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**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**

5 December 2012

English only

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**2012 Meeting**

Geneva, 10–14 December 2012

Item 8 of the provisional agenda

**Standing agenda item: strengthening  
national implementation**

**National implementation of the BTWC: compliance  
assessment: update**

**Submitted by Canada, the Czech Republic and Switzerland**

**I. Background**

1. Mechanisms for the assessment and verification of compliance to the Biological and Toxin Weapons Convention (BTWC) have the goal of ensuring that all States Parties have in place national implementation measures, and, as it as the potential to identify best practices and/or gaps in compliance, can strengthen national implementation overall. Development of an internationally-led on-site inspection regime has never reached consensus in the BTWC, though in 1986, the Confidence Building Measures (CBMs) were introduced which require a State Party to provide detailed national information regarding dangerous biological material research and use within a particular country.

**II. Compliance assessment concept**

2. The concepts of compliance verification can be approached from a focussed perspective such as on-site inspections of facilities, or from the broader perspective of assessing compliance by examining and assessing the regulatory program that has been implemented to ensure compliance by regulatory/legislated requirement. In this regard, the concept paper submitted by Canada (BWC/MSP/2010/WP.3/Rev.1) during the 2010 Meeting of the States Parties detailed a compliance assessment concept which proposed that compliance verification can be achieved by examining the implementation measures a State Party has taken, as well as efforts to administer and enforce the measures on an ongoing basis. Canada proposed to work with interested States Parties to develop initial declarations as a joint project, to demonstrate the effectiveness of compliance assessment.

### **III. Pilot project: initial compliance assessment**

3. In this regard, during the Seventh Review Conference, Canada and Switzerland submitted their initial submission to States Parties, in accordance with the request of the Preparatory Committee of the Seventh Review Conference for background information (BWC/CONF.VII/PAC.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”. This initial submission can be found at BWC/MSP/2012/MX/WP.17.

4. The initial submissions included a detailed description of national legislation and regulations supporting the national implementation of the BTWC, including those that could cover the oversight of human, animal and plant pathogens. In addition to the analysis of the national implementation legislation, the report also included a detailed description of how the program was implemented on a national level.

5. The Czech Republic has joined the pilot project and has prepared an initial declaration, as Annex I, to this paper, to demonstrate the effectiveness of the compliance assessment concept.

### **IV. Pilot project: annual declarations**

6. Moreover, as preparation of initial submissions requires significant effort, to demonstrate the ease of subsequent submissions, which require updating of the tombstone information with annual compliance and enforcement metrics and any new policy initiatives, Canada and Switzerland have prepared sample annual declarations as Annex II (Canada) and Annex III (Switzerland) to this paper.

### **V. Conclusion**

7. Discussions on compliance assessment, as well as other possible measures for verifying compliance to the BTWC, should continue as part of the standing agenda item on strengthening national implementation during the remainder of the 2012–2015 intersessional process and at the Eighth Review Conference in 2016.

## Annex I

### The Biological and Toxin Weapons Convention in the Czech legal system

#### I. Implementation of BTWC in the Czech legal system

1. The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (BTWC) became a part of the legal system of the former Czechoslovak Socialist Republic in 1975 in the form of Decree No. 96/1975 Coll. After the split of Czechoslovakia in 1993, the newly originated Czech Republic adopted and meets the international commitments including BTWC. The basic requirements BTWC have been continuously incorporated into the Czech legal system since the mid-1990s. Subsequently, the requirements arising from other relevant international conventions such as United Nations Security Council Resolution No. 1540 of 2004 also have been incorporated into the Czech legal system.

#### Main legal regulations

2. A key legal regulation is **Act No. 281/2002 Coll.**, on Some Measures Related to Prohibition of Bacteriological (Biological) and Toxin Weapons and on Amendments to Trades Licensing Act, which significantly contributes to the fulfilment of the commitment arising from Article IV of BTWC. Its basic principles are as follows:

- (a) Creation of the supervision of the observance of the prohibition of the development, production and stockpiling and use of biological and toxin weapons,
- (b) Creation of the supervision of the handling of highly hazardous and hazardous biological agents and toxins,
- (c) Introduction of the recording system in the area of handling of highly hazardous and hazardous biological agents and toxins,
- (d) Definition of the conditions for the handling of highly hazardous and hazardous agents and toxins, definition of inspector competencies,
- (e) Imposition of sanctions for possible breach of obligations.

3. The implementing legal regulation to this Act is **Decree No. 474/2002 Coll.** A part of annexes to this Decree are a list of highly hazardous biological agents and toxins, and a list of hazardous biological agents and toxins. This Decree stipulates particulars on the keeping of records of highly hazardous and hazardous biological agents and toxins, and also lays down the requirements for the data contained in declarations, which shall be submitted by persons handling of such agents and toxins to the State Office for Nuclear Safety within the specified time.

4. Another important part of the legal system, which contributes to the fulfilment of Article III and Article IV of BTWC, is **Act No. 594/2004 Coll.**, Implementing the European Community Regime for the Control of Exports, Transfer, Brokering, and Transit of Dual-Use Items. Following the directly applicable regulation of the European Communities, this Act regulates export control of dual-use items, provision of brokering services related to dual-use items and transit while observing the international regimes, international treaties and conventions, the performance of which the Czech Republic is

committed to, as well as some rights and obligations of brokers, exporters of dual-use items and other persons, who participate in the export, rights and obligations of persons transporting dual-use items from the territory of the Czech Republic to the territory of another Member State of the European Union. Furthermore, the Act regulates the control of the provision of technical support related to certain military end-uses, and rights and obligations of persons importing dual-use items to the Czech Republic.

5. To implement the Act, Annex I to the **Regulation (EU) No. 388/2012 of the European Parliament and of the Council**, amending Council Regulation (EC) No. 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items, shall apply. This annex contains a list of dual-use items structured into respective categories.

#### 1. State Office for Nuclear Safety

6. The State Office for Nuclear Safety (SONS) is the central body of the government administration as stipulated by Act No. 2/1969 Coll., on Establishment of Ministries and other Central Bodies of the Czech Republic State Administration. The State Office for Nuclear Safety is headed by SÚJB Chairman, who is appointed by the Government of the Czech Republic. The Office is an independent governmental body reports directly to the Government of the Czech Republic and has its own budget. The State Office for Nuclear Safety is responsible for governmental administration and supervision in the areas of uses of nuclear energy and ionizing radiation, in the area of radiation protection, supervision of non-proliferation of nuclear weapons and prohibition of chemical weapons. Since 2002, the State Office for Nuclear Safety has been responsible for, in addition to the mentioned competencies, governmental administration and supervision in the area of the observance of prohibition of bacteriological (biological) and toxin weapons and at the same time, the function of the National Authority for the fulfilment of BTWC. Therefore, the State Office for Nuclear Safety plays the role of competent authority in the area of non-proliferation and prohibition of all types of weapons of mass destruction. Within the State Office for Nuclear Safety, any and all problems related to the prohibition of biological and toxin weapons are addressed by the **Biological Weapons Prohibition Division**, as part of the Department of Non-Proliferation.

7. Technical support to the supervision activity carried out by the State Office for Nuclear Safety in relation to BTWC is provided by the National Institute for Nuclear, Chemical and Biological Protection.

8. Currently, there is 128 licences or notification registered in the database of SONS that allow handling of highly hazardous or hazardous biological agents or toxins according to Act 281/2002 Coll. In 2012 SONS performed 48 on-site inspections of those registered entities. No misuse, misconduct or any other breach of duties given by the Act 281/2002 Coll. has been found.

#### 2. Ministry of Industry and Trade of the Czech Republic

9. The Ministry of Industry and Trade is the central body of the government administration involved in the supervision of trading with dual-use items within the Czech Republic. The department of the Ministry of Industry and Trade responsible for the control and performance of activities related to the application of the licensing regime in the area of economic contacts with foreign countries is the **Licence Office of the Ministry of Industry and Trade of the Czech Republic**.

10. The Ministry of Industry and Trade and the State Office for Nuclear Safety provide each other with data relating to the permitting and licensing procedure in accordance with special legal regulations in the area of nuclear, chemical and biological items listed in

Annex I to the Regulation (EU) No. 388/2012 of the European Parliament and of the Council. The two bodies of the government administration notify each other immediately of facts important for permitting and licensing procedure, control of the observance of the Council Regulation (EC) No. 428/2009 or Act No. 594/2004 Coll. The State Office for Nuclear Safety provides the Ministry of Industry and Trade with information important for permitting and licensing procedure discovered in the course of performed control activities.

## II. Related legislation in the individual areas of government administration

### A. Health sector

#### 1. Public health protection and relevant legal regulations

11. The main legal pillar to the protection of public health is **Act No. 258/2000 Coll.**, on Public Health Protection. The Act incorporates the relevant regulations of the European Communities and regulates the rights and obligations of persons and the function of the governmental administration in the area of public health protection. At the same time, the Act outlines a system of bodies of public health protection and defines their competence, powers and obligations.

12. The important part of the Act is the area of the prevention of occurrence and propagation of infectious diseases. The implementing regulations to this part of the Act are the following:

(a) **Decree No. 195/2005 Coll.**, which regulates the conditions of the prevention of occurrence and spread of infectious diseases and hygienic requirements for the operation of healthcare facilities and welfare institutions (this Decree deals with the method and range of notifications of infectious diseases, including hospital infections, and addresses the principles for sampling and examination of biological material);

(b) **Decree No. 473/2008 Coll.**, on epidemiological vigilance system for the selected infections (the Decree provides a list of infectious diseases subject to the tighter control by epidemiologists; at the same time, the Decree defines the scope of data collected about such infectious diseases, method and time of notification thereof, laboratory diagnostics, epidemiological examination, and the specification of type and method of the implementation of epidemic-control measures for infectious diseases);

(c) **Decree No. 537/2006 Coll.**, on vaccination against infectious diseases (this Decree deals with the conditions for vaccination and passive immunization, defines the immunity examination methods and governs the area of workplaces with higher risk of infection disease occurrence and regulates the conditions, under which physical persons can work at such workplaces in connection with special vaccination).

#### *Public Health Protection System*

13. Pursuant to Act No. 258/2000 Coll., the public health protection system is composed of the Ministry of Health, the Local Public Health Centres, the Ministry of Defence and the Ministry of Interior. The key role is played by the Ministry of Health, which controls the performance of the governmental administration in the area of public health protection and is responsible for the creation and implementation of national policy in this area. Within its powers, the Ministry of Health manages and controls the local public health centres. Two important institutes, the National Institute of Public Health and the State Institute for Drug Control, operate in direct operation of the Ministry of Health.

14. The National Institute of Public Health monitors long-term trends in the occurrence of infectious diseases and processes data concerning the health of physical persons in connection with the prevention of occurrence and propagation of infectious diseases. It is involved in the infectious diseases surveillance system. This system is based on the provision of information from local level through regional level up to national level. The bearing element of the system are the local public health centres and their territorial workplaces, which ensure the receipt of information from diagnosing physicians, validation of reported data, epidemiological examinations and notification of cases and events to the national level. To provide the obligatory notification, record and analyse the occurrence of infectious diseases, the **EpiDat** program is used. The program works with a statistical unit, which is the selected infectious disease, while notifying of both the acknowledge disease and of the suspicion of disease, carriage and death. The individual cases are statistically monitored. Each physician (healthcare facility), who detected any notifiable infectious or parasitic disease, is considered an intelligence unit in the program. The EpiDat program is part of the **National Health Information System**. The notifications of infectious disease received through the EpiDat program form the basis for local, regional, national as well as supranational control of the propagation of infectious diseases. The received basic documents are used to prepare the national reports of the occurrence of infectious diseases for the World Health Organisation (WHO) and the European Centre for Disease Prevention and Control (ECDC).

15. In the event of the occurrence of zoonotic infections, the bodies of public health protection cooperate with the bodies of veterinary administration within the Czech Republic. They notify immediately each other of the occurrence of such infections and the local bodies shall subsequently decide on the type and method of the implementation of epidemic-control measures in the centre of the infection.

16. A facility designed to isolate and treat persons infected with causative agents of highly dangerous infections has been established in the Czech Republic for the case of the occurrence of serious infectious diseases. This healthcare facility is located in the Infectious, Parasitic and Tropical Disease Clinic of the Hospital Na Bulovce in Prague. The National Centre for Isolation and Treatment of Highly Dangerous Infections operates within the clinic. Technical equipment of this infectious workplace provides the required level of biological protection and trained health personnel. The selected employees of the clinic are trained on a long-term basis in the area of specialized care of patients with highly dangerous infections.

## 2. Occupational safety and health and relevant legal regulations

17. Beside the public health protection, the area of the occupational safety and health is also important. These questions, among others, are addressed by **Act No. 262/2006 Coll.**, the Labour Code. This Act contains the requirements for the prevention of danger to life and health at work and the requirements for the provision of personal protective equipment by employer. In addition to the Labour Code, the questions related to the occupational safety and health safety are addressed by **Act No. 309/2006 Coll.**, stipulating further requirements for health and safety at work in labour relations and concerning occupational health and safety protection in activities or services provided outside labour relations (Act on Further Requirements on Occupational Health and Safety).

18. To implement the mentioned acts, the **Government Regulation No. 361/2007 Coll.**, determining conditions for occupational health protection, was issued. This part defines the term "biological agent", divides the biological agents into four groups by infection risk level and defines the minimum measures to protect the health when working with biological agents. The annex to this regulation includes a list of biological agents with their classification.

19. In addition, the **Decree No. 432/2003 Coll.**, in which there are set conditions for job categorization, limit values of biological exposure test indicators, conditions for biological material sampling for biological exposure tests and requirements on reporting employment involving asbestos and biological agents, is also related to the occupational safety and health.

### 3. International cooperation in the case of occurrence of infectious diseases

20. The Czech Republic is involved in the personal infectious diseases notification system on two levels – notifications to the World Health Organisation and notifications directed to the European Union. The key role in preparing such notifications is played by the National Institute of Public Health, specifically its Infectious Disease Epidemiology Department. This department monitors and analyses the epidemiological situation in the area of infectious diseases both on the national and on the international level.

21. On the basis of the revised version of the **International Health Regulations (IHR)** adopted in 2005, the Czech Republic, as the Member State of the World Health Organisation, is obliged to implement IHR (2005). The objective of the regulations is to prevent, protect against, control and respond to the international propagation of diseases in the area of the public health. For the purpose of implementing IHR (2005), the National Action Plan of the Czech Republic was created for the case of the occurrence of an event subject to the International Health Regulations. The requirement defined by IHR (2005) for the capacities for handover and receipt of information about events, which could pose a threat to the public health on the international scale, is covered by the National Contact Point for IHR (2005), which operates within the Ministry of Health.

22. The Czech Republic is involved in the Early Warning and Response System (EWRS) for general threats of infectious diseases. This is a non-public computer system, through which the Member States of the European Union (EU) can send warnings in those cases, which could have an adverse impact on the Member States of the European Union, share information and coordinate mutually the relevant measures.

23. The Czech Republic is also involved in the Rapid Alert Systems (RAS), while the Rapid Alert System for Food and Feed (RASFF) is probably of the most importance for the public health. The RASFF system is used to exchange rapidly information concerning food and feed, which pose a risk danger to human health and which occur on the joint market of countries involved in the system. The system prevents the unhealthy food from being put into circulation and ensures its withdrawal or disposal in the case of its occurrence. To exchange the information about health threats caused by intentional release of biological, chemical, radiological or nuclear substances and materials, the Rapid Alert System for Biological and Chemical Attack and Threats (RAS-BICHAT) is used.

## B. Agriculture

### 1. Overview of relevant legislation from the area of plant physiology

24. The legislative basis in the area of plant protection forms **Act No. 326/2004 Coll.**, on Phytosanitary Care. The Act regulates the rights and obligations of natural and legal persons concerning especially:

- (a) Protection of plants and plant products against harmful organisms,
- (b) Protection against the spread of organisms harmful to plants or plant products into the Czech Republic and their spread on the territory of the Czech Republic, and against the spread of such harmful organisms on the territory of other Member States of the European Union,

(c) Reduction of adverse impact of harmful organisms and use of agents and other means to protect the human health, animals and the environment.

25. Furthermore, the Act defines the function of administration bodies in the area of phytosanitary care, specifies the range and performance of plant physiological supervision and the definition of emergency plant physiological measures, and specifies special plant physiological activities and the requirements for qualification during their performance, compensation of costs of special actions and penalties for breaching the obligations defined by this Act.

26. The implementing regulations to this Act are **Decree No. 215/2008 Coll.**, on measures against spread of organisms harmful to plants and plant products, and **Decree No. 204/2012 Coll.**, on technical requirements for reference laboratory verification.

#### *State Phytosanitary Administration*

27. The governmental administration in the area of phytosanitary care is carried out by the Ministry of Agriculture and the State Phytosanitary Administration. The State Phytosanitary Administration is governmental administration for the phytosanitary care subordinate to the Ministry of Agriculture. It is the central organisation for plant protection according to the International Plant Protection Convention and the body responsible for the performance of operations in the area of phytosanitary care according to special regulation of the European Communities. Pursuant to the provisions of Act No. 326/2004 Coll., the State Phytosanitary Administration operates mainly in the following areas:

- (a) Protection of plants and plant products,
- (b) Measures against spread of harmful organisms, or invasive harmful organisms,
- (c) Phytosanitary supervision and control in the matters related to phytosanitary care including definition of emergency plant physiological measures, handling of crisis situations and imposition of penalties.

## **2. Overview of relevant legislation from veterinary area**

28. The main pillar of the legislation in the area of veterinary care is **Act No. 166/1999 Coll.**, on Veterinary Care, (the Veterinary Act). The Act lays down the requirements for veterinary care for breeding and health of animals and for animal products, regulates the rights and obligations of individuals and legal entities, system, competence and power of the bodies carrying out the governmental administration in the area of veterinary care as well as some special veterinary activities and their performance.

29. The implementing regulations to this Act are:

- (a) **Decree No. 296/2003 Coll.**, on animal health and its protection, on transfer and transportation of animals and on authorization and qualification for the performance of some special veterinary activities (in addition, the Decree addresses the protection against zoonotic infections and defines the details for location and keeping of animals in isolation),
- (b) **Decree No. 299/2003 Coll.**, on measures to prevent and fight off zoonotic infections (the Decree deals with the measures to fight off animal infections and prevent their spread, defines the method and time of notifying of such infections, addresses animal vaccination and lays down the requirements for national reference laboratories),
- (c) **Decree No. 298/2003 Coll.**, on national reference laboratories (the Decree regulates the requirements for material equipment and staffing of national reference laboratory and reference laboratory, and addresses the questions related to specialization,

organization and methods for the activity of national reference laboratories and reference laboratories),

(d) **Decree No. 329/2003 Coll.**, on information system of the State Veterinary Administration,

(e) **Decree No. 528/2004 Coll.**, on requirements for national reference laboratories and reference laboratories in the area of activities covered by Act on the Central Institute for Supervising and Testing in Agriculture (the Decree regulates the requirements for material equipment and staffing and for specialization, organization and methods for the activity of the national reference laboratory of the Central Institute for Supervising and Testing in Agriculture and other national reference laboratories and reference laboratories).

#### *Veterinary Administration Bodies*

30. The veterinary administration bodies are the **State Veterinary Administration of the Czech Republic** and the Institute for State Control of Veterinary Biologicals and Medicines.

31. The State Veterinary Administration of the Czech Republic participates in the performance of governmental administration in the matters related to veterinary care. Its responsibility is the veterinary protection of the state territory of the Czech Republic, monitoring and maintenance of favourable situation in the area of infectious situation of animals, protection of consumers against potential unhealthy products of animal origin, protection of the comfort of animals and protection against cruelty to animals.

32. The part of the State Veterinary Administration of the Czech Republic are the **State Veterinary Institutes**, which perform the laboratory diagnostics in the area of demonstration of infectious and non-infectious diseases of animals and laboratory diagnostics in the area of health-related suitability of raw materials and food of animal and plant origin, feed and water. These institutes operate the network of national reference laboratories and reference laboratories.

33. The State Veterinary Administration of the Czech Republic has its own information system for the support and control of state veterinary supervision (the Information System of the State Veterinary Administration of the Czech Republic). The system receives information and data collected both within the individual workplaces in the Czech Republic and from international systems. In addition, the information system contains the register of zoonotic infections. The register records data related to the fight off outbreaks of infections of free-living animals, livestock and interest animals, and is adopted from the records of infections of the World Organisation for Animal Health (OIE) and from the Animal Disease Notification System, ADNS) in the European Union. The information system receives also data from the EU RASFF system.

34. For the case of the occurrence of dangerous infections or emergency events, the State Veterinary Administration of the Czech Republic established the Crisis Centre of the State Veterinary Administration of the Czech Republic in Brno.

## **C. Environmental protection**

### **Overview of relevant legislation from environmental protection area**

35. The main pillar of the legislation in the area of environmental protection in relation to BTWC is **Act No. 78/2004 Coll.**, on the use of genetically modified organisms and genetic products. In compliance with the laws of the European Communities, it defines the

rights and obligations of persons and the function of administration bodies in handling of genetically modified organisms (GMO) and genetic products.

36. The implementing regulation to this Act is **Decree No. 209/2004 Coll.**, on detailed conditions for the use of genetically modified organisms and genetic products (in addition, the Decree defines particulars and procedures for risk assessment, requirements for enclosed areas and protective measures for the individual risk categories for enclosed handling of genetically modified organisms, the method and scope of documentation keeping, and particulars for the emergency plan).

*Ministry of the Environment*

37. The central body of the governmental administration and the body of the top state supervision in the area of the environment is the Ministry of the Environment. The activities associated with genetically modified organisms are dealt with by the Genetically Modified Organisms Department. This department establishes the **Czech Commission for Handling of Genetically Modified Organisms and Generic Products**, which addresses special questions in the area of handling genetically modified organisms and products containing genetically modified organisms. The important activity of the Commission is to monitor the scientific and technological development. On the basis of the development, provides the Ministry of the Environment with special opinions on specific questions or materials including international information exchange and recommends the relevant measures to the Ministry.

38. The function of the special body of governmental administration performing the supervision and respecting the legal standards in the area of the Environment is the Czech Environmental Inspectorate.

## Annex II

### Update on the Compliance Report: Canada and BTWC

In accordance with the concept paper detailing a broader approach to assessing compliance submitted by Canada at the 2010 Meeting of States Parties (BWC/MSP/2010/WP.3/Rev.1), this annex provides an update of newly notified and approved activities of contained use in Canada from the period of August 2011 to August 2012. This annex also contains an Addendum of clarifications, modifications, and/or minor additions to Annex I (Canada) of the National Implementation of the BTWC: Compliance Assessment document submitted by Canada and Switzerland in 2011 (BWC/MSP/2012/MX/WP.17).

#### A. Newly notified and approved activities of contained use in Canada for the period from August 2011 to August 2012.

##### Program Compliance Monitoring and Enforcement Metrics (Department of Foreign Affairs and International Trade – Trade and Controls Technical Barriers Bureau)

*Summary of export permit of Australia Group-controlled items in 2012.*

<i>Year</i>	<i>Number of Export Permits for AG-controlled goods</i>	<i>Number of Export Permits for Biological Agents</i>	<i>Number of Permits currently active (October 5 2012)</i>
2012	40	0	89

#### B. Importation of Animal Pathogens

##### Program compliance Monitoring and Enforcement Metrics (Canadian Food Inspection Agency – Office of Biohazard Containment and Safety)

*Summary of Import and Certification Activity between July 28, 2011 - October 15, 2012*

##### Permits and letters

548	Permits issued (1 for risk group 4)
30	Transfer requests granted (0 for risk group 4)
136	"Non-pathogenic" courtesy letters issued for risk group 1

##### Laboratory Compliance (CL2)

503	Areas self-certified as compliant (through satisfactory completion of an inspection checklist)
9	Areas where the self-certification process does not indicate compliance
8	CL2 On-site Inspections

##### Laboratory Compliance (CL3 and Prion; CL4; AQC2; AQC3; PPC2A; PPC3)

6	High containment on site inspections
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## C. Importation of Human Pathogens

### Program compliance Monitoring and Enforcement Metrics (Public Health Agency of Canada – Pathogen Regulation Directorate)

*Summary of Import and Certification Activity between October 1, 2011 –September 30, 2012*

<b>Permits and letters</b>	
1080	Permits issued (1 for risk group 4)
65	Transfer requests granted (0 for risk group 4)
419	"Non-pathogenic" courtesy letters issued for risk group 1
0	Refusal / denial letters
<b>Laboratory Compliance (CL2)</b>	
783	Areas self-certified as compliant (through satisfactory completion of an inspection checklist)
0	Areas where the self-certification process does not indicate compliance
2	CL2 On-site Inspections
<b>Laboratory Compliance (CL3 and Prion; CL4; AQC2; AQC3; PPC2A; PPC3)</b>	
17	High containment on site inspections
87	Remote verifications (re-certification of CL3 laboratories)
51	Pre-certification requests (review of architectural drawings, performance and verification testing reports and standard operating procedures)
<b>Other</b>	
3	Enforcement activities for e.g. importation without valid permit, transferring imported material without approval, etc.
7	Accidents and incidents reported (potential laboratory acquired infections)

## D. Addenda

This *Addendum* contains clarifications, modifications, and/or minor additions to the National Implementation of the BTWC: Compliance Assessment document submitted by Canada and Switzerland, as follows:

### Page 8, section 1 – Introduction

2011: "This report covers the period January 2007 to August 2011"

2012: "This report covers the period of January 2007 to August 2012."

### Page 13, subsection 1.2.1.1.4 – General Trends

*Section on Chlamydia:*

2011: "Reported rates of chlamydia have been..."

2012: “Rates of reported cases of chlamydia have been...”

2011: “The observed increase in reported chlamydia rates in 2008 is in line with the longer-term trend.”

2012: “The observed increase in reported chlamydia rates in 2010 is in line with the longer-term trend,”

*Section on Hepatitis B:*

2011: “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 practises...”

2012: “In recent years, rates of reported cases of hepatitis B in Canada have been stable, following an increase in 2008 that was largely driven by a change in reporting practices in Alberta...”

2011: “...from 0.97 per 100,000 in 2005 to 0.49 per 100,000 in 2010.”

2012: “...from 0.97 per 100,000 in 2005 to 0.40 per 100,000 in 2010.”

*Section on Hepatitis C:*

2011: “Reported rates of hepatitis C have decreased since 2005.”

2012: “Rates of reported cases of hepatitis C have decreased since 2005.”

*Section on Infectious Syphilis:*

2011: “In recent years, sustained high rates of infectious syphilis have been documented throughout much of the country, suggesting that syphilis is once again becoming endemic in much of Canada.”

2012: “In recent years, high rates of reported cases of infectious syphilis have been documented throughout much of the country, suggesting that syphilis is once again becoming endemic in much of Canada.”

**Page 14, subsection 1.2.2.3 – Annual notifiable diseases (for laboratories only)**

2011: “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.”

2012: “Annually notifiable diseases are additional diseases for which Canada must also submit a six-month report to the World Organisation for Animal Health (OIE) indicating their presence or absence within Canada.”

**Page 14, subsection 1.2.2.4 – Exceptional epidemiological events**

2011: “Between 2007 and present, Canada has had 11 notifications to the OIE under this provision as follows”

2012: “Between 2007 and present, Canada has had 14 notifications to the OIE under this provision as follows:”

2012: Addition of the following: “2012 – 3 outbreaks of Infectious salmon anaemia (1 outbreak was a first occurrence of the disease in a new area and 2 outbreaks were associated with a new pathogen strain)”

**Page 23, subsection 3.4.3.3 – Scope (Health of Animals Act)**

The following sentence was present in the 2011 document, and has been deleted from the 2012 document: “With the Regulations, the Minister is empowered to exempt persons dealing with veterinary biologics from the requirements of the Regulations.”

**Page 24, subsection 3.4.4.3 – Scope (Plant Protection Act)**

2011: “The Act has controls over both importation and exportation of plant pests (i.e. plant pathogens, nematodes, insects etc).”

2012: “The Act has controls over the importation, exportation and domestic movement of plant pests (i.e. plant pathogens, nematodes, insects etc).”

**Page 24, subsection 3.4.4.4 – Associated Penalties (Plant Protection Act)**

2011: “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.

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.”

2012: “Persons who contravene provisions of the Plant Protection Act or the regulations, refuse or neglect to perform duties imposed by or under the Plant Protection Act or the regulations, fail to comply with notices communicated under certain sections of the Plant Protection Act or the regulations, or contravene prohibitions or restrictions imposed under certain sections of the Plant Protection Act, are:

- (a) Guilty of an offence punishable on summary conviction, or an indictable offence; and
- (b) Liable to a fine and/or to imprisonment.

Furthermore, certain offences under the Plant Protection Act and the regulations are tied to the system of administrative monetary penalties established by the Agriculture and Agri-Food Administrative Monetary Penalties Act. Offences designated as violations under the Agriculture and Agri-Food Administrative Monetary Penalties Regulations are subject to administrative monetary penalties.”

**Page 25, subsection 3.4.5.2 – Purpose (Export and Import Permits Act)**

2011: 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.

2012: The Export and Import Permits Act (EIPA) provides the Minister of Foreign Affairs wide discretionary powers to control the flow of goods and technology 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 ensuring that exports of military and strategic goods and technology:

- (a) do not cause harm to Canada or its allies;
- (b) do not undermine national or international security;
- (c) do not contribute to national or regional conflicts or instability;
- (d) do not contribute to the development of nuclear, biological or chemical weapons of mass destruction, or of their delivery systems;
- (e) are not used to commit human rights violations; and are consistent with existing international and domestic sanctions.

**Pages 25-26, subsection 3.4.5.3 – Scope (Export and Import Permits Act)**

2011: “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.”

2012: “The EIPA sets out the purposes for including items or countries on these lists. The ICL generally comprises a list of goods, including certain chemical, armaments, steel products, food and textiles, which, with certain exceptions require an import permit in order to be lawfully imported into Canada. The ECL is a list of goods and technology, mostly comprised of military and strategic items, which, with certain exceptions to the United States, require an export permit in order to be lawfully export or transferred from Canada. The ACL is a list of countries for which export permits are required to export any and all goods and/or technology.”

2011: “...dual-use biological agents...”

2012: “...biological agents...”

2011: “...have been implemented in Canada on the Export Control List as Group 7.”

2012: “...have been implemented in Canada on the ECL as Group 7.”

**Page 26, subsection 3.4.5.4 – Associated Penalties (Export and Import Permits Act)**

2011: “As described in section 19 of the EIPA, every person who contravenes any provision of this Act or the regulations...”

2012: “As described in section 19 of the EIPA, every person who contravenes any provision of the EIPA or its regulations...”

**Page 27, subsection 3.5.1.4 – Associated Penalties (Canadian Environmental Protection Act)**

2011: “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...”

2012: “Additionally, any individual who provides false or misleading information with respect to any matter covered by the CEPA or its regulations is subject to the following penalties. Knowingly providing false or misleading information is considered a most serious offence, section 272(1)(k), and therefore, an individual is liable on conviction on indictment...”

2011: “...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.”

2012: “...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. Negligently providing false and misleading information is considered an ‘other offence’, and for the first offence for an individual, section 272(1)(g) on conviction on indictment, to a fine of not more than \$100,000; and on summary conviction, to a fine of not more than \$25,000.”

2011: “...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.”

2012: “...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 or a fine as per section 274(1).”

**Pages 28-29, subsection 3.5.2.2 – Purpose (Department of Public Safety and Emergency Preparedness Act, and the Emergency Management Act)**

2011: “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. “

2012: “The purpose of the Department of Public Safety and Emergency Preparedness Act (DPSEPA) was to establish the Department of Public Safety and Emergency Preparedness. The Emergency Management Act (EMA) sets out the general responsibilities of federal ministers in relation to “emergency management matters.

2011: “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...”

2012: “When the DPSEPA came into force on April 4, 2005 it specifically enabled the Minister of Public Safety to co-ordinate the activities...”

2011: “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. 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...”

2012: “On the coming into force of the EMA on August 3, 2007, the Minister of Public Safety was given the responsibility for exercising leadership relating to emergency management in Canada...”

2011: “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.”

2012: “To enable a cohesive Canadian response, the Government of Canada established Government Operations Centre as the national focal point for emergency operations, and it will be used to coordinate efforts with the U.S. Department of Homeland Security and its Federal Emergency Management Agency.”

2012: Addition of the following paragraph “The DPSEPA, in combination with the EMA, 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.”

2011: “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...”

2012: “In January 2011, Federal, Provincial, and Territorial Ministers responsible for Emergency Management approved an Emergency Management Framework for Canada (second edition). These are cornerstone documents for...”

2012: Correction of typo “January”.

2011: “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...”

2012: “The Strategy and its supporting five-year period Action Plan guide policy and decision makers to better prevent/mitigate, prepare for, respond to and recover from CBRNE events. In addition, this Strategy and Action Plan is currently in Phase 2 of implementation, and takes into account policy priorities, plans and operations, and science and technology investments. This strategy is consistent with...”

**Page 30, subsection 3.5.1.2 – Purpose (Pest Control Products Act)**

2011: “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.”

2012: “The purpose of the Pest Control Products Act is to regulate products used for pest control to protect the environment, and human health and safety. The current Act entered into force June 8, 2006. It replaced a previous Act that had been in force since November 25, 1972, and which was designed to control products used to control pests of animals and plants, in both the environment and in agriculture.”

2011: “The *Pest Control Products Act*’s impact on biosecurity and non-proliferation is found in its regulations.”

2012: “The impact on biosecurity and non-proliferation is found more in the *Pest Control Products Regulations*.”

2011: “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...”

2012: “The controls under the Act and the Regulations are therefore important...”

2011: “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.”

2012: “The Act applies to products within Canada that are manufactured, represented, distributed, or used as a means for directly or indirectly controlling, destroying, attracting, or repelling animal or plant pests. Subject to specified exceptions, the Act prohibits various activities (including possession) of a pest control product unless it has been registered with the Government of Canada. The Act also prohibits the storage, import, export, and distribution of a pest control product that is not packaged as required.”

2011: “Within the Act’s regulations are controls on the use of live microbial agents in pest control product”

2012: “The Regulations define a “microbial agent” as a pest control product whose active ingredient is a microorganism. The Regulations provide limited exemptions for research that involves the use of a microbial agent provided the research meets certain tests – including that the research does not involved aerial application, and that the microorganism is indigenous to the area where it is intended to be used.”

#### **Pages 30-31, subsection 3.5.4.4 – Associated Penalties (Pest Control Products Act)**

2011: “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...”

2012: “Under section 69 of the Act, a contravention of the Regulations is an offence, and the offender is liable...”

2011: “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.”

2012: “Under section 68(1), a contravention to the Act is a separate offence if it causes 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. The potential penalties are the same as described above. Under section 68(3), it is a separate offence to contravene the Act or the Regulations and willfully or recklessly cause the same risks or harm referred above. The offender is liable on summary conviction to a fine of not more than \$300,000 or 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.”

#### **Pages 31-32, subsection 3.5.5.3 – Scope (Fertilizers Act)**

2011: “Pursuant to the Act, most supplements and some fertilizers require registration from the Crop Inputs Division of the Canadian Food Inspection Agency.”

2012: “Pursuant to the Act, most supplements and some fertilizers require registration from the Field Crops and Inputs Division of the Canadian Food Inspection Agency.”

2011: "...and properly-labelled to avoid misrepresentation in the marketplace and fraud."

2012: "...and properly-labelled to avoid misrepresentation in the marketplace and consumer fraud."

2011: "...efficacy and labelling standards is verified through pre-market assessment or marketplace monitoring activities."

2012: "...efficacy and labelling standards is verified through pre-market assessment and/or marketplace monitoring activities."

2012: Addition of the following paragraph "The CFIA currently administers standards for trace metals, dioxins and furans as well as pathogens. The latter consist of thresholds for indicator organisms (Fecal coliforms and Salmonella) to determine the effectiveness of the treatment and processing of fertilizers and supplements."

2012: Addition of the following paragraph "The Fertilizer program administration and scope is currently undergoing change. As of April 2013 the CFIA will no longer regulate fertilizer and supplement efficacy and quality. Safety standards and requirements will remain unchanged. "

**Page 32, subsection 3.5.6.2 – Purpose (Hazardous Products Act)**

2011: "...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*."

2012: "...including amendments in 1987 to implement the Workplace Hazardous Materials Information System (WHMIS) with the addition of Part II and consequential amendments in 2010 as a result of the Canada Consumer Products Safety Act (CCPSA) when it came into force in 2011. The HPA does not apply to the sale or importation of certain types of materials, substances and products, and including, explosives within the meaning of the *Explosives Act*; cosmetics, devices, drugs or foods within the meaning of the *Food and Drugs Act*, and consumer products as defined in section 2 of the *CCPSA*."

**Page 33, subsection 3.5.6.3 – Scope (Hazardous Products Act)**

2011: "...material or substance specified by regulations to be included in certain classes – one of which is Poisonous and Infectious Material."

2012: "...material or substance specified by regulations made pursuant to paragraph 15(1)(a) to be included in any of the classes listed in Schedule II– one of which is Poisonous and Infectious Material."

2011: "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. "

2012: "Part II of the *Hazardous Products Act* was enacted in 1987 to require the provision of material safety data sheets (MSDSs), labelling of containers of hazardous materials upon their sale or importation into Canada. WHMIS also includes a mechanism for ruling on claims for exemption from disclosure of confidential business information on MSDSs and labels as well as appeals to these rulings. WHMIS is a national system to provide information on hazardous materials used in the workplace recognizing the interests of

workers, employers, suppliers and regulators balancing workers' right-to-know with industry's right to protect confidential business information.”

2011: “The Regulations include criteria for biohazardous infectious material under Division 3 of Class D (Poisonous and Infectious Material).”

2012: “The Regulations include criteria for biohazardous infectious material under Division 3 of Class D (Poisonous and Infectious Material) which is an organism that has been shown to cause disease or to be a probable cause of disease in persons or animals and the toxins of that organism.”

2011: “There is an allowance to disclose less information on the label than is normally required...”

2012: “There is an allowance to disclose less information on the label than what is normally required...”

**Page 35, subsection 3.5.8.2 – Purpose (Transportation of Dangerous Goods Act)**

2011: “The purpose of the *Transportation of Dangerous Goods Act* is to promote public safety during the importation, handling, or transport of dangerous goods.”

2012: ” The purpose of the *Transportation of Dangerous Goods Act* is to promote public safety during the importation, handling, offering for transport, or transport of dangerous goods.”

2011: The Act is criminal law and applies to all modes of transport (road, rail, sea, or air).”

2012: “The Act is criminal law and applies to all modes of transport (road, rail, marine, or air).”

**Please note, the change of term from “sea” to “marine” transportation also occurs in subsection 3.5.8.3 –Scope, and will not be repeated in this *Addendum*.**

**Page 35, subsection 3.5.8.3 – Scope (Transportation of Dangerous Goods Act)**

2012: Addition of the following text “The federal government leads the development of dangerous goods regulations for Canada. The federal Transportation of Dangerous Goods Regulations (TDGR), adopted by all provinces and territories, establishes the regulatory requirements for the importing, handling, offering for transport and transport of dangerous goods by all modes within Canada.”

2011: “The legislative provisions on which this new prevention and response security program will be based include...”

2012: “The legislative provisions on which this new prevention and response security program is based include...”

**Page 50, subsection 4.1.1 – Legislative Authority (Export and Import Permits Act)**

2011: “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”

2012: “Export and import permits are issued under the authority of the *Export and Import Permits Act (EIPA)*. The EIPA authorizes the government to control the import and export of certain goods and technology for various reasons, including the implementation of an intergovernmental arrangement or commitment.”

**Page 50, subsection 4.1.1 – Overview of the Program (Export and Import Permits Act)**

2011: “An export permit is required before an item included in the Export Control List (ECL) may be exported from Canada...”

2012: “An export permit is required before an item included in the Export Control List (ECL) can be lawfully exported from Canada...”

2011: “Nuclear and nuclear dual-use material and equipment, certain arms (automatic firearms), miscellaneous wood and wood products, various food products are among some of the items requiring permits for export to the United States.”

2012: “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.”

2011: “This requirement enables Canada to meet international commitments...”

2012: “This export permit requirement enables Canada to meet international commitments...”

2011: “At present only Belarus and Burma (Myanmar), and North Korea are on the ACL.”

2012: “At present only Belarus and North Korea are on the ACL.”

2011: “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).”

2012: “Responsibility for the administration on Canada’s export control regime for all military and strategic goods and technology included on the ECL (all items excluding ECL item numbers 5101, 5102, 5103, 5104, 5201, 5202, and 5204) rests with the Export Controls Division of the Trade Controls and Technical Barriers Bureau.”

2011: “Group 7 of the ECL provides a Chemical and Biological Weapons Non-Proliferation List which outlines goods whose export is...”

2012: “Group 7 of the ECL identifies the Chemical and Biological Weapons Non-Proliferation List which outlines goods and technology whose export is...”

**Page 50-51, subsection 4.1.4 – Program Compliance Monitoring and Enforcement Metrics (Department of Foreign Affairs and International Trade – Trade and Controls Technical Barriers Bureau)**

2011: “Canada has issued a total of 220 export permit of Australia Group-controlled goods since January 1st, 2007.”

2012: “Canada has issued a total of 260 export permit of Australia Group-controlled items since January 1st, 2007.”

**Please note, the change of term from “goods” to “items” also occurs column 1 of the table in this section.**

**Page 52, subsection 4.2.1.3.1 – Importation of Animal Pathogens (Canadian Food Inspection Agency – Office of Biohazard Containment and Safety)**

2011: “The Animal Pathogen Import Program (APIP) within OBSC is responsible...”

2012: “The Animal Pathogen Import Program (APIP) within OBSC is responsible...”

2011: “All inspections are announced.”

2012: “The majority of inspections are announced.”

**Page 54, subsection 4.2.1.4 – Compliance and Enforcement (Canadian Food Inspection Agency – Office of Biohazard Containment and Safety)**

2011: "...APIP has the following possible tools available to them..."

2012: "...APIP has the following enforcement tools available to them..."

## Annex III

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

1. Newly notified and approved activities of contained use in Switzerland of the period from 1 December 2011 to 31 October 2012<sup>1</sup>.

#### I. Permits and notifications

<i>Notifications</i>	
Activities of class 1	73
Activities of class 2	162
<i>Autorisations<sup>2</sup></i>	
Activities of class 3	8
Activities of class 4	3

#### II. Compliance monitoring activities

2. The decentralised Biosafety control system in Switzerland complicates the gathering of information on inspection activities. Therefore, only confirmed inspections are cited below. The actual number of inspections is certainly higher.

<i>Biosafety level</i>	<i>Number of inspections (announced)</i>	<i>Number of inspections (unannounced)</i>
BSL1	5	-
BSL2	37	10
BSL3	2	-
BSL4	3	-

#### III. Failures to comply with Swiss biosafety standards

- Disposal of infectious BSL2 waste without permit of the competent authority

<sup>1</sup> Source: Contained Systems: Public register, <http://www.ecogen.ch/ecogen/Forms/Register/RegisterSearch.aspx>

<sup>2</sup> Only approved activities. Submitted license applications that have not yet been approved are shown in the public register as well, but are not cited here.

- Insufficient labelling of infectious BSL2 waste
  - Improper intermediate storage of infectious BSL2 waste
  - Lack of Standard operating procedures for managing incidents BSL2 production facility
  - State of the art of biosafety cabinet class II (BSCII) not attained
  - Lack of Standard operating procedures for the use of BSCII
  - Improper cleaning of incubators
  - Lack of contact addresses on relevant equipment
  - Test-of-function not performed on autoclaves
  - Unsuccessful inactivation of BSL2 waste in animal rooms
  - Lack of validation of inactivation procedures
  - Improper access control in BSL2 Laboratories
  - Insufficient cleaning of lab clothes
  - Improper use of the Biohazard sign (not required in BSL1 facilities)
  - Handling of BSL2 agents without BSCII (requires authorisation by the competent authority)
-