiological Nuclear Sciences Unit) United Kingdom: Home Office (Met Police) Defence Science and Technology Laboratory (dstl), National Police Improvement Agency (NPIA) Australia: Australian Federal Police (AFP), Defence Science and Technology Organization (DSTO)
Project Value	N.A.
Project Duration	2011 and 2013
Area Affected	International event which in 2011 took place in the UK and in 2013 is planned for the US

256. In 2011, the RCMP, along with partners in Canada, the United States, the United Kingdom, and Australia, participated in CAPEX, a demonstration of the capabilities of the National CBRNE response teams. Various scenarios representing chemical, biological, radiological, nuclear, and explosive threats were studied, centring on threat identification and mitigation, as well as intelligence and fast forensics. The CAPEX event took place in the United Kingdom in 2011, and the next one is planned for 2013 in the United States.

Project Title	Operation Maple Leaf - Advanced Technical CBRNE Training Program
Relevance to Theme	CBRNE training
Canadian Department/ Agency Responsible	RCMP Explosives Disposal and Technology Section
Other Partners	Canadian Police College, Defence Research & Development Canada (DRDC)-Suffield, Counter Terrorism Technology Centre, Department of National Defence, Ottawa Police Service, Niagara Regional Police Service, Allen-Vanguard Corporation as well as representatives from Belgium, Denmark, South Africa, Sweden, USA and Israel
Project Value	N.A.
Project Duration	2008 and 2009
Area Affected	International event that took place in Ottawa, Canada and an advanced course at DRDC Suffield Alberta in the fall 2008.

257. The RCMP's Explosive s Disposal and Technology Section, with support from other domestic and international police forces, hosted Operation Maple Leaf, a CBRNE training program which ensures that first responders have the capability to effectively counter CBRNE threats. The Operation Maple Leaf courses were held in Canada in 2008 and 2009 and included a variety of international partners.

Project Title	INTERPOL Prevention of Bioterrorism Curriculum Workshop
Relevance to Theme	CBRNE training
Canadian Department/ Agency Responsible	Royal Canadian Mounted Police
Other Partners	INTERPOL, EUROPOL
Project Value	N.A.
Project Duration	2010
Area Affected	International event that took place in Lyon, France

258. The RCMP participated in a workshop with members of INTERPOL and the European Police Office (EUROPOL) to develop the curriculum for a course on the prevention of bioterrorism. The workshop, which was held in Lyon, France in 2010, began the development process, which is still ongoing. The curriculum will allow member countries to train police and other first responders on bioterrorism prevention.

B. Technical assistance provided

Project Title	CBRNE International First Responder Training Program in Southeast Asia (Phases One through Five): Provide leadership, guidance and technical assistance to beneficiary state trainers delivering the Integrated Intermediate Level and Train-the-Trainer Courses
Relevance to Theme	Disease containment
Canadian Department/ Agency Responsible	Counter-Terrorism Capacity Building Program of Foreign Affairs & International Trade Canada
Other Partners	Counter-Terrorism Technology Centre of Defence Research & Development Canada (DRDC)

Project Value	$2,400,000 CAD
Project Duration	2005-2010
Area Affected	Philippines, Malaysia, Thailand and Indonesia

259. The CTCBP has been creating and sustaining CBRNE training programs in the Philippines, Malaysia, Thailand, and Indonesia from 2005 to 2010. The most recent activity is to ensure that these national training programs are sustainable by each beneficiary state in the long term. New lesson plans and personal protective equipment is being provided by the Counter-Terrorism Technology Centre for Defence Research and Development Canada (DRDC).

Project Title	Training for *Trichinella* Detection, and Parasitology/Food Safety
Relevance to Theme	Disease surveillance
Canadian Department/ Agency Responsible	Canadian Food Inspection Agency
Other Partners	Canadian International Development Agency, Université de Montréal
Project Value	N.A.
Project Duration	2010
Area Affected	Vietnam

260. In 2010, the CFIA, along with CIDA and the Université de Montréal, provided training to officials in the government of Vietnam on the detection of food-borne parasites, such as Trichinella, and on food safety in general.

Project Title	NATO Deployment Health Surveillance
Relevance to Theme	Disease surveillance
Canadian Department/ Agency Responsible	Department of National Defence
Other Partners	NATO
Project Value	N.A.
Project Duration	Since 2003
Area Affected	NATO deployments

261. Limitations to the joint North Atlantic Treaty Organization (NATO) disease and injury surveillance system known as EpiNATO became apparent in 2003. Canada's Department of National Defence (DND) has contributed to efforts to improve or replace this current surveillance system through evaluations, input at NATO Force Health Protection Working Group meetings, and presentations at specific NATO workshops. This should result in an improved disease surveillance capacity at all NATO deployments.

Project Title	Enhanced disease surveillance for the Cricket World Cup 2007
Relevance to Theme	Disease surveillance
Canadian Department/ Agency Responsible	Counter-Terrorism Capacity Building Program of Foreign Affairs & International Trade Canada
Other Partners	Caribbean Epidemiology Centre (CAREC) under the auspices of the Pan-American Health Organization (PAHO)
Project Value	$907,136 CAD

Project Duration	2006-2008
Area Affected	21 member countries of the Caribbean Epidemiology Centre

262. The objective of this project by the CTCBP was to rapidly detect unusual disease situations, patterns, or outbreaks that might require intervention before, during, or after the Cricket World Cup in 2007. The project resulted in an improved capacity to detect and respond to public health emergencies, including bioterrorist attacks. Technical assistance and laboratory supplies were provided to host nations and to the Caribbean Epidemiology Centre (CAREC) to ensure that these enhanced measures could be maintained for the duration of the event.

Project Title	Design and Construction of BSL3 National Diagnostic Centre for Human and Animal Health in the Kyrgyz Republic
Relevance to Theme	Disease containment, biosafety and biosecurity
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	Public Health Agency of Canada, Royal Canadian Mounted Police, Public Works and Government Services Canada, Canadian Commercial Corporation, United Kingdom Ministry of Defence
Project Value	$18 million CAD (to March 2011); $60 million total (to March 2013)
Project Duration	2007-2013
Area Affected	Kyrgyz Republic

263. To address a significant biological proliferation and terrorism threat, GPP committed to spend up to $60M to assist the Government of the Kyrgyz Republic to enhance its biosecurity, biosafety, and biocontainment, including through the design, construction, commissioning, and start-up of a new human & animal health facility in Bishkek. The new Facility, which was also meant to serve as the central repository for the consolidation of dangerous pathogens from several existing, vulnerable facilities in the Kyrgyz Republic, would reduce the significant threat posed by theft, sabotage accidental release and/or terrorist acquisition of dangerous pathogens in the Kyrgyz Republic. The design process for the Facility began in July 2008 and was completed in October 2009. While Canada anticipated that construction of this Facility would commence in May 2011, the Kyrgyz Government advised Canada in early May that construction could not proceed at the allocated site, which was selected and provided by the Kyrgyz Government. The Kyrgyz Government subsequently confirmed that it required additional time to re-examine its position on whether to proceed with construction of the Facility at the agreed site. In this context, it may not be possible to proceed with the Project.

Project Title	Biological Non-proliferation Policy Programming in the Former Soviet Union
Relevance to Theme	Non-proliferation
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$348,000 CAD
Project Duration	2007-2013

Area Affected	Afghanistan, Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyz Republic, Tajikistan, Turkmenistan, Ukraine, Uzbekistan

264. Canada's Global Partnership Program (GPP) is funding various biological non-proliferation activities within the Former Soviet Union (FSU), such as funding certain delegations for the 2008, 2009, and 2010 BTWC intersessional meetings, and funding/preparing workshops on export controls in Bishkek, Kyrgyz Republic (March 2009), BTWC national implementation in Astana, Kazakhstan (September 2009), and funding representatives from Central Asia (among others) to the BTWC Review Conference workshop in Beijing, China (November 2010).

Project Title	Biological Security Upgrades in the Kyrgyz Republic
Relevance to Theme	Biosafety and Biosecurity
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$1,350,000 CAD
Project Duration	2008-2010
Area Affected	Kyrgyz Republic

265. GPP implemented security upgrades at three biological facilities in the Kyrgyz Republic that required enhanced security to safeguard their pathogen collections. These upgrades were designed to address near-term requirements while a proposed BSL3 Facility was being built. Areas addressed include perimeter security, laboratory security, personnel security, and the purchase and installation of prescribed biosafety and biocontainment equipment. GPP also supported Kyrgyz efforts to enhance transportation of dangerous goods (TDG) practices to and between Kyrgyz biological facilities, including through the provision of three dedicated TDG vehicles and secure shipping containers.

Project Title	Biorisk Management in the FSU
Relevance to Theme	Biosafety and Biosecurity
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$279,000 CAD
Project Duration	2008-2012
Area Affected	FSU

266. GPP has supported the translation and dissemination of the Laboratory Biorisk Management Standard CWA: 15793:2008, for use in the FSU, and supported its implementation through the development of guidance documents and workshops.

Project Title	Biosafety Association for Central Asia and the Caucasus (BACAC)
Relevance to Theme	Biosafety and Biosecurity
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada

Other Partners	N/A
Project Value	$372,000 CAD
Project Duration	2008-2011
Area Affected	Afghanistan, Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyz Republic, Mongolia, Pakistan, Tajikistan, Turkmenistan, Uzbekistan

267. GPP has provided extensive support to the creation, evolution, and maturation of the Biosafety Association for Central Asia and the Caucasus (BACAC). Biosafety associations play an important role in addressing the bioterrorist threat, both by promoting biosafety as a scientific discipline, and by providing a forum for the continued and timely exchange of pertinent information.

Project Title	Biosafety Cabinet Certification Training Program in the FSU
Relevance to Theme	Diagnosis and Containment Capacity Building, Biosafety and Biosecurity
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$876,000 CAD
Project Duration	2008-2011
Area Affected	Kyrgyz Republic, Tajikistan, Georgia, Azerbaijan, Ukraine, Kazakhstan

268. In furtherance of GPP's objectives to enhance security and safety at biological facilities of the FSU, a long-term, sustainable Biosafety Cabinet (BSC) certification and train-the-trainer program was developed. The program's main objective is to create a self-sustaining BSC certification capacity in FSU laboratories where modern biosafety cabinets have been purchased and installed through threat-reduction programs or on a bilateral basis.

Project Title	Complex Therapy and Prophylaxis of Anthrax Infection with Specific Bacteriophages and Immunoglobulins
Relevance to Theme	Disease diagnosis and treatment
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	-
Project Value	$498,600 USD
Project Duration	2008-2011
Area Affected	Russia

269. GPP funded a project of multi-step laboratory research whereby Bacillus anthracis virulent bacteriophages are characterized and certified. Bacterial phages that hold promise as preventative, therapeutic, and diagnostic means for Anthrax will be deposited in the International Bacterial Phage Collection. If selected phages meet international requirements, patent application will be deposited in Russia and possibly in other countries. On the basis of the bacteriophages, a catalogue of collection specimens will be made.

Project Title	Development and Modernization of Guidelines, Standards and Regulations on Biosafety and Biosecurity in Kyrgyz Republic
Relevance to Theme	Biosafety and Biosecurity
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$295,750 USD
Project Duration	2011-2013
Area Affected	Kyrgyz Republic

270. Biosafety and biosecurity remains a major priority for GPP. This project is for the creation and improvement of standards, guidelines and legislation for establishing and maintaining a framework for biological security in the Kyrgyz Republic and Central Asia. This project will result in the modernization of the Kyrgyz Republic's standards and guidelines for biosafety and biosecurity, bringing them in line with those of the World Health Organization (WHO) and international best practices.

Project Title	Development of Biosafety and Biosecurity Training Tools
Relevance to Theme	Biosafety and Biosecurity
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$208,848 CAD
Project Duration	2007-2011
Area Affected	FSU

271. In order to address the wide range of security and safety issues related to working with dangerous pathogens, GPP has been developing and disseminating various biosafety and biosecurity training tools, translated into Russian and Kazakh. The development of these tools directly supports the sustainability of Canada's biological non-proliferation efforts in the FSU by helping ensure that increased attention is paid to biocontainment, biosafety, biosecurity and overall biorisk management by those who handle dangerous pathogens.

Project Title	Ecology-Episotologic Monitoring of Murine Rodents as Basis Carriers of Parasitic and Infection Diseases in Central Tajikistan
Relevance to Theme	Disease surveillances
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	-
Project Value	$299,624 USD
Project Duration	2009-2012
Area Affected	Tajikistan

272. This GPP-funded project for the investigation of parasite fauna in murine rodents and the various parasites for different types of hosts, including a determination of the infectiousness of the rodents by the pathogenic organisms and parasite diseases, will lead to

the development and implementation of measures to regulate numbers of murine rodents (thereby reducing the likelihood of epidemic and epizootic diseases.)

Project Title	Establishment of Biosafety and Biosecurity Training Centres in the FSU
Relevance to Theme	Biosafety and Biosecurity training
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$1,108,000 CAD
Project Duration	2007-2011
Area Affected	FSU

273. GPP is supporting the establishment of national and regional train-the-trainer biosafety and biosecurity training centres in Kazakhstan (Kazakh Science Centre for Quarantine and Zoonotic Diseases, Almaty), Ukraine (Ukrainian Anti-Plague Research Institute, Odessa) and the Russian Federation (Novosibirsk State University). The development of regional training centres is a key component of Canada's goal of creating a self-sustaining biosafety and biosecurity training capacity in the FSU.

Project Title	General Biosafety Training for FSU Scientists
Relevance to Theme	Biosafety and Biosecurity
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$579,000 CAD
Project Duration	2007-2011
Area Affected	FSU

274. In support of its efforts to enhance biosafety, biosecurity and biorisk management, GPP has supported the participation of FSU scientists in relevant training events and conferences in Canada and worldwide. Since the collapse of the Soviet Union, many biological institutes in the FSU have lacked the financial resources to provide modern biosafety and biosecurity training for their personnel. This situation represents a serious risk, as poor training increases the risk of a biological accident or of improper pathogen accounting, storage and transportation, all of which can lead to serious breaches of biocontainment and potential proliferation of dangerous pathogenic material.

Project Title	International Advisory Group on Biosafety and Biosecurity (IAG)
Relevance to Theme	Biosafety and Biosecurity
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$194,000 CAD
Project Duration	2007-2009
Area Affected	Russian Federation

275. The International Advisory Group (IAG) was created, with assistance from GPP, to facilitate the implementation of international best practices in biosafety and biosecurity in the Russian Federation. Additionally, it served to integrate Russian scientists into the broader global biosafety community.

Project Title	Investigation of Plague Epidemiology and Epizootiology for the Purpose of Biosafety of the Population in Issyk-Kul Region of the Kyrgyz Republic
Relevance to Theme	Disease surveillance and containment
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	Canadian Food Inspection Agency
Project Value	$244,220 USD
Project Duration	2010-2013
Area Affected	Kyrgyz Republic

276. This project aims to evaluate the natural and artificial factors associated with the circulation of plague pathogen in the alpine part of Central Asia. Funded by GPP and supported by CFIA, this project's long-term goal is breaking the natural cycle of marmot–flea–marmot–man plague infection. This will help control the spread of plague infection in the Issyk-Kul region and neighbouring areas of Kazakhstan and China.

Project Title	Monitoring of the Epizootiological Conditions and Prevention of Occurrence of Rabies in People and Animals
Relevance to Theme	Biosafety and Biosecurity
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$385,005 USD
Project Duration	2008-2011
Area Affected	Kyrgyz Republic

277. GPP is funding a project on the surveillance or Rabies in the Kyrgyz Republic, with the goal of facilitating Rabies control.

Project Title	Prevention of Distribution of Infectious Diseases by Trans-Boundary Rivers of the South of the Kyrgyz Republic with the Purpose of Maintenance of Bacteriological Safety in Fergana Valley
Relevance to Theme	Disease surveillance and treatment
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	UK Ministry of Defence
Project Value	$268,155 USD
Project Duration	2011-2013
Area Affected	Kyrgyz Republic

278. GPP is funding the development of research centres to analyze water distribution in the Fergana Valley of the Kyrgyz Republic, with the goal of developing treatments against infectious diseases using local raw materials.

Project Title	Support for Biosafety & Human/Animal Health Capacity Building in the Kyrgyz Republic
Relevance to Theme	Biosafety and Biosecurity
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$861,000 CAD
Project Duration	2007-2011
Area Affected	Kyrgyz Republic

279. While creating a secure and safe laboratory environment is essential, so too is ensuring that the laboratory personnel are well and fully trained, and that they possess clear and modern standards and guidelines to implement. Likewise, close affiliation with international colleagues and associations with expertise and experience in biosafety/biosecurity, human and animal health is critical to the long-term sustainability of the laboratory. Consequently, GPP is supporting a range of complementary initiatives in the Kyrgyz Republic, valued at $861,000 from 2007 to 2011, including the provision of biosafety/biosecurity & human/animal health diagnostics training, assisting with development and implementation of effective and practical national standards.

Project Title	National Microbiology Laboratory (NML) Prion Diseases Program (PDP)
Relevance to Theme	Disease surveillance and diagnosis
Canadian Department/ Agency Responsible	Infectious Disease Prevention and Control Branch of the Public Health Agency of Canada
Other Partners	Health Canada, Canadian Food Inspection Agency
Project Value	N.A.
Project Duration	Ongoing
Area Affected	All 11 members of EUROCJD – Australia, Austria, Canada, France, Germany, Italy, Netherlands, Slovakia, Spain, Switzerland, and UK

280. NML's Prion Diseases Program (PDP) is the only public health program for researching human prion diseases in Canada. It provides technical assistance and does surveillance on these diseases in Canada. The PDP is also a member of European and Allied Countries Collaborative Study Group on Creutzfeld-Jakob Disease (EUROCJD), an 11-country partnership who share data and test practices to optimize public health approaches for prion diseases. These activities are also essential at countering trade issues arising from animal prion diseases such as Bovine Spongiform Encephalopathy (Mad Cow Disease) and Chronic Wasting Disease.

Project Title	Office of Biorisk Management
Relevance to Theme	Disease containment
Canadian Department/ Agency Responsible	Infectious Disease Prevention and Control Branch of the Public Health Agency of Canada

Other Partners	Canadian Food Inspection Agency, Foreign Affairs and International Trade Canada, World Health Organization, other international biosafety associations
Project Value	N.A.
Project Duration	Ongoing
Area Affected	Worldwide

281. The Office of Biorisk Management (OBM) works with WHO, PHAC, and other Canadian departments to advance the public health agenda by promoting risk management for both domestic and international laboratories. The OBM advises Foreign Affairs and International Trade Canada on biological non-proliferation and the Canadian Space Agency on planetary protection.

Project Title	Public Health Agency of Canada – Mobile Lab
Relevance to Theme	Disease diagnosis and containment
Canadian Department/ Agency Responsible	Microbiological Emergency Response Team (MERT) - Infectious Disease Prevention and Control Branch of the Public Health Agency of Canada
Other Partners	N/A
Project Value	N.A.
Project Duration	As needed
Area Affected	Worldwide, where needed (mobile)

282. NML maintains mobile laboratory units that can be deployed on very short notice to assist with public health crises anywhere in the world. Teams of PHAC scientists deploy with the laboratory unit and work closely with the WHO and local officials for the in-field identification and diagnosis of high-risk pathogens. These teams also train their national and international partners at in-field diagnosis and sampling procedures.

Project Title	Real Property Safety and Security
Relevance to Theme	Disease containment
Canadian Department/ Agency Responsible	Infectious Disease Prevention and Control Branch of the Public Health Agency of Canada
Other Partners	Broad list of international partners
Project Value	N.A.
Project Duration	Ongoing
Area Affected	Worldwide

283. Having established itself as a leader domestically and internationally in the operation and maintenance of high containment laboratory, Real Property Safety and Security provides review services, technical resources and expertise, and decontamination technologies to laboratories throughout Canada and the world.

Project Title	*Trichinella* diagnostics, Proficiency Testing and Lab Certification for *Trichinella* Testing
Relevance to Theme	Disease surveillance
Canadian Department/ Agency Responsible	Canadian Food Inspection Agency

Other Partners	OIE, International Commission on Trichinellosis, and National reference labs in EU, US, etc.
Project Value	N.A.
Project Duration	Ongoing
Area Affected	Worldwide

284. The CFIA provided support in the creation of international standards, quality-assurance mechanisms, and laboratory certification procedures for the detection of Trichinella in wildlife and in pork products, for worldwide distribution. CFIA also offers confirmatory testing of positive international samples.

Project Title	World Health Organization (WHO)
Relevance to Theme	Disease surveillance
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$3,130,100 CAD
Project Duration	2010-2012
Area Affected	Global

285. Since 2010, GPP has provided funding to the WHO to support international capacity building and the implementation of the International Health Regulations worldwide. Funding is also used to support activities pertaining to Global Alert and Response.

Project Title	World Organisation for Animal Health (OIE)
Relevance to Theme	Disease surveillance, detection, diagnosis, and response
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$2,000,000 CAD
Project Duration	2010-2012
Area Affected	Global

286. GPP has provided funding to the OIE for capacity building in the surveillance, detection, diagnosis, and response to diseases that afflict animal populations. This includes supporting emergency preparedness and response strategies, strengthening disease surveillance capabilities and laboratory capacities, evaluating and strengthening relevant legislation, and supporting international oversight of rinderpest eradication.

C. Other collaborations related to BTWC compliance

287. The Public Health Agency of Canada (PHAC) and the University of Bradford, United Kingdom (UoB) are collaborating in the development and delivery of a curriculum for a university-level accredited pilot course on Applied Dual-use Biosecurity; Biosafety and Bioethics to be co-delivered at Carleton University, in Ottawa in 2012. With the aim of promoting BTWC awareness and compliance in Canada, the objectives of this course are to develop a foundation of the concepts of biosafety and biosecurity in the trainee such that increased awareness in regards to the ethical, legal and social relevance of dual-use

biosecurity, as well as the responsible conduct of research can provide a foundation for the development of policies and procedures to enhance responsibility and prevent the malicious or misuse of pathogens and toxins.

288. This course will also assist in compliance promotion, and therefore, compliance with those undertaking activities with human pathogens and toxins in Canada, within the sphere of oversight of the Human Pathogens and Toxins Act (HPTA), one of Canada's primary tools in BTWC compliance. This course is intended for those with low-level knowledge of biosafety, but a high level of responsibility with respect to compliance with the HPTA.

289. Dependent on a successful delivery of the first course, future plans include expansion into a 60 UK credit Post-graduate Certificate for delivery across Canada, and potentially the transition to a full MA programme (180 UK credits) accessible by the global community.

Project Title	ASEAN Workshop on Preventing Bioterrorism
Relevance to Theme	Disease surveillance, detection, and containment
Canadian Department/ Agency Responsible	Counter-Terrorism Capacity Building Program of Foreign Affairs & International Trade Canada
Other Partners	ASEAN Secretariat
Project Value	$60,000 CAD
Project Duration	2007-2008
Area Affected	Developing member countries of ASEAN

290. In 2007 and 2008, the CTCBP worked with the ASEAN Secretariat to host a workshop on preventing bioterrorism. It allowed law enforcement, customs, immigration, and public health officials from developing ASEAN countries to identify their needs and create anti-bioterrorism units and designate biosecurity authorities. Information and best practices were shared among the member countries to induce international and inter-agency cooperation and to sensitize lawmakers and the public to the threat and challenges of bioterrorism.

Project Title	Global Health Security Action Group – Lab Network
Relevance to Theme	Disease surveillance
Canadian Department/ Agency Responsible	Infectious Disease Prevention and Control Branch of the Public Health Agency of Canada
Other Partners	Other Global Health Security Action Group Working Groups, WHO (Observer) European Commission
Project Value	N.A.
Project Duration	2001 - Ongoing
Area Affected	G7 + Mexico

291. The G7 countries and Mexico led to the establishment of the Global Health Security Action Group (GHSAG) shortly after 9/11. PHAC’s National Microbiology Laboratory (NML) plays a central role in this laboratory network. The network’s goals are to coordinate the diagnostic capabilities of all participants and contribute to disease surveillance around the world.

Project Title	Global Health Security Initiative / Global Health Security Action Group
Relevance to Theme	Disease surveillance
Canadian Department/ Agency Responsible	Strategic Policy and International Affairs Directorate of the Public Health Agency of Canada
Other Partners	None
Project Value	N/A
Project Duration	N/A
Area Affected	Canada, European Commission, France, Germany, Italy, Japan, Mexico, the United Kingdom, the United States and the World Health Organization

292. PHAC is a major participant in the Global Health Security Initiative (GHSI), an international partnership that strengthens health preparedness and response to CBRN terrorism and pandemic influenza. The GHSI discusses issues in global health security and identifies areas needing work. The senior members of GHSI form the GHSAG. The GHSI also commissions working groups to carry out work and advance scientific cooperation.

Project Title	European Enforcement Project
Relevance to Theme	Capacity Building
Canadian Department/ Agency Responsible	Pathogen Regulation Directorate – Emergency Management and Corporate Affairs Branch of the Public Health Agency of Canada
Other Partners	International partners
Project Value	N/A
Project Duration	Ongoing
Area Affected	Global

293. The European Enforcement Project (EEP) annual meeting of federal inspectors responsible for human pathogens in the E.U. and forms a Europe-wide network for inspectors and inspectorates of the EU Member States to exchange experiences (breaches and failures of biocontainment; threats etc) and establish methodologies for the harmonisation of approaches to inspection and enforcement of work with contained use of microorganisms. Since 1997 network members have produced practical documents such as procedures and checklists for inspection, guidance on sampling methodologies, hosted shared inspection visits of facilities and deliberate release sites, and held annual conferences. As the sole non-E.U. member permitted entry into these closed-door meetings, PHAC's participation in these frank discussions by federal authorities allows PHAC a unique opportunity to share international best practices and lessons.

Project Title	Biological Non-proliferation Policy Programming
Relevance to Theme	Participation in Non-Proliferation events
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$686,160 CAD
Project Duration	2010-2012
Area Affected	Global

294. GPP has implemented a variety of biological non-proliferation policy projects that promote Canada's arms control objectives worldwide. This includes the provision of funding the Biological and Toxin Weapons Convention (BTWC) Implementation Support Unit (ISU) to support travel and outreach, co-hosting a Review Conference workshop with the Chinese government, and funding work on legislation and implementation by the Verification Research, Training and Information Centre (VERTIC).

Project Title	International Federation of Biosafety Associations (IFBA)
Relevance to Theme	Biosafety and Biosecurity
Canadian Department/ Agency Responsible	Global Partnership Program of Foreign Affairs and International Trade Canada
Other Partners	N/A
Project Value	$499,000 CAD
Project Duration	2009-2012
Area Affected	Global

295. An important part of GPP's mandate is the promotion and implementation of biosafety measures through collaboration among national and regional biosafety associations, such as through the International Federation of Biosafety Associations (IFBA). Consequently, GPP has been an observer within IFBA and has supported its initiatives since 2009.

Project Title	Joint US-Canada Science and Technology Collaboration for Animal Health Threats
Relevance to Theme	Disease surveillance, diagnosis, risk assessment, preparedness, and response
Canadian Department/ Agency Responsible	Canadian Food Inspection Agency
Other Partners	USDA's Agricultural Research Service, USDA's Animal and Plant Health Inspection Service, US Department of Homeland Security, DRDC's Centre for Security Science, RCMP
Project Value	N/A
Project Duration	Ongoing
Area Affected	Canada -US

296. The objective of this Canada-US initiative is to enhance both countries' abilities to respond to biological threats, natural or intentional, that affect animal health. Bilateral working groups on disease surveillance, risk assessment, and response/research coordination have been established, with information shared using new web-based share points. This collaboration enhances not only Canada's ability to respond to a biological threat, but also to provide assistance to others if requested to do so under Article VII.

Project Title	Effects of Aerosolized Bacteria on Fingerprint Impression Evidence
Relevance to Theme	Research
Canadian Department/ Agency Responsible	Royal Canadian Mounted Police
Other Partners	DYCOR Technologies, Technical Support Working Group
Project Value	N.A.

Project Duration	Published in 2009
Area Affected	International Forensic community

297. In 2009, the RCMP, along with the Technical Support Working Group and DYCOR Technologies Limited, published research on how contamination of a crime scene with biological agents does not affect the performance of fingerprint detection methods. This research was shared with the international forensic community.

VI. Observations

298. Implementation of the BTWC has evolved in Canada since the entry into force of the Convention in 1975. Developments in the legislative and regulatory framework in Canada over the last two decades illustrate the dynamic requirements effective implementation of international obligations imposes on Canada. In stark terms there has been a shift from a confirmatory approach to compliance, whereby Canada confirmed through statements that it was in compliance with its obligations, to a demonstrative approach to compliance, whereby Canada provides to other parties evidence of its compliance through information sharing on its implementation mechanisms and practices. This approach began with the annual information sharing procedures under the CBMs and was supplemented by the compliance reports provided at review conferences. Over the last decade the procedures have included additional submissions to the United Nations Security Council and to states parties under the meetings of experts.

299. As States Parties observed in 1991 at the Third Review Conference, scientific and technological developments since 1975 have shifted the capabilities for potential offensive (and prohibited) use of biological and toxin agents from the state to sub-state actors and individuals. As a consequence implementation of the Convention has required a similar shift beyond government (state) facilities and laboratories to embrace public and private facilities in industry, universities, and other entities. Canada's existing legislative and regulatory framework is fundamentally and undergoes periodic review and updating, as evidenced by HPTA (2009). What has developed over time is a layered system of legislation and regulations covering human, animal, and plant pathogens and toxins, safety and security, import and export procedures, and a compliance architecture that moves beyond the precise requirements of the BTWC.

300. This more comprehensive approach entails focusing on compliance and undertaking activities that assist facilities, industry, and individuals in understanding what actions are required in order to comply with the BTWC and the associated legislation and regulations within Canada that give effect to Canada's obligation to biological disarmament and non-proliferation. Such activities involve extensive outreach to facilities, the developments of standards, and co-ordination across government departments and agencies. Canada continues to work with its international partners on compliance with the Convention and implementation of international law and any associated guidelines from organizations such as the WHO on biosafety and biosecurity.

Annex II

BTWC Compliance Report of Switzerland on oversight of human, animal and plant pathogens in laboratories, animal units, greenhouses and production facilities

I. Implementation of Legislation and Regulations of oversight of human, animal and plant pathogens (Relevant Departments, Agencies, Programs, and Initiatives)

A. General Overview of legislation and regulations and of measures taken toward implementation

1. Federal acts (issued by the Swiss Parliament)

1. Federal acts (issued by the Swiss Parliament):

(a) Federal act on the protection of the Environment

(b) Federal act on the non-human Genetic Engineering

(c) Federal act on the Control of Communicable Human Diseases

(d) Federal act on Animal Diseases

(e) Federal act on Agriculture

(f) Federal Act on work

2. Federal ordinances (issued by the Federal Council and based on the cited Federal Laws)

Ordinance on the Contained Use of organisms

2. This ordinance has been issued in order to protect people and the environment, in particular communities of animals and plants and their habitats, against harmful effects or nuisances of work with organism in contained systems. It should also contribute to maintaining biological diversity and soil fertility. The ordinance regulates the contained use of organisms, in particular genetically modified or pathogenic organisms. This includes human, animal and plant pathogens.

Ordinance on the Protection against major accidents

3. The protection of the population and the environment against major accidents, in particular with organisms of risk group 3 and 4. The ordinance applies, among others, to facilities working with RG 3 and 4 organisms. It regulates the prevention of an extraordinary event with substantial negative effects off site the institution‘s area.

Ordinance on Occupational Safety in Biotechnology (SAMV)

4. This ordinance regulates the protection of employees when handling microorganisms or when exposed to them. It describes how to determine general and specific safety measures, in order to prevent occupational diseases induced by microorganisms.

Ordinance on the Control of Animal Diseases

5. This ordinance determines the highly contagious epizootics and other animal diseases and the control measures to be taken.

Ordinance on Plant Protection

6. This ordinance regulates the use of very dangerous damaging organisms and goods, that are potentially bearing such organisms. It also regulates the monitoring and control of such organisms as well as the use, monitoring and control of weeds.

Ordinance on the Swiss Federal Expert Committee for Biological Safety

7. The committee advises the Federal Council on issues regarding the protection of humans and the environment from communicable diseases, the health of workers, the protection of animals and plants as well as their habitat.

B. Name of Department/Agency/Program/Initiative

1. Legal Authority/Mandate

Federal Office of Environment (FOEN)

8. The FOEN is the competent office for the contained use of animal and plant pathogens. In addition, it hosts the Federal Coordination Center for Biotechnology (FCCB) which gathers all the notifications and license applications for contained use. Whoever performs activities with pathogenic or genetically modified organisms has to notify (activities with organisms of risk group 1 and 2, low risk) or obtain a licence from the competent authority (activities with organisms of risk group 3 and 4). The project leader who intends to carry out an activity has to notify or submit an authorization application. He has to assess the risk and classify the activities according to the risk group of the organisms (1 to 4), the genetic modifications and the kind of activity and implement the adequate safety measures. The internet page of the FCCB hosts many relevant documents and information on biosafety, e.g. lists of organisms, guides for biosafety officers and safety concepts (http://www.bafu.admin.ch/biotechnologie/01744/01745/index.html?lang=de).

Federal Office of Public Health (FOPH)

9. The FOPH is the competent office for the contained use with human pathogens. It issues the licences for activities with organisms belonging to the groups 3 and 4.

Federal Veterinary Office (FVO)

10. The aims of the Federal Veterinary Office (FVO) in the field of animal health cover the control and the monitoring of diseases which pose a risk to livestock, which could be transmitted to humans, could have a serious economic impact or could compromise the international trade. Therefore all activities in a laboratory involving highly contagious animal diseases (former OIE list A diseases) require an authorization of the SFVO. The legal basis are the law and the ordinance on animal diseases. Based on this legislation, the risk assessment of the applicant (according to the contained use ordinance) and the current situation with regard to highly contagious animal diseases the application will be examined. An authorization will only be issued if the cantonal veterinary office agrees.

Federal Office of Agriculture (FOAG)

11. The aim of the Federal Office of Agriculture (FOAG) is to prevent the introduction and spread of organisms (quarantine pests) harmful to plants or plant products through the application of phytosanitary measures according to the plant protection ordinance. These regulations are based on the principles and norms of the International Plant Protection Convention (IPPC). The Swiss Federal Plant Protection Service (SPPS), constituted by the Federal Office of Environment FOEN and the Federal Office of Agriculture (FOAG), is responsible for this task .

12. The FOAG implements the provisions of the plant protection ordinance (PPO) and referring regulations in the sector of agricultural and horticultural crops.

Swiss Expert Committee for Biological Safety (SECB)

13. The SECB is a permanent federal advisory committee. The experts play an important role in advising the Federal Council and the Federal Offices on the drafting of laws, ordinances, guidelines and recommendations. They also advise the federal and cantonal authorities on the enforcement of these regulations. The SECB issues Statements on licence application and recommendations on safety measures for studies using genetically modified or pathogenic organisms. Numerous information of all kind of different biosafety aspects can be found on their website (http://www.efbs.ch).

Swiss National Accident Insurance Fund (Suva)

14. Suva insures employees and unemployed people against the consequences of accidents and occupational diseases. In addition, it is active in prevention and rehabilitation. Suva is self-supporting, operates without any state subsidies and its profits go to the benefit of its injured persons in the form of lower premiums. Suva's social partners, employers and employees, are represented on the Board of Directors, as is the Swiss federal government.

15. Suva is the competent authority for the enforcement of SAMV. Activities with pathogenic microorganisms have to be notified. Notification includes a risk assessment and can be combined with notification according to the Ordinance on the Contained Use of Organisms. With the intention to prevent occupational diseases, Suva advices and inspects companies that perform activities with microorganisms.

Cantonal Services for Biological Safety

16. The inspections of laboratories handling pathogenic or genetically modified organisms are delegated to the cantonal governments by law. The inspectors control and enforce the correct implementations of safety measures according to the class of activity. The 26 cantonal services and the service of the Principality of Liechtenstein can be found at http://www.kvu.ch/d_afu_adressen.cfm?Nav.Command=Fachbereiche&Module.Method=showFachbereiche&fach_id=8 .

2. Articles of the BTWC

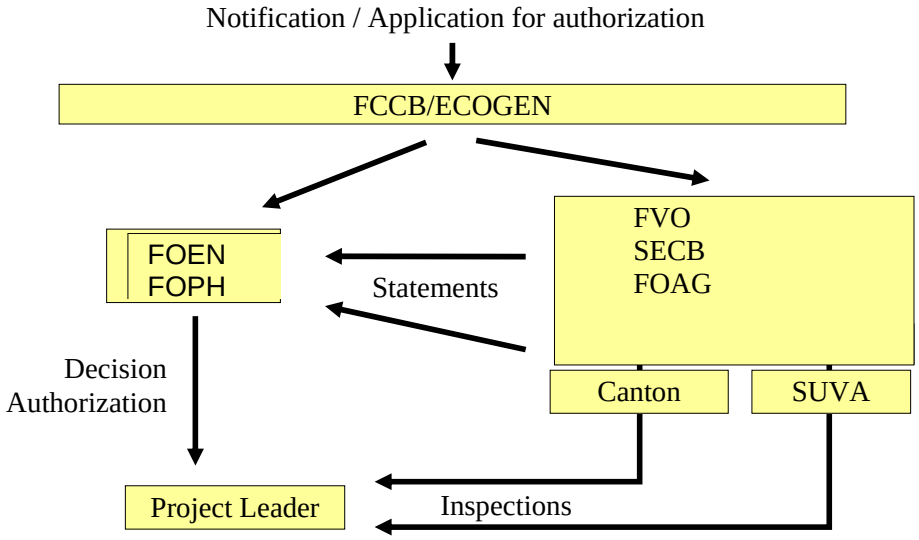
17. Articles I, III & IV

C. Program Compliance Monitoring and Enforcement Metrics

1. Notification/authorization mechanism

18. The project leader who intends to carry out an activity has to notify or submit an authorization application to the Federal Coordination Center for Biotechnology (FCCB), e.g. electronically by accessing the internet database ECOGEN. The FCCB distributes the

incoming documents to the offices and bodies stated in the ordinances for consultation. The competent bodies (FOEN, FOPH) then decide, based on the statements, on the classification and communicate their decision to the project leader (class 1 and 2) or they deliver a permit (class 3 and 4). The laboratories are inspected by cantonal authorities. At the FCCB are the central documentations and it regularly publishes the notified and authorized activities on its website.



2. Permits and Notifications

19. Contained use in Switzerland 2000-2011[1]

Notifications and authorizations of activities

Notifications	**2123**
activities of class 1	1020
activities of class 2	1103

[1] Source: Contained systems: Public register (as of 2011-11-24)
http://www.ecogen.ch/ecogen/Forms/Register/RegisterSearch.aspx

Authorizations	**70***
activities of class 3	66
activities of class 4	4

3. **Description of compliance monitoring activities (Inspections)**

20. The decentralized control system of the Biosafety legal system in Switzerland complicates the gathering of information on inspection activities. Therefore, only confirmed inspections are cited below. The true number of inspections is with certainty much higher and efforts are under way to collect these data.

Number of inspections (2008-2011)

*Biosafety level***	*Number of Inspections*
1	2
1,2	13
2	7
1,2,3	14
2,3	4

* Only approved activities. Submitted license applications that have not yet been approved are shown in the public register as well, but not cited here.

** Where two or more Biosafety levels are indicated, exact data on how many inspections have been performed on the respective single Biosafety Level are not available.