Implementing Canada's Obligations Under the Prospective Protocol to the Biological and Toxin Weapons Convention: Planning for a National Authority

Marc Miller

International Security Research and Outreach Programme
Non-Proliferation, Arms Control and Disarmament Division

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Department of Foreign Affairs and International Trade
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TABLE OF CONTENTS

PREFACE

The Department of Foreign Affairs and International Trade commissioned a study to examine the constitutional and legal challenges inherent in establishing a National Authority for the Biological and Toxin Weapons Convention. This report is the product of that study.

The views expressed in this report are those of the author, and do not necessarily reflect the views or positions of the Department of Foreign Affairs and International Trade or the Government of Canada.

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EXECUTIVE SUMMARY

Canada is currently involved in the multilateral negotiation of a verification Protocol for the *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons*. The effectiveness of the prospective Protocol depends in large part on the degree of intrusiveness of its verification regime. This will include, among other things, declarations, visits, and inspections of relevant sites in Canada. However, a balance must be struck between the need for in-depth verification and the protection of national security, commercial business information and the right of industry to engage in licit research and development, as well as other business activities in this field. Moreover, in order to ensure implementation of the compliance mechanism, the Protocol requires the creation of a National Authority to serve as a focal point for liaison between the States Parties and the Organisation provided for under the Protocol. These aspects are examined in this report.

Within Canada, many challenges will exist with respect to the implementation of the Protocol. On a purely legal level, some concern exist as to the constitutionality of regulating business activities by the federal parliament. Nevertheless, it has been argued that legislation enacted pursuant to the Protocol would be upheld as a proper use of the federal parliament's criminal law power. More significant concerns reside in the types of visits provided for under the Protocol and their potential infringement on the *Charter* provision guaranteeing against unreasonable searches and seizures.

The protection of commercially sensitive information is a priority for Canada and there are insufficient provisions in the Protocol to remedy loss suffered from revelation of, for example, a trade secret. Given the state of the industries most likely to be affected by the inspection mechanism, the loss of a trade secret could spell disaster for, as an example, a cutting-edge biotechnology company. However, this concern must not be overstated, as many of the reporting requirements generally require a reporting of activities rather than in-depth probing into scientific processes. Moreover, there are many provisions in the Protocol providing for the maintenance of confidentiality including the right for a State Party to manage the access of the inspection team to sensitive areas.

The National Authority that will be created pursuant to the Protocol will face many challenges, the first of which will be to ensure that the verification mechanism is properly implemented within Canada. To that end, several measures must be taken; they will include informing the relevant industries of their obligations, collecting the proper declarations, and assisting potential international inspections. The dissemination and gathering of declarations will constitute a primary task. The National Authority must also assist in the international visits and inspections. In view of this, proper composition and delineation of tasks have been emphasised by this report. It must also maintain relationships with other Federal institutions such as Health Canada and DND that have an interest and expertise in the subject matter of the Protocol. Moreover, not only must the National Authority enforce the parts of the Protocol for which it is responsible, but also foster compliance by undertaking outreach programmes and providing relevant and up-to-date information

via important media sources. Finally, as a focal point for activities relevant to the Protocol, the National Authority for Canada must play an important role at the international level, given Canada's privileged position in the international community, especially in the area of disarmament.

RÉSUMÉ

Le Canada participe actuellement à la négociation multilatérale d'un protocole de vérification pour la *Convention sur l'interdiction de la mise au point, de la fabrication et du stockage des armes bactériologiques (biologiques) ou à toxines*. L'efficacité du futur Protocole dépend en grande partie du degré d'intrusion de son régime de vérification. Ce qui comprendra, entre autres, des déclarations, des visites et des inspections des sites appropriés au Canada. Cependant, il faut trouver un juste milieu entre la nécessité d'une vérification approfondie et la protection de la sécurité nationale, des renseignements sur les affaires commerciales et le droit de l'industrie d'entreprendre des recherches et du développement licites, ainsi que d'autres activités commerciales dans ce domaine. De plus, afin d'assurer l'application du mécanisme de conformité, le futur protocole exige la création d'une autorité nationale qui servira de centre de liaison entre les États parties et l'Organisation prévue en vertu du Protocole. Ces aspects sont étudiés dans le présent rapport.

Le Canada fait face à de nombreux défis concernant la mise en oeuvre du Protocole. D'un point de vue purement juridique, il existe certaines préoccupations concernant la constitutionnalité d'une réglementation des activités commerciales par le Parlement fédéral. Néanmoins, on a allégué qu'une loi promulguée en exécution du Protocole serait maintenue puisqu'elle constituerait un emploi correct du droit criminel par le Parlement fédéral. Les préoccupations les plus importantes résident dans les genres de visites prévues en vertu du Protocole et leur transgression possible de la disposition de la Charte garantissant contre les fouilles et les saisies abusives.

La protection des informations commercialement sensibles est une priorité pour le Canada, et il n'existe pas assez de dispositions dans le Protocole pour remédier à une perte subie par suite de la révélation, par exemple, d'un secret commercial. Compte tenu de l'état des industries les plus susceptibles d'être touchées par le mécanisme d'inspection, la perte d'un secret commercial pourrait être désastreuse, par exemple, pour une entreprise de biotechnologie d'avant-garde. Cependant, cette préoccupation ne doit pas être exagérée, puisque bon nombre des exigences relatives aux déclarations nécessitent généralement une déclaration des activités plutôt qu'un examen approfondi des processus biologiques. De plus, il existe de nombreuses dispositions dans le Protocole prévoyant le maintien de la confidentialité, notamment le droit pour un État Partie de limiter l'accès de l'équipe d'inspection aux secteurs sensibles.

L'autorité nationale qui sera créée en vertu du Protocole fera face à de nombreux défis, dont le premier sera de veiller à ce que le mécanisme de vérification soit correctement mis en application au Canada. À cette fin, plusieurs mesures doivent être prises; il faudra notamment informer les industries visées de leurs obligations, recueillir les déclarations requises et prêter une assistance aux éventuelles inspections internationales. La diffusion et la collecte des déclarations constitueront une tâche fondamentale. L'autorité nationale doit également prêter son concours aux visites internationales et aux inspections. À cet égard, le présent rapport insiste sur la composition et la description appropriées des tâches. L'autorité nationale doit également entretenir des relations avec d'autres institutions fédérales, telles que Santé Canada et le ministère de la Défense, qui ont un intérêt et une expertise dans le domaine couvert par le Protocole. Par ailleurs, en plus de faire

respecter les parties du Protocole dont elle est chargée, l'autorité doit aussi favoriser la conformité en entreprenant des programmes de sensibilisation et en fournissant des renseignements pertinents et à jour par l'entremise d'importantes sources de média. Finalement, comme point central des activités ayant trait au Protocole, l'autorité nationale du Canada doit jouer un rôle important à l'échelle internationale, étant donné la position privilégiée qu'occupe le Canada dans la communauté internationale, particulièrement dans le domaine du désarmement.

IMPLEMENTING CANADA'S OBLIGATIONS UNDER THE PROSPECTIVE PROTOCOL TO THE BIOLOGICAL AND TOXIN WEAPONS CONVENTION: PLANNING FOR A NATIONAL AUTHORITY

1. INTRODUCTION

The threat from weapons of mass destruction has challenged humanity during the latter part of the twentieth century. One aspect of this burgeoning threat is the potential use of biological toxins and agents as a means to such mass destruction. International efforts have sought to restrict the use of biological weapons in war, together with the development, production and stockpiling of biological and toxin weapons. Canada is currently involved in negotiations for a Protocol[1] to ensure compliance with the *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons*.[2] The effectiveness of this Protocol depends in large part on the degree of intrusiveness of the verification regime. This would include, among other things, declarations, visits, and inspections of relevant sites in Canada. However, a balance must be struck between the need for in-depth verification and the protection of national security, commercial business information and the right of industry to engage in licit research and development, as well as other business activities in this field. Moreover, in order to ensure implementation of the compliance mechanism, the prospective protocol requires the creation of a National Authority to serve as a focal point for liaison between the States Parties and the Organisation provided for under the Protocol.

This report attempts to address a series of issues which would be raised subsequent to a Canadian ratification of the Protocol. First, it offers a brief background of the negotiations that have led to the present rolling text and summarises both the Protocol and the BTWC. Second, the report then addresses the constitutional repercussions of ratifying such a type of convention as well as enacting laws to implement it. In this section, two potential challenges to implementation legislation are presented: the distribution of powers, and the issue of constitutional search and seizures. In its third section, the report then focuses on the degree to which the subject matter germane to the Protocol is presently regulated through a survey of the relevant federal legislation. This survey serves two purposes: first it shows that the subject matter warrants serious attention even when used for peaceful purposes, and second, it demonstrates the degree of already existing regulation concerning potentially affected industries. It also offers considerable insight into the tasks to be performed by a National Authority, together with the implementing instruments with which such an

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[1] Currently a rolling text entitled *Rolling Text of a Protocol to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Ad Hoc Group 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, 28 June- 23 July 1999 Geneva BWC/AD HOC GROUP/46 [hereinafter referred to as the Protocol].

[2] 10 April 1972, U.N.J.Y.B. (United Nations Juridical Year Book) 118 [hereinafter BTWC or Convention].

Authority might coordinate its activities. The discussion also sets the stage for an examination of the protection of confidential business information and the process necessary for the creation of a National Authority for the Protocol. Since the Protocol requires declarations, visits, and inspections of industries within Canada, the protection of their legitimate business secrets will constitute a priority issue. The complexities of this issue are explored in this report and some solutions are presented. The fourth part of this report concentrates on the creation of a National Authority for the Protocol to the BTWC. To this end, it analyses the issues faced by the *Chemical Weapons Convention*[3] National Authority and incorporates the lessons learned by the latter in order to establish an efficient National Authority for the BTWC Protocol. This part also describes the potential shape for such a National Authority by examining its likely tasks and determining the degree of coordination between it and existing regulatory bodies necessary for it to discharge its duties. This section argues that an active, as opposed to reactive, National Authority is necessary for Canada, both at the domestic and international levels.

2. BACKGROUND TO THE CURRENT PROTOCOL

The irony of governing methods of warfare is inescapable. Nevertheless, the idea that warfare should be conducted subject to certain rules can be traced back to the restrictions on poisoned weapons by the Greeks and the Romans and the Hindu Codes of the Laws of Manu.[4] More recently, the 1868 *Declaration of St-Petersburg* regarding explosive projectiles and the 1899 *Hague Declaration* concerning Asphyxiating Gases provide further examples of the desire to limit unconscionable behaviour in war.[5] *The Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare* (Geneva Protocol) was signed in 1925. It prohibited the use of chemical and bacteriological weapons when it entered into force on 8 February 1928 and was ratified by Canada on 6 May 1930.

The emergence of such treaties stems from the desire to conduct warfare in a humanitarian fashion and in a way which does not shock the conscience, something which has resulted in the emergence of a customary principle prohibiting the use of warfare causing unnecessary suffering.[6] Propelled by the horrors of the First World War, the Geneva Protocol prohibited the use of such

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[3] *Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction*, 13 January 1993, 32 I.L.M. (International Legal Materials) 800 [hereinafter *Chemical Weapons Convention* or CWC].

[4] A. Roberts & R. Guelff, *Documents on the Laws of War* (Oxford: Clarendon Press, 1982) at 2 and 29.

[5] *Ibid.* at 36.

[6] *Ibid.* at 30.

methods, to which many States Parties implied only first use.[7] Moreover, the Geneva Protocol only targeted the use of such weapons and did not prevent their acquisition, production, stockpiling, as well as other dangerous practices. Furthermore, it did not manage to prevent the well-documented use of chemical and biological agents during the 20th century.[8] The BTWC was negotiated in the Conference of the Committee on Disarmament between 1969 and 1972 against this background.[9] After much pressure for a completed document, which came in large part from the need to maintain the momentum on arms control, the desire to focus more intensely on chemical weapons, and the belief that biological weapons were less militarily viable, the Convention was signed in April 1972, without any type of verification mechanism.[10]

Since its coming into force, there have been four review conferences. In 1980, the first review conference was held under the tense political climate surrounding the invasion of Afghanistan and international concern over the outbreak of anthrax in Sverdlovsk. Despite the general lack of progress, some headway was made with regard to the description of terms and clarification procedures.[11] Amidst US allegations of Soviet violations, the second review conference concluded with a commitment on the part of the participating governments to develop remedies to the shortcomings of the Convention, with particular emphasis upon the need for effective mechanisms to address compliance concerns. Of particular significance were the reporting requirements developed in 1987 by the *Ad Hoc* Group of Scientific and Technical Experts.[12] The third review conference, which met in September 1991, built on the confidence measures agreed to in the Second Review Conference. It was also instrumental in establishing the *Ad Hoc* Group of Governmental Experts, whose mandate was to "identify and examine potential verification measures from a scientific and technical standpoint"[13] (more commonly known as VEREX). In September of 1994, a special conference of States Parties created another *Ad Hoc* Group whose mandate was to consider verification measures for the purpose of strengthening the BTWC.[14] The discussions of the *Ad Hoc*

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[7] J. C. Kessler, *Verifying Non-Proliferation Treaties: Obligation, Process, and Sovereignty* (Washington, DC: National Defence U.P., 1995) at 52-53.

[8] See E. Geissler & R.H. Haynes, eds., *Prevention of a Biological and Toxin Arms Race and the Responsibility of Scientists* (Berlin: Akademie Verlag, 1991).

[9] *Supra* note 7 at 53.

[10] *Ibid.*

[11] *Ibid.* at 55.

[12] *Ibid.* at 62.

[13] *Ibid.* at 65.

[14] J.-P. Zanders, S. Eckstein & J. Hart, "Chemical and Biological Weapon Developments and Arms Control" in *Sipri Yearbook 1997: Armaments, Disarmament and International Security* (Oxford: Oxford U.P., 1997) 437at 453.

Group where endorsed and given further encouragement during in the fourth review conference held in December 1996.

The work of the *Ad Hoc* Group has subsequently resulted in the production of a rolling-text of a legally binding Protocol designed to establish an effective verification mechanism for the BTWC.[15] Current efforts concentrate on the production of a final document to be open for signature by the fifth review conference. It is this desire to create a viable verification mechanism, encouraged in part by the United Nations Special Commission's discoveries in Iraq, as well as concerns regarding production and use by various other states, which has invigorated efforts to forge such a final document. However, legitimate concerns have also arisen over the intrusiveness of the potential verification regime, born in part of national security issues as well as various business interests in preserving confidentiality.

The challenges that face a State Party to any convention are numerous. These are examined by this report, together with the specific concerns facing the current rolling text of the Protocol. Both the BTWC and the current version of the Protocol are summarised in the following sections.

2.1. Summaries of the BTWC and Protocol

On 10 April 1972, Canada signed the *Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction.*[16] It deposited its Instrument of Ratification on September 18, 1972, and the Treaty itself entered into force on 25 March 1975.

2.1.1. The BTWC

The BTWC is composed of fifteen brief articles. The preamble affirms the States Parties' commitment to the complete disarmament of weapons of mass destruction, as well as the prohibition of the development, production and stockpiling of chemical and bacteriological weapons. It also emphasises the importance of the Geneva Protocol of 17 June 1925.

Article I prohibits the development, production, stockpiling, or otherwise acquisition or retention of microbial or other biological agents or toxins, whatever their origin or method of production, of types and in quantities that have no prophylactic, protective or other peaceful purposes, together with related weapons, equipment or means of delivery. Article II states that each Party shall destroy or divert to peaceful purposes, while respecting proper safety precaution, all items

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[15] *Ibid.* at 472.

[16] *Supra* note 2.

described in Article I. Article III provides that each Party to the Convention undertakes not to transfer, assist, or encourage in any way whatsoever, directly or indirectly, a state to acquire or manufacture any agents, toxins, weapons, equipment or means of delivery specified in Article I. Article IV furthers the three previous articles by requiring the States Parties to take appropriate measures in accordance with their constitutional processes to prohibit and prevent activities prohibited in Article I.

The first four articles of the Convention contain the bulk of the responsibilities taken on by the States Parties. The remaining articles attempt to establish a cooperation and dispute resolution mechanism,[17] as well as undertake to participate in the fullest exchange of equipment, materials, and scientific and technological information for peaceful purposes.[18] Finally, the Convention provides for the withdrawal of a State Party if that State Party decides that extraordinary events related to the subject matter of the Convention have jeopardised its supreme interests. Notice must be given three months in advance and must state the nature of the extraordinary events.[19]

2.1.2. The Protocol to the BTWC

Contrary to the BTWC, the Protocol, in its current version, is a detailed document providing mainly for the articulation and the establishment of a comprehensive verification mechanism.

The general provisions of the Protocol are found in Article I, which states that each State Party reaffirms its obligations under the BTWC and adds the verb 'use' as part of the undertaking. The Article further requires States Parties not to use pests and vectors as a method of warfare, to foster economic and social development through multilaterally negotiated sensitive technology agreements, and to protect commercial and proprietary information. Article II provides a series of definitions for the purposes of the Protocol. Article III delineates the specific measures required of the States Parties and contains the core of the verification regime. The Article also requires States Parties to declare domestic work with specific toxins and agents, as well as equipment used in specified facilities. Furthermore, a series of declarations are required from each State Party, beginning with past offensive and defensive programmes and legislation governing activities referred to in the Protocol. Annual declarations must be made regarding current defensive programmes, vaccine production facilities, maximum biological containment facilities, high biological containment facilities, work with listed agents and/or toxins, production facilities and other relevant facilities, transfers, declarations of implementation of Article X of the BTWC, and outbreaks of

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[17] *Ibid.* Articles V and VI.

[18] Article IX.

[19] Article XII.

disease. In order to measure and ensure compliance, procedures are described for the carrying out of randomly selected visits, clarification visits, request visits, voluntary visits, and investigations.

Article IV provides for the confidentiality of information acquired through implementation of the Protocol. Article V describes measures to be taken in order to redress a situation and to ensure compliance under the Protocol. Article VI contains measures for assistance and protection in the event of the use of biological and toxin weapons and reaffirms the right of the States Parties to undertake activities not prohibited by the Convention. Article VII requires States Parties to participate in the exchange of materials, equipment, and technology for peaceful purposes. It contains specific measures to foster and encourage cooperation. Article IX describes the structure and composition of the Organisation for the Prohibition of Biological and Toxin Weapons.[20] It describes such organs as the Conference of States Parties, the Executive Council, and the Technical Secretariat, together with their powers and functions, and the privileges and immunities of their staff.

National implementation measures are found in Article X. This Article requires States Parties to take the proper and necessary measures to implement its obligations under the Protocol. In particular, States Parties must prohibit natural and legal persons from undertaking activities prohibited by the Convention. Furthermore, a National Authority must be designated as a focal point for liaison with the Organisation and with other States Parties.

The subsequent Articles of the Protocol deal with administrative measures regarding the settlement of disputes, the review of the Protocol, questions pertaining to amendments, duration and withdrawal, the status of the annexes and appendices, signatures, ratification, accession, entry into force, reservations, depositaries, and authentic texts. The appendices and annexes contain a considerable amount of detail regarding declarations, visits, measures to strengthen the terms of Article III, investigations, confidentiality, and scientific and technological exchange for peaceful purposes and technical cooperation.

Although the Protocol contains an intrusive and comprehensive verification mechanism and constitutes an important step forward in ensuring the eradication of biological weaponry, many preliminary issues arise as to the constitutionality of implementing the terms of this document within the framework of Canadian law. This issue is dealt with in the following section.

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[20] Hereinafter OPBTW or Organisation.

3. THE CONSTITUTIONAL VALIDITY OF REGULATING THE DEVELOPMENT, PRODUCTION, AND STOCKPILING OF BACTERIOLOGICAL AND TOXIN WEAPONS PURSUANT TO AN OBLIGATION UNDER INTERNATIONAL LAW

3.1. Canada's International Obligations

Since 25 March 1975, Canada has been under an obligation to respect the provisions of the BTWC. This treaty, being an agreement entered into between states, is binding in international law.[21] In Canada, treaty-making power is vested in the Governor General. There is no need for a treaty to be passed by Parliament. This is perhaps why, in contrast to the United States where treaties must be passed by the Senate, treaties in Canada do not automatically become the law of land. Were a treaty to automatically repeal any inconsistent domestic law, such a development would offend the principle of parliamentary supremacy. Consequently, domestic laws, which are inconsistent with treaties signed by Canada, take precedence over the conflicting treaty provisions.[22] Generally, courts have tended to interpret domestic laws in light of Canada's international obligations but this approach is sometimes inadequate where, for example, the provisions are in direct conflict.

Where a treaty cannot be implemented without domestic legislation, federal states such as Canada face a significant constitutional problem. Although the federal government in Canada is fully competent to sign treaties and bind itself at the level of international law on a full spectrum of issues, the federal legislature can only pass laws for which it is competent. Should a province, for example, refuse to implement the necessary legislation, a federal state could find itself in breach of its international obligations. Moreover, in such countries, the federal legislature can be powerless in the face of a refusal to implement on the part of the provincial legislature. Such is the case with Canada. As stated by Leslie Claude Green:

> "While it may happen that a part of a federal state enters into an arrangement with individuals which appears in the form of a treaty, but nevertheless because of its terms only binds that constituent and attaches no obligation to the federal state, perhaps the general principle is best expressed in the words of the Supreme Court of Canada in *Ref. Re Offshore Mineral Rights (B.C.)*: "it is Canada, not the Province of British Columbia, that will have to answer the claims of other members of the international community for breach of the obligations and responsibilities imposed by the Convention."[23]

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[21] Such agreements can be called protocols, agreements, charters, or conventions. See P. W. Hogg, *Constitutional Law of Canada*, looseleaf, 3rd ed. (Toronto: Carswell, 1992) at 11-1.

[22] *Ibid.* at 11-6.

[23] L.C. Green, International Law: A Canadian Perspective 2nd ed., (Toronto: Carswell, 1988) at 85.

Implementation of the BTWC did not result in the creation of a new piece of domestic legislation. With many of the activities being loosely captured by other pieces of legislation, the general requirements of the BTWC were such that the obligations created remained general and a large degree of discretion remained in the hands of the States Parties. The present rolling text of the Protocol changes this in that it calls for the creation of a National Authority, as well as a complex process of inspections and declarations. As such, it would be expected that such a comprehensive piece of legislation would be introduced in a manner similar to that of the *Chemical Weapons Convention Implementation Act*,[24] essentially by establishing various measures for the creation of a National Authority and the coordination of activities relevant to the execution of the Protocol.

The following discussion deals primarily with the constitutional validity of a law, passed by the federal parliament, which would attempt to regulate the development, production, and stockpiling of bacteriological and toxin weapons. The analysis will also reflect upon the utility of the CWCIA as a guide in the construction of such a law.

3.2. Constitutional Validity of a Biological and Toxins Weapons Convention Implementation Act

The rolling text of Article X of the Protocol states that "[e]ach State Party shall, in accordance with its constitutional processes, take any necessary measures to implement its obligations under this Protocol." Particularly, it impels the State Parties to prohibit natural and legal persons from undertaking activities prohibited under the Convention and to set up a National Authority for the purposes of coordinating activities under the Protocol. This Article closely follows the language of Article VII of the *Chemical Weapons Convention*, for which domestic implementation legislation was necessary.

Any domestic legislation passed in order to implement the Protocol would, most likely, parallel the organic structure of CWCIA. The CWCIA provides a legislative scheme that establishes a National Authority to coordinate activities provided for under the CWC, including the submission of information and the inspection of relevant facilities. Moreover, the Act prohibits the development, production, acquisition or retention of a chemical weapon, together with the transfer, direct or indirect, of a chemical weapon to anyone. It also prohibits the use of chemical weapons, the engagement in military preparations to use a chemical weapon or the encouragement of any activity prohibited by the CWC.

Sections 8, 9, 10, 11, and 18 of the CWCIA seek to control the production, use, acquisition, or possession of some chemicals and prohibit the import and export of others. For the purposes of this discussion it is not necessary to elaborate on the specifics of the scheduled chemicals, but to

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[24] Chapter C-27.6 (1995. C.25) [hereinafter CWCIA]. This act implements Canada's obligations under the CWC.

conclude that there is federal regulation of the production of some of them. Additionally, a scheme is set up for the inspection and declaration of facilities, but this issue will be set aside for the moment and dealt with in a subsequent section of this report.

An Implementation Act for the Protocol will likely mimic the imposed structure for prohibition and regulation of activities found in the CWCIA. Furthermore, any piece of legislation would necessarily comport the prohibitions in Article X of the Protocol. As well, it would provide for the necessary declarations to be made and inspections to be carried out in the relevant industries. It is important here to canvass a range of scenarios under which a challenge to this legislation might be brought. Two types of categories can be identified: a challenge under the distribution of powers provided for in the *Constitution*, and a challenge based on an unreasonable search and seizure as per the terms provided for by the *Charter*.

3.2.1. A Distribution of Powers Challenge under the Constitution

Any party affected by legislation has the right to challenge that legislation's constitutionality. In Canada challenges have traditionally followed the classical division of powers contained in the text of sections 91 and 92 of the Constitution.[25] Since the adoption of the *Charter of Rights and Freedoms*,[26] Charter challenges have become considerably more common. This section deals with both types of challenges, starting with a challenge based on section 92 of the *Constitution*.

In deciding whether a piece of legislation falls under the competency of the provincial or federal legislature, Canadian courts have focused on the "pith and substance" or matter of the legislation at issue. If such matter falls within one of the powers enumerated either in section 91, then it is of federal competency and, similarly, if such matter falls within the enumerated powers in section 92, the power belongs to the provincial legislature.

3.2.1.1. The Regulation of Trade and Commerce, and Property and Civil Rights

Section 92 (13) of the *Constitution* allows the provinces to make laws regarding "Property and Civil Rights in the Province". A company, for example, could contest the federal legislature's power to make laws regarding what it felt it could maintain were in fact property and civil rights. Historically, laws regarding marketing and business have fallen under the sphere of the provinces' legislative authority. Although the power to regulate trade and commerce falls to the federal legislature under section 91 (2), this provision has been interpreted narrowly by the courts. For

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[25] *Constitution Act 1982*, being Schedule B to the *Canada Act 1982* (U.K), 1982, c.11 [hereinafter *Constitution*].

[26] Part 1 of the *Constitution Act 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11 [hereinafter *Charter*].

example, in *Labatt Breweries* v. *A.-G. Canada*,[27] where provisions of the *Food and Drug Act* were challenged, it was stated that the trade and commerce power could not serve to authorise the regulation of a single trade or industry on a nation-wide basis.[28] The *Competition Act* has also been similarly challenged. In *McDonald* v. *Vapor Canada*,[29] the Supreme Court laid out the criteria under which the general regulation of trade and commerce could be achieved by the federal branch. Provisions of the *Competition Act* were then upheld under this scheme in *General Motors* v. *City National Leasing*.[30] Under section 91 (2), the trade and commerce power does allow the federal legislature to make laws in relation to imports and exports.[31]

While it is clearly within the federal legislature's power to regulate the import and export of chemicals, the question of internal regulation of these chemical and agents is a somewhat more vague unless such measures can be demonstrated to follow the criteria laid out in *Vapor Canada.* Any regulation of the biological toxins, agents and material related thereto would be shaped by this argument.

3.2.1.2. Peace, Order, and Good Government

The preceding argument underscores one aspect of the present constitutional dynamic which exists between the two levels of government within the Canadian federation. However, in certain circumstances, the federal legislature holds the power to make laws for the peace, order and good government of the Dominion. Section 91 of the Constitution allows the federal parliament to "Make Laws for the Peace, Order, and Good Government of Canada, in relation to all Matters not coming within the Classes of Subjects by this Act assigned exclusively to the Legislatures of the Provinces". Under the "national concern" branch,[32] for example, in *Johannesson* v. *West St-Paul*,[33] the regulation of aeronautics was upheld as a valid use of the federal power. Similarly, and extremely relevant to this discussion, in *Ontario Hydro v. Ontario*,[34] the Supreme Court upheld the *Atomic Energy Control Act*. As reported by Peter Hogg:

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[27] (1979) [1980] 1 S.C.R. (Canada Supreme Court Reports) 914.

[28] *Supra* note 21 at 20-10.

[29] (1976), [1977] 2 S.C.R. (Canada Supreme Court Reports) 134 [hereinafter *Vapor Canada*].

[30] [1989], 1 S.C.R. (Canada Supreme Court Reports) 641.

[31] *Supra* note 21 at chapter 20.

[32] See *Canada Temperance Case,* [1946] A.C. (Appeal Cases U.K.) 193.

[33] [1952], 1 S.C.R. (Canada Supreme Court Reports) 292.

[34] [1993], 3 S.C.R. (Canada Supreme Court Reports) 327.

> "The production, use and application of atomic energy constitute a matter of national concern", because "it is predominantly extra-provincial and international in character and implications"; he also pointed to the "strategic and security aspects of nuclear power in relation to national defence" and to its potential for environmental catastrophes."[35]

Given the preceding examples, it would seem unlikely that the production, development and stockpiling of biological weapons and toxins could be otherwise characterised. Indeed this statement, when applied to biological weapons, would epitomise the spirit of both the BTWC and the Protocol specifically, as well as weapons of mass destruction generally. Furthermore, the national concern branch was used in *Crown* v. *Zellerbach*,[36] where a federal scheme to regulated marine pollution was upheld as a valid use of the federal parliament's power.

3.2.1.3. The Criminal Law

In a recent decision, *R.* v. *Hydro-Quebec*,[37] the Supreme Court upheld the validity of certain provisions of the CEPA as a valid use of the criminal law power conferred under section 91 (27) of the *Constitution*. This ruling, in essence, established that there was a wide area of environmental policy open to concurrent operation of provincial and federal statutes.[38] In the majority's decision, Justice Laforest held that section 34 of the CEPA, which defines situations where the use of a substance is prohibited and subject to penal consequence, was a valid use of the criminal law power conferred upon the federal legislature.[39] He however also emphasised the provincial role in concurrent regulation.[40] The *Hydro-Quebec* decision exemplifies an area in which the federal legislature enjoys considerable latitude for defining the scope of the criminal law. Indeed, as stated by Sven Deidman:

> "Parliament enjoys the discretion to identify real as well as potential evil, injurious or undesirable effects upon the public against which the law is directed. Thus the criminal law power uniquely invests Parliament with the appropriate constitutional authority to further a central element of modern, sustainability-oriented environmental policy, namely the precautionary principle."

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[35] *Supra* note 21 at 379.

[36] [1988], 1 S.C.R. (Canada Supreme Court Reports) 401.

[37] [1997] 3 S.C.R. (Canada Supreme Court Reports) 213 [hereinafter *Hydro-Quebec*].

[38] S. Deidman, *R. v. Hydro-Quebec: Federal Environmental Regulation as Criminal Law* (1998) 43 McGill Law Journal 923.

[39] *Ibid.* at 932-933.

[40] *Supra* note 37 at para. 131.

This decision would give weight to an argument attempting to uphold an act for the implementation of the BTWC, particularly since the toxins and agents regulated are clearly dangerous and possess significant potential destructive capacity. Use of the criminal law power would, in such an instance, be clearly appropriate.

Given the preceding discussion it is likely that any legislation dealing with the prohibition of biological weapons, together with the regulation of certain aspects of the industry, would be upheld either as a valid use of the criminal law or the "national concern" branch of the clause pertaining to peace, order and good government. Although some concern would be raised if the Federal legislature were attempting to regulate trade and commerce, the preceding discussion makes it sufficiently clear that the purpose of implementation arises out of the issues of national concern and criminal purpose. However, a possible issue does lie with regard to a consideration of the *Charter* concerning visits and inspections provided for under the Protocol.

3.2.2. Section 8 of the Charter

The sole foreseeable *Charter* consideration rests in section 8, which reads: "Everyone has the right to be secure against unreasonable search and seizure". As such, this section requires that police or other agents of the state be reasonable when undertaking a search or seizure.[41] A search is "an examination, by the agents of the state, of a person's property in order to look for evidence. A seizure is the actual taking away by the agents of the state, of things that could be used as evidence."[42] This requirement is highly relevant to the Protocol as the present rolling text calls for randomly selected visits, voluntary visits, and investigations pursuant to Article III, section D, subsections A through E. To that end, any Canadian legislation enacted to implement these obligations would have to respect the section 8 requirements. A breach of section 8 would most likely result in the exclusion of evidence resulting from the search or seizure, or any other appropriate remedy provided for by section 24 of the *Charter*.

Section 8 also protects the privacy interest of the individual. *Katz* v. *United States*,[43] an important American case based on the Fourth Amendment, underlined the importance of protecting privacy and not simply property rights[44] as grounds for restrictions on searches and seizures. This decision was echoed by the Supreme Court of Canada in *Hunter* v. *Southam*,[45] which emphasised

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[41] *Supra* note 21 at 45-2.

[42] *Ibid.* at 45-4.

[43] (1967) 389 U.S. (United States Reports) 347.

[44] The Common law protected property rights from search and seizure and not privacy.

[45] [1984] 2 S.C.R. (Canada Supreme Court Reports) 145 [hereinafter *Hunter*].

the importance of the reasonable expectation of privacy protected by section 8. *Hunter* v. *Southam* involved a challenge to a search and seizure provision authorised by the *Combines Investigation Act*[46] and performed on the business premises of a corporation. In the case, the Court assumed that a corporation possessed the same expectation of privacy as individuals.[47] Statutory authority had been used to search the premises of the *Edmonton Journal* as part of a combines investigation into the newspaper industry. The Supreme Court held that this kind of search would be reasonable only if three conditions were met by the enabling statute. Those conditions were: 1) the obtaining of a search warrant in advance; 2) that the warrant be issued by a person capable of acting judicially, and; 3) that the issuing of the warrant be subject to an oath that reasonable and probable grounds existed that an offence had been committed and that evidence would be found on the premises.[48]

Hunter has created a situation where any search or seizure performed without a warrant is presumed to be unreasonable. Such presumption must then be rebutted. However, there are various instances where warrantless searches have been deemed to be reasonable. Although it is not necessary here to detail these instances, it is sufficient for the purposes of this report to state that searches incidental to arrest, border searches, and regulatory inspections have all been areas where warrants have been unnecessary.

With regard to the acceptability of a search warrant, one test that must be adhered to is that of "reasonable expectation of privacy" as referred to by J. Wilson in *R.* v. *McKinlay Transport Ltd.*[49] This case involved a challenge to sections 231 (3) and 238 (2) of the *Income Tax Act* as being a violation of section 8 of the Charter. The Court found that the relevant sections were, in fact, reasonable seizures. In essence, the Court decided that the *Income Tax Act* was regulatory in nature, based on a principle of self-reporting and self-assessment. In order to ensure compliance, it was deemed necessary for the Minister of National Revenue to possess broad powers to audit returns and inspect relevant records, regardless of any belief on the part of the authorities that reasonable grounds for believing that a breach of the Act had occurred. As such, a taxpayer's expectation of privacy in relation to the Minister was relatively low.[50] In this case, it was stressed that a distinction must be drawn between the full rigours of the test in *Hunter*, as opposed to legislation that is essentially regulatory in nature.

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[46] R.S.C. 1970, c. C-23.

[47] *Supra* note 21 at 45-5.

[48] *Ibid.* at 45-17.

[49] [1990] 1 S.C.R. (Canada Supreme Court Reports) 627.

[50] *Ibid.* at 628.

This argument is of immediate relevance to the implementation of the Protocol regarding the conduct of voluntary visits, random visits, and inspections. These types of visits, especially random and voluntary visits, would be regulatory in nature.

3.2.2.1. Random Visits

In the case of randomly selected visits, the third criteria in *Hunter* would be impossible to meet. In fact, random visits are to some extent at odds with the type of investigations considered in the *Hunter* decision. The whole point of visits, as stated in Article III, section D, subsection A, is to ensure that declarations are consistent with the obligations of the Protocol. They are also confidence-building in nature, and as such, do not rest on any presumption of wrongdoing. For these reasons, and also for those relating to the confidentiality measures taken, there would be a diminished expectation of privacy for a company or business undertaking an activity which was regulated in this fashion.

This idea was also echoed in *Thomson Newspapers* v. *Dir. of Inv. and Res.*[51] where, with regard to the issue of section 8 and the expectation of privacy, Justice Sopinka stated that such an expectation is reduced considerably in regulated activities and that the *Hunter* requirements should be reserved for those situations where state intrusion is truly out of keeping with what individuals have come to expect in a modern state. Random visits would then seem to be exempt from a warrant requirement as they are eminently regulatory and the provisions of the Protocol should contain sufficient safeguards to prevent undue intrusion into business activities.

3.2.2.2. Voluntary Visits

With regard to voluntary visits, these are equally regulatory in nature and, following Article III, section D, subsections C through E, call for the visit of certain declared facilities within the State Party's territory or jurisdiction. As stated in subsection C, the purpose of these visits is to help individual facilities and national declarations, to further the cooperation and assistance provisions contained within the Protocol's rolling text, and to resolve specific concerns. Although accedence to such visits is voluntary on the part of the State Party, the investigated facility's consent does not seem to be required. As such, any investigation or visit would have to remain within the realm of a regulatory activity rather than that of a criminal investigation.[52] This was confirmed by a challenge to a provision of the *Income Tax Act*, which contained similar provisions for inspection.[53]

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[51] [1990] 1 S.C.R. (Canada Supreme Court Reports) 425.

[52] J.A. Fontana, *The Law of Search and Seizure in Canada*, 4th ed. , (Toronto: Butterworths, 1997) at 281.

[53] *R.* v. *Norway Insulation Inc.*, (1995) 2 C.R.R. (Canadian Rights Reporter) 163, (Ont. Gen. Div.)

3.2.2.3. Investigations

The wording of investigations under the Protocol is slightly more problematic since it borders on criminal investigation. Article III, section G, subsection A, states that each State Party shall have the right to request an investigation for the sole purpose of determining the facts relating to a specific concern about non-compliance with the Convention by any other State Party. This contrasts with a similar provision in the *Chemical Weapons Convention* at Article IX, paragraph 8 which states that the sole purpose of challenge inspections are for the clarification and resolution of any questions concerning non-compliance. The latter provision is clearly more limited in scope than the extent of the provision envisaged by the Protocol. As such, the emphasis of investigations under the Protocol could possibly be seen as more criminal in nature and thus subject to the full warrant requirements of *Hunter*.

Additionally, the CWCIA in section 15 (2) requires the obtaining of a warrant where consent to access of a facility is refused. Regardless of whether these types of warrants are required for such regulatory activity, they do point to the concern on the part of the legislators for assurances of the protection of privacy with regard to the places to be investigated. The warrant requirement in the CWCIA is an attenuated version of the safeguards provided for in *Hunter*. It should be noted that in *Baron* v. *Canada*,[54] a similar type warrant was struck down where such a warrant was used to search a private dwelling house because of the higher expectation of privacy enjoyed in a private dwelling.[55] Similarly, the idea of warrantless searches has been of significant concern in the United States given the stringent requirement in the Fourth Amendment. Regarding the nature of any federal statute that would implement the CWC (at that time a rolling text), Edward Tanzman stated:

> "First, an implementing statute might create a system of pervasive regulation of chemical weapons. Second, a new law redefining the remedies available to the subjects of on-site arms control inspections might overcome many of the problems that cannot be solved by other means. Passage of a statute might assure that a court would find the declared facilities covered by Article VI to be pervasively regulated, thereby qualifying them for warrantless routine systematic systematic international on-site verification inspections under the Supreme Court criteria quoted above. Certainly an enormous government interest exists in eliminating chemical weapons. The necessities of international diplomacy appear to dictate that warrantless on-site inspections be an important deterrent to violations."[56]

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[54] [1993] 1 S.C.R. (Canada Supreme Court Reports) 416.

[55] *Supra* note 21 at 45-26.

[56] E. A. Tanzman, "Legal Aspects of Implementing a Global Chemical Weapons Convention Under Domestic Laws" (1989 Annual Meeting of the American Association for the Advancement of Science, San Francisco, California, 16 January 1989) Conf-890124, Argonne National Laboratory, US Department of Energy, at 12-13.

The undertaking of regulatory regimes in Canada is further qualified by Peter Hogg:

> "The administration of most regimes of regulation involves the use of inspectors who regularly visit the locations of the regulated activity in order to check for compliance with the law. These routine or random inspections are in the nature of spot checks. They are not premised on the suspicion that an offence is being committed; and therefore there would be no point in requiring inspectors to obtain a warrant or other prior authorization for each building site, restaurant, factory, office, recreation area or other place subject to regulation."[57]

To sum up, the creation of a regime of inspections and visits poses a challenge given the nature of the rights as guaranteed by the *Charter*. Consequently, careful wording must be sought if the regulatory regime is to pass constitutional muster. If, for example, the scope of an investigation is seen as criminal in nature, the requirement for a warrant will be much stronger. Moreover, the CWCIA, as well as several other acts in which regulatory regimes are created, provide for a warrant for the purposes of searches and seizures. Regardless of whether such warrants are constitutionally required, and, if required, are sufficient, they do point to the degree of sensitivity surrounding the issue. As well, given the Protocol's concern for the issue of confidentiality, especially at Article IV where the Organisation is impelled to undertake its activities with the greatest of concern for confidentiality, privacy constitutes a critical political imperative for many States Parties. Ensuring that information is kept confidential when disclosed to the Organisation would constitute a further safeguard that would ensure that any regulatory inspection would be deemed constitutional. Just as a taxpayer has a diminished expectation of privacy with respect to documents relating to the earning of income or other taxable transactions vis-à-vis the Minister of National Revenue,[58] a business engaged in activities regulated by the Protocol should have a diminished expectation of privacy vis-à-vis the future Organisation. However, it still should enjoy a degree of confidentiality with respect to third parties.

3.3. Conclusion

To conclude, the implementation of a verification protocol to the BTWC is critical to the effectiveness of the Convention. National implementation through legislation is an important step towards ensuring that obligations assumed under the BTWC and the Protocol are properly discharged. As such, several constitutional issues are of considerable relevance with regard to the application of the BTWC and the Protocol in Canada. In particular, the distribution of powers entrenched in sections 91 and 92 of the *Constitution* raises some challenges to the federal legislature. As discussed above, sufficient power exists for the federal parliament to implement its obligations,

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[57] *Supra* note 21 at 45-25.

[58] *Ibid.* at 45-26.

but it may also be desirable to seek provincial cooperation, especially in field where provincial authority may have particular expertise and where the Protocol calls for scientific cooperation.

Furthermore, section 8 of the *Charter* protects persons, moral and physical, from unreasonable search and seizure. Considerable care must be given in the Implementation Act to guarantee that this right is not impinged upon. In some cases, particularly investigations, a type of warrant may be required, but generally speaking, regulated activity of this nature does not benefit from a full expectation of privacy. However, given the emphasis on the protection of commercial proprietary information in the Protocol, considerable care should be taken with respect to the targeted facilities and the terms of the regulatory framework that address these issues.

Finally, although some concern does exist regarding the constitutional validity of a prospective Implementation Act, such concern must not be overstated. None of the Protocol's provisions contained within the current rolling text are in flagrant opposition to any provision of the *Constitution* and, as stated above, careful drafting should be able to balance any possible concern in this area.

4. CHALLENGES FACED BY A NATIONAL AUTHORITY

The following section attempts to identifies the challenges to a National Authority tasked with the implementation of the Protocol. In order to establish the most relevant role for a National Authority, the explicit requirements imposed on the State Party by the Protocol must first be examined. Identifying the degree of federal regulation regarding the subject matter of the Protocol is equally crucial and has several purposes. First, it can inform the reader as to the type of controls that exist on the matter regulated by the Protocol. Second, a whole range of inferences can be drawn relating to the need for future federal regulation to complete the requirements of the Protocol. Third, the legislative mechanisms can shed light on the methods used to safeguard information, as well as demonstrate the degree of intrusiveness of current federal requirements on related industries. Finally, the acts that will be covered point to the implementation bodies for which coordination with the National Authority will be necessary. Also, since the Protocol involves declarations, visits, and inspections of relevant industries, the specific challenge of protecting commercially sensitive information is also addressed. The final part of this section deals with the creation of the National Authority for the BTWC by drawing upon an analysis of the Protocol, the federal legislation relevant to it, and the lessons learned from the National Authority for the CWC. This part will consider the establishing of an institutional mechanism that can effectively discharge its duties under the Protocol, as well as address and remedy implementation issues.

4.1. Requirements of the Protocol from the State Party

The Protocol, while reaffirming and qualifying the duties of the States Parties, is essentially a verification mechanism designed to complement the BTWC. The duties imposed upon the States Parties are designed to ensure that activities prohibited by the BTWC are not in fact undertaken.

4.1.1. The BTWC's requirements

The activities prohibited by the BTWC are listed in Article I of the Convention. Under Article I, the States Parties undertake never to develop, produce, stockpile or otherwise acquire or retain microbial or other biological agents, or toxins regardless of origin or method of production in types and in quantities that have no prophylactic, protective or other peaceful purpose. This undertaking includes weapons, equipment, or means of delivery. Moreover, in Article III each State Party undertakes not to transfer to any recipient, directly or indirectly, nor to assist or encourage any state to manufacture or acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I. Article IV stipulates that each State Party shall take the necessary measures in accordance with its constitutional processes to prohibit and prevent the development, production, stockpiling, acquisition or retention of the items, or activities described in Article I. Finally, Article X encourages States Parties to participate in the fullest exchange of equipment, materials, and scientific and technological information for the use of bacteriological agents and toxins for peaceful purposes. As well, the Article also encourages participation and cooperation in the development and application of scientific discoveries.

The BTWC has a dual purpose. The first is to prohibit the processes leading to the development and use of a weapon of mass destruction. The second purpose is to encourage and promote the peaceful use of technologies and know-how so as to prevent disease and encourage scientific discoveries. Although the BTWC has been in force in Canada since 1975, it does not identify specific requirements for States Parties regarding lists of toxins, agents, or equipment and does it contain specific measures to ensure that the States Parties actually implement the Convention. This is the principal remedy sought by the Protocol in that it is more a verification mechanism than a reformulation of the 1972 treaty.

4.1.2. The Protocol's Requirements

The requirements from the States Parties under the Protocol are essentially contained in Articles I, III, VII, and X.

4.1.2.1. Article I: General Provisions

Article I of the Protocol contains the general provisions of the Convention and states the States Parties' reaffirmation of their obligations under the BTWC, particularly never to develop,

produce, otherwise acquire, or transfer, directly or indirectly, biological and toxin weapons to anyone. States Parties undertake never to use biological and toxin weapons or to engage in any military preparations to use biological and toxin weapons, or to assist, encourage, or induce, in any way, anyone to engage in any activity prohibited to as State Party under the Convention. As well, States Parties undertake not to use pests and vectors as a method of warfare. The Parties also undertake to negotiate non-discriminatory sensitive technology transfer agreements and take into account commercial and proprietary information when implementing the Protocol. Article I outlines the general purpose of the Convention as well as include the word "use" which was not explicitly contained in the BTWC.

4.1.2.2. Article III: Compliance Measures

The main article regarding the duties of States Parties is Article III, which requires the declaration of agents and toxins from the lists set out in Annex A, Section I and in accordance with formats for declarations of facilities, activities and transfers referred to in annex A, section V. In essence, section I of annex A lists a number of human, animal, and plant pathogens which require proper reporting according to section V of annex A. As well, Article III requires States Parties to supply information concerning equipment installed at declared facilities from the list contained in section II of annex A and pursuant to the declaration requirements of section V. Moreover, Article III in section C establishes thresholds for State Parties participating in a program of protection against biological weapons. Section D of Article III outlines the declarations to be provided to the Organisation. Each State Party is required to declare, regardless of the form of ownership or control, all activities and facilities in existence on its territory or in any other place under its jurisdiction during the period specified. Declarations to be provided to the Organisation are as follows: 1) initial declarations for past offensive or defensive programmes as defined; 2) initial declaration for national legislation and regulation governing the activities regulated by the Protocol; 3) annual declarations for current defensive programmes as defined; 4) annual declarations for vaccine production facilities; 5) annual declarations for maximum biological containment facilities; 6) annual declarations for high biological containment facilities; 7) annual declarations for work with listed agents and/or toxins; 8) annual declarations for work with other production facilities; 9) annual declarations for defined other facilities; 10) annual declarations regarding international transfers of agents, toxins, or equipment; 11) annual declarations on the implementation of Article X of the BTWC and Article VII of the Protocol, and; 12) notification regarding outbreaks of disease.

Title II of section D of Article III provides for follow-up after submission of declarations and, generally, outlines the types of visits that can be organised by the Technical Secretariat. These visits are divided into randomly-selected visits, clarification visits, request visits, and voluntary visits, the purpose of which is, essentially, a confidence-building measure and to assist in the proper submission of declarations.

Section E of Article III encourages the State Parties to consult and cooperate amongst themselves and with the Organisation or a relevant international procedure in order to resolve any

concern which might arise. This section also outlines the procedure for cooperation, clarification, and consultation.

Section F of Article III aims to strengthen the implementation of Article III of the BTWC. To that end, it states that States Parties shall only transfer dual-use microbial and other biological agents, toxins, and equipment for purposes not prohibited by the Convention. As well it establishes the following guidelines: 1) that any request made by a State Party for the procurement of an agent/toxin reagent is to be accompanied by information on the purpose, quantity required, site for proposed use, quantity to be produced at the site/facility, place to be stored and end-use certificate; 2) that any request for transfer or procurement of equipment envisaged to be declared under CBM's, for use by a state participating in the compliance regime in a biosafety level 4 facility, including details of its proposed application and the site/facility for intended use is to be communicated to the organisation; 3) that any transfer of technology related to the means of delivery of toxins and pathogens is to be communicated to the Organisation; 4) and that transfer of agents, equipment, and material it not to be allowed to non-States Parties of the compliance regime under the Convention without prior approval of the Organisation. Additionally, section F states that Parties must ensure that any transfer will only be used for peaceful non-prohibited purposes under the Convention. This effort, however, is not to impede the peaceful economic and technological development of States Parties. As such, an end-use certificate may be required for such transfers.

The final section of Article III, section G, establishes a comprehensive scheme for the conduct of investigations. Subsection A, at paragraph 2 states that each State Party shall have the right to request an investigation for the sole purpose of determining the facts relating to a specific concern about possible non-compliance with the Convention by any other State Party. As well as laying down the procedure for such requests, section G regulates the process by which such an investigation shall take place and the obligation of each party to the investigation. Of particular interest for national coordination efforts are those procedures relevant to the leading up to and issuance of the investigation mandate. Section G also outlines the duties and obligations of the State Party whose facilities and sites may fall under investigation.

To sum up, Article III establishes an extensive schema for compliance measures and constitutes the main article for the entrenchment of a verification mechanism in the Protocol. The obligations required from each State Party are extensive and require in depth coordination with the Organisation.

4.1.2.3. Article VII: Scientific and Technological Cooperation

Article VII of the Protocol is a provision regarding the scientific and technological exchange for peaceful purposes and technical cooperation. Generally, it requires the States Parties to fulfill their obligations in a manner compatible with Article X of the BTWC. In section B of Article VII, each State Party endeavors to undertake the implementation of Article X so as to ensure the promotion of the exchange of materials, equipment, and technology for peaceful purposes. In this section, States Parties also undertake to assist and promote peaceful research activities and the

dissemination of knowledge concerning, amongst other things, laboratory safety, vaccine production, and biosciences research projects and activities. Following this, sections C, D, and E reinforce the right of each State Party to conduct research, develop, produce, acquire, retain, and transfer and use biological agents and toxins for peaceful purposes, as well as describe measures and institutional mechanisms designed to promote peaceful exchange. Finally, section G requires annual submissions to be made regarding measures taken to implement Article X of the BTWC and Article VII of the Protocol.

4.1.2.4. Article X: National Implementation

Article X concerns the measures to be taken on the national level in order to ensure proper implementation of the Protocol. In particular, it requires States Parties to prohibit natural or legal persons from undertaking activities prohibited by the BTWC. As well, this Article requires States Parties to establish a National Authority which would then serve as the national focal point for liaison activity with the Organisation, as well as with other State Parties. Each State Party is to inform the Organisation of legislative and administrative matters taken pursuant to Article X and to ensure that all necessary steps are taken in ensuring the safety of people and the protection of the environment. Although short, this Article constitutes one of the most important obligations of the Protocol *viz.* that each State Party prohibit natural and legal persons from undertaking activities prohibited by the BTWC and establish a National Authority to serve as a focal point for liaison with the Organisation and with other States Parties.

4.1.3. Conclusion

The Protocol establishes a number of requirements on the part of the States Parties in order to ensure that verification measures are properly implemented. The role played by a National Authority is incompletely defined in Article X, which simply specifies that the National Authority is to serve as a 'focal point'. The role to be played by a National Authority will depend, to some extent, on the degree and manner to which activities are already subsumed within existing governmental bodies. At the very least, the wording of Article X, paragraph 3 suggests that the National Authority should play an extensive coordination role with respect to the responsibilities imposed by the Protocol. In essence, not only must a National Authority fill gaps created by ratification of the Protocol, but this body must also coordinate the various domestic activities insofar as they relate to it. As will be seen in the following survey of federal legislation, many activities relating to the Protocol are governed by a variety of institutions, albeit for many different and seemingly unrelated purposes. In this regard, a survey of federal legislation in extremely salient to this report, as it can offer important insight into the tasks that need to be assumed by the National Authority, as well as offering an overview of the industry that it will have to regulate.

4.2. The Regulation of the Subject Matter of the Protocol

In order to grasp fully the tasks faced by a National Authority it is critical to understand the degree to which the subject matter of the Protocol is regulated. This makes it possible to identify, among other things, the pertinent enforcement mechanisms which exist as well as the relevant areas of expertise in the field. From this survey of legislation, certain patterns will emerge: 1) that the matter dealt with is highly dangerous; 2) that any activity relating to the matter is highly regulated by certain federal bodies; 3) that the federal institutions that regulate these activities have considerable expertise, and; 4) that the prohibited use of such matter is not explicitly regulated, except through general provisions of the Criminal Code.

These patterns will serve as useful reference points from which the prospective National Authority can carve out its role.

4.2.1. Acts Regulating the Peaceful Use of the Subject Matter

4.2.1.1. The Food and Drugs Act

The primary example of the degree of regulation of those industries susceptible to being affected by the Protocol is embodied in the *Food and Drugs Act*.[59] This Act extensively regulates the field of food, drugs, cosmetics and therapeutic devices. In Section 4, the FDA states that:

> "4. No person shall sell an article of food that
> a) has in or on it any poisonous or harmful substance;
> b) is unfit for human consumption;
> c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
> d) is adulterated; or
> e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions."

Moreover, sections 7 and 11 prohibit the unsanitary manufacture, preparation, preservation, packaging, or storage for sale of food and drugs. As well, in section 6 (1) the FDA regulates the importation and interprovincial movement of food. The Act goes on, in section 30, to provide for regulations regarding the conditions of packaging, marketing, labeling and so on for the sale of foods, drugs, cosmetics, or devices. For example, the *Food and Drug Regulations*,[60] enacted pursuant to the FDA, require under Section B 21.025 that no person sell certain marine products unless their container has been heated so as to ensure that spores of *Clostridium botulinum* are not present. As well, certain drugs such as *Botulinum* toxin type A can only be sold under restrictive

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[59] R.S.C. (Revised Statutes of Canada) 1985, c. F-27 [hereinafter FDA].

[60] C.R.C (Consolidated Regulations of Canada), c. 870 [hereinafter FDR].

conditions.[61] Moreover, in part C, the FDR provide for extensive regulation and licensing of activities related to drugs. As well as providing for licensing of an extensive range of activities such as the manufacturing of certain drugs, the FDR require under C.04.018 that:

> "A fabricator shall immediately segregate, and report the fact to the Minister, any animal with actual or suspected vesicular stomatitis, foot and mouth disease, encephalomyelitis, infectious anaemia, glanders, anthrax, tetanus or any other serious infectious disease."[62]

The FDA does not directly concern the Protocol in that the Protocol does not prohibit the peaceful use of agents and toxins such as *Clostridium botulinum*. However it does demonstrate the measure of concern on the part of the FDA regarding the dissemination of pathogens and points to the degree of control over obvious vectors for pathogens. The Act and Regulations also point to the degree of supervision by the Minister of Health and the Minister of Agriculture and Agri-Food, especially through the use of inspectors for the purpose of enforcement of the act under sections 13 and 22(1) of the Canadian Food Inspection Agency Act.[63]

The enforcement of the FDA is assured in section 23 (1) *et seq*. which provide for the inspection of premises where an inspector believes on reasonable grounds that a violation of this Act has occurred. These powers include the right to examine articles, take samples, enter into a conveyance which is believed to carry articles, open receptacles or packages, examine and copy books, documents and records, or detain or seize any article where the inspector reasonably believes that any provision of the Act or Regulations has been contravened. Moreover, offences and punishment for contravention of this act or its regulations are provided in s. 31 *et seq*., which include fines up to $250,000 and/or prison terms of up to three years.

Finally, the FDA and the FDR significantly regulate the quality of foods, cosmetics, and drugs so as to ensure their safety for consumption. It should be noted that this act epitomises the peaceful purposes to which certain listed agents or toxins in the Protocol are used and, as such, their control does not fall directly under the scope of the Protocol. However, the FDA and the FDR demonstrate the degree of regulation to which industries capable of producing listed pathogens are continually subjected.

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[61] See s. C. 01.041 ss. (1.1).

[62] S.O.R./97-12 (Statutory Orders and Regulations), s. 61.

[63] 1997, S.C. (Statutes of Canada) 1997, c. 6.

4.2.1.2. The Health of Animals Act

Another prime example of the degree to which domestic industries could be affected by the Protocol is that of the *Health of Animals Act*.[64] This Act deals primarily with diseases and toxic substances that may affect animals or that may be transmitted by animals to persons, together with the protection of animals. Again, as with the FDA, while the HAA pursues its own purpose it also provides an example of the control exerted in Canada on the potential spread of noxious substances.

The HAA attempts to control diseases and toxic substances in animals. Section 5, particularly, states that:

> "(1) A person who owns or has the possession, care or control of animal, shall notify the nearest veterinary inspector of the presence of a reportable disease or toxic substance, or any fact indicating its presence, in or around the animal, immediately after the person becomes aware of the presence or fact.
>
> (2) Immediately after a person who is a veterinarian or who analyses animal specimens suspects that an animal is affected or contaminated by a reportable disease or toxic substance, the person shall notify a veterinary inspector."

As well, the HAA requires in section 7 that persons who have the possession, ownership, care and control of an animal capable of being affected by a disease or toxin in an area are to affix a notice forbidding entry into the building or enclosed space where the animal is kept. Additionally, the HAA sets up prohibitions with respect to suspected or diseased animals. In section 14 *et seq.* the HAA controls the importation of certain animals so as to prevent the disease or toxic substance from being introduced. Section 19 *et seq.* controls the exportation of an animal subject to prior notice to customs officers and presentation to a veterinary inspector, together with a certificate from the veterinary inspector attesting to the health of the animal.

Sections 22 through 28 deal with infected places and control areas. In these sections, inspectors are empowered to declare a place infected if the inspector is of the opinion that a disease or toxic substance exists in a place and that the said disease or toxic substance could spread or that animals or things entering the place could become affected or contaminated. Subject to such a declaration of an infected place, section 25 states that a license is required to remove or introduce any animal or thing into the infected place. As well, section 27 empowers the Minister to take all reasonable measures consistent with public safety for the purpose of remedying any dangerous condition, or mitigate any danger to life, health, property or the environment that results or may reasonably result from the existence of a disease or toxic substance in a control area.

For the purposes of the administration of the HAA, inspectors are provided in Section 32 with a range of powers similar to those stipulated to in the FDA for the purposes of enforcement.

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[64] 1990, S.C. (Statutes of Canada) 1990, c. 21[hereinafter HAA].

Additionally, section 48 provides for the disposal of an affected or contaminated animal or thing. Regarding regulations, section 64 (1)[65] lists an extensive range of activities which can be subject to

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[65] 64. (1) The Governor in Council may make regulations for the purpose of protecting human and animal health through the control or elimination of diseases and toxic substances and generally for carrying out the purposes and provisions of this Act, including regulations
(a) prohibiting or regulating the importation, exportation and possession of animals and things in order to prevent the introduction of any vector, disease or toxic substance into Canada or into another country from Canada;
(b) for subjecting animals and things that may transmit a disease or toxic substance to quarantine or requiring their destruction on importation into Canada and for requiring the disposal on importation into Canada of things that may transmit a disease or toxic substance;
(c) requiring proof of the fact that animals imported into or passing through Canada have not been brought from any place where there was, at the time of their embarkation, a disease or toxic substance;
(d) prohibiting or regulating the importation of garbage into Canada and regulating the handling and disposal of garbage imported into Canada;
(e) governing the use of food lockers on ships in Canadian waters in order to prevent the introduction of any disease or toxic substance into Canada;
(f) for controlling or eradicating, or preventing the spread of, vectors, diseases and toxic substances and for quarantining, segregating, treating or disposing of, or for dealing generally with, animals or things that
(i) are, or are suspected of being, affected or contaminated by a disease or toxic substance,
(ii) have been in contact with or in close proximity to animals or things that were, or are suspected of having been, affected or contaminated by a disease or toxic substance at the time of contact or close proximity, or
(iii) are, or are suspected of being, vectors, the causative agents of disease or toxic substances;
(g) for segregating and confining animals within certain limits, establishing areas of inspection or quarantine and establishing eradication areas where animals may be inspected, segregated and tested for any disease or toxic substance;
(h) prohibiting or regulating the movement in Canada of
(i) animals, animal products, animal by-products, vectors, the causative agents of disease, animal food, hay, straw and fodder, and
(ii) things that are used in respect of animals and that may be affected or contaminated by a disease or toxic substance;
(i) for the humane treatment of animals and generally
(i) governing the care, handling and disposition of animals,
(ii) governing the manner in which animals are transported within, into or out of Canada, and
(iii) providing for the treatment or disposal of animals that are not cared for, handled or transported in a humane manner;
(j) for declaring as infected, and constituting as an infected place, any airport, market, pen, railway yard, stockyard, conveyance or wharf on or in which any animal, animal product, animal by-product, animal food, hay, straw or fodder, or any other thing used in respect of animals, is exposed for sale or is placed for the purpose of transit;
(k) prohibiting or regulating the movement of persons and conveyances within, into or out of infected places;
(l) for purifying any place or thing that is likely to contain a vector or be contaminated by any disease or toxic substance;
(m) for causing or requiring notice to be given of the appearance of any disease or toxic substance among animals;
(n) prohibiting or regulating the holding of markets, fairs, exhibitions or sales of animals;
(o) for exempting any disease or toxic substance from the operation of any of the provisions of this Act or any regulation, for the imposition of terms and conditions governing the exemption and for otherwise dealing with the disease or toxic substance;
(p) regulating the conduct and operation of zoos and game farms;
(q) prescribing sanitary and health measures for establishments in which animal semen and animal embryos are collected, stored, frozen or processed and generally regulating the manner in which they are collected, stored and distributed;
(r) prohibiting or regulating testing for diseases;
(s) prohibiting or regulating the importation, preparation, manufacturing, preserving, packing, labelling, storing, testing,

regulation. The *Health of Animals Regulations*[66] control a comprehensive set of conditions under which activities relating to animals which could be infected or contaminated can take place. The regulations are divided into 14 parts and include 171 sections. Particularly, the regulations control the segregation and inspection of animals, importation, importation of animal products, importation of animal by-products, animal pathogens and other things, quarantine of imported animals, exportation of animals and animal by-products, eradication, transportation of animals, and permits and licenses. For example section 34 states that:

> "34. (1) No person shall import milk or milk products into Canada from a country other than the United States or from a part of such a country, unless
> (a) the country or part of the country is designated as free of foot and mouth disease pursuant to section 7; and
> (b) the person produces a certificate of origin signed by an official of the government of the country of origin that shows that the country of origin or part of such a country is the designated country or part thereof referred to in paragraph (a).
> (2) Subject to subsection (3), no person shall import unfertilized bird eggs or egg products into Canada from a country other than the United States or from a part of such a country, unless

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transportation, sale, conditions of sale, advertising for sale, use and disposal of veterinary biologics and regulating their purity, potency, efficacy and safety;
(t) prohibiting or regulating the feeding to animals of any thing that could introduce or spread any disease or toxic substance to animals;
(u) regulating the construction, operation and maintenance of animal deadyards, rendering plants and animal food factories;
(v) regulating the importation, preparation, manufacturing, preserving, packaging, labeling, storing, distribution, sale, conditions of sale and advertising for sale of products of animal deadyards, rendering plants and animal food factories;
(w) governing the issue, renewal, amendment, suspension and revocation of licences, permits, approvals, certificates or other documents on such terms and conditions as may be required for the purposes of this Act;
(x) requiring animals and things to be marked or to have affixed to them tags, seals or other devices for the purposes of this Act, authorizing inspectors or officers to mark animals and things or to affix to them tags, seals or other devices for the purposes of this Act, and prohibiting the removal, breaking, tampering with or altering of those marks, tags, seals or other devices;
(y) establishing and governing a national identification system for animals that provides for standards and means of identification;
(z) requiring animals to be identified under the system established under paragraph (y) when the ownership or possession of them changes or when they are transported or otherwise dealt with;
(z.1) governing the manufacture, sale, distribution and use of the means of identification to be used in the system established under paragraph (y);
(z.2) governing the collection of information and statistics, the publication of studies and the conduct of surveys on any matter related to this Act or the regulations;
(z.3) requiring records to be kept respecting activities in respect of which this Act or the regulations apply;
(z.4) prescribing any fees or charges, or the manner of calculating any fees or charges, required for carrying out the purposes and provisions of this Act or the regulations; and
(z.5) prescribing anything required by this Act to be prescribed, other than anything to be prescribed by the Minister.

[66] C.R.C. (Consolidated Regulations of Canada), c. 296.

(a) the country of origin or part of such a country is designated as free of avian pneumoencephalitis (Newcastle disease) and fowl plague pursuant to section 7;
(b) the person produces a certificate of origin signed by an official of the government of the country of origin that shows that the country of origin or part of such a country is the designated country or part thereof referred to in paragraph (a); and
(c) the eggs are packed in containers that are clean and free from dirt and residue of eggs.
(3) Paragraph (2)(a) does not apply to eggs imported into Canada if they are transported under seal of an inspector direct from the place of entry to a registered processed egg station approved by the Minister.

34.1 (1) Notwithstanding subsections 34(1) and (2), a person may import an animal product referred to therein if the person produces a document that shows the details of the treatment of the animal product and the inspector is satisfied, based on the source of the document, the information contained in the
document and any other relevant information available to the inspector and, where necessary, on an inspection of the animal product, that the importation of the animal product into Canada would not, or would not be likely to, result in the introduction into Canada, or the spread within Canada, of a vector, disease or toxic substance."[67]

These sections illustrate the degree to which activities, in this case those pertaining to importation, are strictly controlled by Canadian authorities. Many of the animal and human pathogens listed in annex I are subject to stringent regulations in this Act. Violation of the provisions of the Act and its regulations are covered in sections 65 through 73 of the HAA and can be sanctioned by a fine of up to $200,000 and/or to imprisonment for up to two years. Finally, the reporting of diseases required pursuant to Sections 2 (2) of the HAA are contained in the *Reportable Diseases Regulations*[68] and reproduce many of the animal and human pathogens enumerated in annex 1 of the Protocol.[69]

To conclude with respect to the HAA, this Act controls a great range of activities so as to ensure that diseases that may affect animals or that may be transmitted from animals to human are controlled. Equally, it tightly regulates conditions under which activities involving infectious substances or potentially infectious situations may take place. To that end, activities such as importation, exportation, production, transportation as well as other related activities are subject to extensive licensing, safety, and health standards.

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[67] S.O.R./78-69, s. 21; S.O.R./92-650, s. 1; S.O.R./97-85, s. 28 (Statutory Orders and Regulations).

[68] S.O.R. 91-2 (Statutory Orders and Regulations) [hereinafter RDR].

[69] These reportable diseases include: anaplasmosis, equine infectious anemia, brucellosis systicercosis (bovine), bovine spongiform encephalopathy, swine vesicular exanthema, bluetongue, foot-and-mouth disease, anthrax, sheep scab, mange, avian influenza, dourine (mal du coït), swine vesicular disease, contagious equine metritis, glanders, rinderpest, African swine fever, hog cholera, equine piroplasmosis, avian pneumoencephalitis (Newcastle disease), pseudorabies (Aujeszky's disease), pullorum disease, rabies, vesicular stomatitis, scrapie, trichinosis, tuberculosis, fowl typhoid, varroasis.

4.2.1.3. The Plant Protection Act

The *Plant Protection Act*[70] operates in much the same way as the HAA. The Act, as stated in the preamble, seeks to prevent the importation, exportation and spread of pests injurious to plants, as well as to provide for their control and eradication together with the certification of plants and other things. Section 6 (1) stipulates that:

> "Except as permitted under this Act or regulations, no person shall move, grow, raise, culture or produce any thing that there are reasonable grounds to believe is a pest, that is or could be infested with a pest or that constitutes or could constitute a biological obstacle to the control of pest."

Additionally, section 7 provides for the controlled importation and exportation of any thing that is a pest or could constitute a pest, including a biological obstacle to the control of a pest. The PPA confers upon inspectors[71] much the same enforcement powers as those contained within the HAA and the FDA, and provides for punishment of up to a $250,000 fine and/or two years imprisonment.[72] The regulations provided for under section 47 are extensive. The *Plant Protection Regulations*,[73] for example, authorise a period of detention of up to three years in order to permit an inspector to identify a virus, viroid, mycoplasma, mycoplasma-like organism, rickettsia-like organism, bacterium or fungus that is either present or suspected of being present in a thing.[74] Furthermore, the Canadian Food Inspection Agency provides a list of pests called the "List of Pests Regulated by Canada" for the purpose of further strengthening these regulations.

4.2.1.4. The Feeds Act, Fertilizers Act, and Seeds Act

The *Feeds Act*[75] regulates the manufacture, sale, and importation of feed in Canada. It also prohibits the manufacture, sale or importation in Canada of any feed that, in contravention of the regulations, may adversely affect animal or human health. The *Fertilizers Act*[76] controls the sale and importation into Canada and prohibits the sale of fertilizer or supplement that contains destructive

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[70] 1990, S.C. (Statutes of Canada) 1990, c. 22 [hereinafter PPA].

[71] S. 21 *et seq.*

[72] See ss. 48 through 56.

[73] S.O.R./95-212 (Statutory Orders and Regulations) [hereinafter PPR].

[74] *Ibid.* at subsection 26 (2) a).

[75] R.S.C. (Revised Statutes of Canada) 1985, c. F-7

[76] R.S.C. (Revised Statutes of Canada) 1985, c. F-9.

ingredients or properties harmful to plant growth when used according to directions.[77] The *Seeds Act*[78] provides for the grading of seeds and establishes standards of purity for the sale, import or export of seeds from Canada. All three Acts are administered by the Minister of Agriculture and Agri-Foods Canada and provide relatively the same measure of penalties for violation of their provisions *viz.* punishment of up to two years imprisonment and/or $250,000.[79] Moreover, the powers of inspection parallel those provided under the previously mentioned Acts. Finally, the associated regulations[80] further specify the degree to which fertilizers, seeds, and feeds may be governed.

4.2.1.5. Further Relevant Acts

Three other Acts regarding the regulation of the subject matter are also worth some mention. The *Meat Inspection Act*[81] states in its preamble that it is:

> "An Act respecting the import and export of and interprovincial trade in meat products, the registration of establishments, the inspection of animals and meat products in registered establishments and the standards for those establishments and for animals slaughtered and meat products prepared in those establishments."

Its regulations prescribe appropriate standards, together with the licensing of activities to be undertaken under the Act.[82] Similarly, the *Fish Health Protection Regulations*[83] enacted pursuant to the *Fisheries Act*[84] provide measures for the establishment and enforcement of safety standards

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[77] See s. 4 of *Fertilizers Act*.

[78] R.S.C. (Revised Statutes of Canada) 1985, c. S-7.

[79] *Feeds Act*, s. 10; *Fertilizers Act*, s. 10; *Seeds Act* s. 9.

[80] The *Feeds Regulations*, S.O.R./83-593 (Statutory Orders and Regulations); *Seeds Regulations*, C.R.C. (Consolidated Regulations of Canada), c. 1400; *Fertilizers Regulations* C.R.C. (Consolidated Regulations of Canada), c. 666.

[81] R.S.C. (Revised Statutes of Canada) 1985 (1st Supp.), c. 25.

[82] *Meat Inspection Regulations*, S.O.R./90-288 (Statutory Orders and Regulations).

[83] C.R.C. (Consolidated Regulations of Canada), c. 812.

[84] R.S.C. 1985, c. F-14.

regarding activities germane to the Act. Finally, the *Pest Control Products Act*[85] and its regulations[86] provide measures to ensure that the manufacture, storage, display, distribution or use of pest control products is done under proper conditions. For example, the regulations require the registration of certain pest control products and extensive information to be submitted as per section 6 of the *Pest Control Products Regulations*. As well, where the product has not been previously assessed, further information is required as per section 9 of the regulations, in order to assess the safety, merit, and value of the product in question.

4.2.1.6. Conclusion

The preceding Acts illustrate not only the degree of regulation involved in the peaceful use of some of the matter also affected by the Protocol, but also point to the institutions within the Federal administration capable of ensuring compliance with them. The Minister of Health, particularly, plays a substantial role in ensuring and fostering compliance to the FDA, the Pest Control Products Act, and the Feeds Act. The Department of Health works in conjunction with Agriculture and Agri-Foods Canada, together with the Canadian Food Inspection Agency for the purpose of monitoring compliance with these Acts. The Canadian Food Inspection Agency and Agriculture and Agri-Food Canada administer the HAA and the PPA through a comprehensive inspection mechanism: they also promote compliance through the dissemination of information.

4.2.2. General Measures to Prevent the Spread of Disease

Three other acts govern, generally, situations where the spread of disease is of particular concern. The *Quarantine Act*[87] aims to prevent the introduction into Canada of infectious or contagious diseases. In particular, it empowers inspectors to take certain measures with respect to conveyances, goods, and cargo,[88] the cleansing or removal of conveyance, goods, and cargo,[89] medical examination for infectious, contagious or dangerous diseases,[90] as well as various forms of

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[85] R.S.C. 1985, c. P-10.

[86] *Pest Control Products Regulations*, C.R.C. (Consolidated Regulations of Canada), c. 1253.

[87] R.S.C. (Revised Statutes of Canada) 1985 (1st Supp.), c. .33. See also the *Quarantine Regulations*, C.R.C. (Consolidated Regulations of Canada), c. 1368, for further provisions.

[88] S. 5.

[89] S. 7.

[90] S. 8 and s. 11.

detention, disinfestation and quarantine.[91] Under the *Department of Health Act*[92] various measures are available to the Minister of Health with respect to the protection of the public health. According to sections 4 and 5 of the Act, these powers are:

> "4. (1) The powers, duties and functions of the Minister extend to and include all matters over which Parliament has jurisdiction relating to the promotion and preservation of the health of the people of Canada not by law assigned to any other department, board or agency of the Government of Canada.
>
> Particulars
>
> (2) Without restricting the generality of subsection (1), the Minister's powers, duties and functions relating to health include the following matters:
> (a) the administration of such Acts of Parliament and of orders or regulations of the Government of Canada as are not by law assigned to any other department of the Government of Canada or any minister of that Government relating in anyway to the health of the people of Canada;
> (a.1) the promotion and preservation of the physical, mental and social well-being of the people of Canada;
> (b) the protection of the people of Canada against risks to health and the spreading of diseases;
> (c) investigation and research into public health, including the monitoring of diseases;
> (d) the establishment and control of safety standards and safety information requirements for consumer products and of safety information requirements for products intended for use in the workplace;
> (e) the protection of public health on railways, ships, aircraft and all other methods of transportation, and their ancillary services;
> (f) the promotion and preservation of the health of the public servants and other employees of the Government of Canada;
> (g) the enforcement of any rules or regulations made by the International Joint Commission, promulgated pursuant to the treaty between the United States of America and His Majesty, King Edward VII, relating to boundary waters and questions arising between the United States and Canada, in so far as they relate to public health;
> (h) subject to the Statistics Act, the collection, analysis, interpretation, publication and distribution of information relating to public health; and
> (i) cooperation with provincial authorities with a view to the coordination of efforts made or proposed for preserving and improving public health."

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[91] See *inter alia* ss. 3 and 11-16.

[92] 1996, S.C. 1996, c. 8.

Pursuant to the *Department of Health Act*, the *Human Pathogens Importation Regulations*[93] were enacted to control the importation and transfer of certain human pathogens. Section 4 specifies that no person shall import a human pathogen belonging to risk group 2, 3, or 4 of the *Laboratory Biosafety Guidelines* unless, *inter alia*, it is in accordance with a subsisting import permit issued after it has been ascertained that certain aspects of the handling of the pathogen are in conformity with the guidelines.[94] Moreover, section 16 requires that particular imported pathogens be kept within the prescribed facilities and be subjected to further regulations with regard to transfers. It should also be noted that risk groups 3 and 4 cover most of the pathogens contained in the Protocol.

Finally, in dire circumstances, the *Emergencies Act*[95] may be of use. Briefly, this Act enables the Governor-in-Council to declare, for the purposes of public safety, a "public welfare emergency", which could include an emergency caused by a real or imminent disease in plants, human, or animals. This declaration would offer the Governor-in-Council a wide degree of discretion in the making of orders and regulations pursuant to section 8 of the Act for the purposes of remedying the situation.

The previous three Acts demonstrate the great degree of concern which exists with respect to the potential outbreak of disease in humans, animals, or plants. They also illustrate the varying measures available in order to ensure that such outbreaks do not occur.

4.2.2.1. Conclusion

As explicitly listed above, the Minister of Health, has significant powers in relation to matters concerning public health generally. As will be discussed in a later section, the coordinating of activities with the Minister of Health will be pivotal to the success of a National Authority for two principal reasons: 1) the expertise of the Minister in health and safety issues generally, and 2) as an example of an already existing compliance mechanism that combines enforcement and information to achieve its goals. The Minister of National Defence's cooperation will also be necessary since the Department of National Defence is partially responsible for the *Emergencies Act* and largely responsible for the *Emergencies Preparedness Act*.[96]

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[93] S.O.R/94-558.

[94] See ss. 4-8.

[95] R.S.C. (Revised Statutes of Canada) 1985 (4th Supp.), c. 22.

[96] R.S.C (Revised Statutes of Canada) 1985 (4th Supp.), c. 6. The Minister is responsible for advancing civil preparedness.

4.2.3 Acts Specifically Regulating the Subject Matter of the Protocol

4.2.3.1 The Canadian Environmental Protection Act

The CEPA is the foremost mechanism used for the control of toxic substances. The Act, as indicated by its title, aims to protect the environment. Its relevance to the Protocol is significant in that it provides extensive measures for ensuring that toxic substances are regulated at several stages, including that of production and manufacturing. The Act defines a substance as toxic if it enters or may enter the environment in a certain quantity or concentration, or under conditions that may have immediate or long term effects on the environment, in a manner which constitutes or may constitute a danger to the environment on which human life depends, or that may constitute a danger in Canada to human life or health.[97] As well, it provides for the establishment of a *Toxic Substances List* in subsection 13 (1), listed in schedule I. Those particular substances then become the object of considerable regulation as provided for in subsection 34 (1). The first six conditions under which the Minister of the Environment may provide regulations are illustrative of the level to which these substances are controlled:

> "(a) the quantity or concentration of the substance that may be released into the environment either alone or in combination with any other substance from any source or type of source;
> (b) the places or areas where the substance may be released;
> (c) the commercial, manufacturing or processing activity in the course of which the substance may be released;
> (d) the manner in which and conditions under which the substance may be released into the environment, either alone or in combination with any other substance;
> (e) the quantity of the substance that may be manufactured, processed, used, offered for sale or sold in Canada;
> (f) the purposes for which the substance or a product containing the substance may be imported, manufactured, processed, used, offered for sale or sold."

Additionally, section 17 requires that any person who imports, manufactures, transports, processes, or distributes a substance for commercial purposes or uses a substance in a commercial or manufacturing activity and has information that reasonably supports the conclusion that the substance is toxic or capable of becoming toxic, must inform the Minister of the Environment unless the person has actual knowledge that the Minister has the information. The Act then permits the Minister to order a person involved in an activity which may involve use of a toxic substance to produce further information and undertake certain activities surrounding the use of the substance in question.

Another measure provided for under the Act by section 25 *et seq.* regards the establishment of a *Domestic Substance List* and a *Non Domestic Substances List*. In short, the provisions provide that any person wishing to undertake certain activities such as the importing, manufacturing, or sale

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[97] See s. 11 of CEPA.

of these substances must establish whether the substance is listed in the *Domestic Substance List*. If it is not found, specific information relating to the substance is then required. Section 32 specifies the regulations that may be enacted to govern these specific provisions. To this end, the *New Substances Notification Regulations*[98] provide for extensive controls together with requirements on the part of persons wishing to undertake specific activities regarding substances on the *Non Domestic Substances List*, but especially new substances as defined by the CEPA.

Of direct application to the Protocol is the provision of subsection 71 (4), which reads:

> "(4) Where, in the opinion of the Minister, the circumstances referred to in paragraph (3)(c) exist in relation to a substance specified in Schedule III, no permit may be granted in respect of the substance unless
> (a) consultation has, if practicable, taken place with any foreign state that is likely to be affected by the proposed dumping; and
> (b) notification of the proposed dumping has been given to the organization responsible under the Convention for secretariat duties."

Indeed, item 7 of schedule III lists "substances in whatever form, produced for biological and chemical warfare". As such, specific measures, over and above those provided for in requesting a permit for ocean dumping, must be taken when dealing with biological and chemical warfare substances. Finally, section 100 *et seq.* of the CEPA provide for significant powers of inspection and an extensive range of penalties including fines up to $1,000,000[99] as well as potential prosecution for criminal negligence.[100]

To conclude, the CEPA provides for the comprehensive regulation of activities susceptible of having toxic effects on the Canadian environment. It contains measures through which substances can be prohibited or subject to strict regulation. Specifically, schedule I lists toxic substances whose use is extensively restricted. Many of the pathogens relevant to the Protocol could be listed as such and regulated in a similar fashion. Moreover, the Act, through its regulations, requires a number of declarations to be made, especially with respect to new substances. These formats could be readily adopted by a National Authority seeking to control activities relating to pathogens of concern to the Protocol.

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[98] S.O.R./94-260 (Statutory Orders and Regulations).

[99] S. 133.

[100] S. 115.

4.2.3.2 Transportation of Dangerous Goods Act

The *Transportation of Dangerous Goods Act*[101] seeks to promote and enforce safety regarding the transportation of dangerous goods. The general prohibition contained in section 5 states 1) that no person shall handle, offer for transport, transport, or import any dangerous goods unless that person complies with all appropriate prescribed safety requirements; 2) that the goods are accompanied by all applicable prescribed documents, and; 3) that the means of containment and transport comply with all applicable prescribed safety standards and display all applicable prescribed safety marks. The term "dangerous goods", as defined, refers to any product, substance, or organism included by its nature or by the regulations in any of the classes listed in the schedule.[102] The schedule includes "class 6", poisonous (toxic) and infectious substances. These infectious substances are further defined in the *Transportation of Dangerous Goods Regulations*[103] as:

> "[S]ubstances containing viable micro-organisms, including, but not limited to, a bacterium, virus, rickettsia, parasite or fungus, or a recombinant, hybrid, or mutant thereof, that are known or reasonably believed to cause disease in humans or animals, and that are included in risk group II, III or IV of Division 2 of Class 6, in accordance with the classification for risk groups set out in Part III or in the tables set out in Schedule VII."

The Act regulates many of the animal and human pathogens relevant to the *Protocol*, as well as many other contagious diseases, and subjects them to strict transportation requirements. S. 15 *et seq.* of the Act establish a compliance regime whereby inspectors are empowered to verify that measures are being taken to transport dangerous goods safely.

4.2.3.3. The Hazardous Products Act

The *Hazardous Products Act*[104] is designed to prohibit the sale, advertising, and importation of hazardous products. The Act provides for different classes of products, each of which is subject to a different level of control. Generally, it divides products into three categories: prohibited, restricted, and controlled. Section 4 states that no person shall advertise, sell, or import a prohibited product and that no person shall advertise, sell, or import a restricted product except as authorised by the relevant regulations. Section 6 provides that the Governor-in-Council may, by order, add to part I (prohibited) or part II (restricted) or schedule I, in particular:

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[101] 1992, S.C. (Statutes of Canada) 1992, c. 34.

[102] S. 1.

[103] S.O.R./85-77 (Statutory Orders and Regulations), s. 1.2.

[104] R.S.C. (Revised Statutes of Canada) 1985, c. H-3.

> "[A]ny product, material or substance that is or contains a poisonous, toxic, flammable, explosive, corrosive, infectious, oxidizing or reactive product, material or substance or other product, material or substance of a similar nature that the Governor in Council is satisfied is or is likely to be a danger to the health or safety of the public."[105]

Regarding controlled products, the Act provides that any controlled product must not be sold or imported without relevant information provided on a material safety data sheet. Products deemed to be controlled are listed in schedule II, which includes class D, poisonous and infectious materials. The *Controlled Products Regulations*[106] specify further information to be disclosed, especially the toxicity of the product.[107] Part III of the Act contains provisions for the administration and enforcement of the Act, including inspections and punishment of up $1,000,000 and/or two years of imprisonment.[108]

4.2.3.4. Export and Import Permits Act

The *Export and Import Permits Act*[109] is the principal legislative document used to control the import and export of strategic and other goods. The Act enables the Governor-in-Council to establish a list of goods (called the *Export Control List*[110]), delineating articles which the Governor-in-Council deems necessary to control, the purpose of which is, particularly:

> "a) to ensure that arms, ammunitions, implements or munitions of war, naval, army or air stores or any articles deemed capable of being converted thereinto or made useful in the production thereof or otherwise having a strategic nature or value will not be made available to any destination where their use might detrimental to the security of Canada."[111]

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[105] S. 6 (1) (a).

[106] S.O.R./88-66 (Statutory Orders and Regulations).

[107] See s. 43 *et seq.* of regulations.

[108] S. 28.

[109] R.S.C. 1985, c. E-17 [hereinafter EIPA]

[110] S.O.R./89-202 (Statutory Orders and Regulations) [hereinafter ECL.]

[111] Supra note 109, S. 3.

As well, the Act enables the Governor-in-Council to establish an *Import Control List*[112] for, *inter alia*, similar purposes.[113] Section 7 of the Act allows the Governor in Council to issue permits for the export of goods listed on the ECL. It also allows for the imposition of restrictions as to quantity, quality, persons, places or persons and other conditions described in the permit or in regulations. Section 8 applies in the same fashion with respect to import permits. The Act also provides for general export permits and general import permits subject to established terms and conditions. Punishment for contravention of the Act can be established in the form of a fine at the discretion of the court and/ or a term not exceeding ten years.[114] Finally, section 24 *et seq*. specify the duties of the Customs Officers in relation to the Act.

For the purposes of this chapter, the ECL and the ICL are of particular relevance. The ECL, *inter alia*, lists a number of goods as group 7 items in the Schedule "Chemical and Biological Non-Proliferation". These goods are described in group 7 of "A Guide to Canada's Export Controls".[115] These goods cover most of the human, animals, and plant pathogens listed in annex I of the Protocol. Category 7021 of the *Guide* lists biological weapons agents, except where the agent is in the form of a vaccine, thus again reproducing the Protocol's listed agents.[116] Moreover, category 7022 controls the exportation of listed biological test, together with such inspection and production equipment as certain containment facilities, fermenters, centrifugal separators, cross-flow filtration equipment, steam sterilizable freeze-drying equipment, and aerosol inhalation chambers.[117]

In addition to these specific controls exerted on biological agents and specific dual-use equipment, the *ECL* controls dual-use goods in group 1, munitions in group 2, prohibited weapons in category 5500, and goods in accordance with the Guidelines for Sensitive Missile-Relevant Transfers, issued by the *Missile Technology Control Regime* in group 6. The export of items in categories 7021 and 7022 is permit-free regarding member countries of the Australia Group.[118]

In essence, the EIPA provides significant controls for the exportation and importation of goods deemed to be strategic. This is significant in that the efficient implementation of the

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[112] C.R.C. (Consolidated Regulations of Canada), c. 604.[hereinafter ICL].

[113] S. 5.

[114] S. 19.

[115] Department of Foreign Affairs and International Trade, *A Guide to Canada's Export Controls* (Ottawa: September 1996) [hereinafter *Guide*].

[116] *Guide* at 90.

[117] *Guide* at 91-92.

[118] S.O.R./98-264 (Statutory Orders and Regulations).

Protocol's division F of Article III may require specific measures regarding transfers. Particularly, division F of Article III may require the States Parties not to transfer certain elements to non-States Parties without approval of the Organisation together with the production of an end-user certificate in some circumstances.

4.2.3.5. The Criminal Code

Provisions of the *Criminal Code*[119] are, perhaps, the most important legislative tools by which the Canadian government might prohibit the use of biological and toxin weapons. Article I of the Protocol explicitly bans the use of such biological weapons and toxins. Generally, sections 219 to 239 of the *Criminal Code's* application to offenses such as murder, manslaughter, criminal negligence, and attempted murder readily cover instances where the use of biological weapons would be punished. Moreover, the *Criminal Code* does prohibit the possession of prohibited weapons in Section 90 of the Code. This section reads, in part:

> "90 (1) Every one who has in his possession a prohibited weapon
> (a) is guilty of an indictable offence and liable to imprisonment for a term not exceeding ten years; or
> (b) is guilty of an offence punishable on summary conviction."

A prohibited weapon, *inter alia*, includes as defined in the *Regulations Prescribing Certain Firearms and other Weapons, Components and Parts of Weapons, Accessories, Cartridge Magazines, Ammunition and Projectiles as Prohibited or Restricted*[120] in part III, the following:

> "1. Any device designed to be used for the purpose of injuring, immobilizing or otherwise incapacitating any person by the discharge therefrom of (a) tear gas, mace or other gas, or (b) any liquid, spray, powder or other substance that is capable of injuring, immobilizing or otherwise incapacitating any person."

Finally, section 87 states that everyone who carries in his possession a weapon or imitation thereof, for a purpose dangerous to the public peace or for the purpose of committing an offence is also guilty of an offence. This purposive definition is much broader and may cover a number of unforeseen devices.[121]

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[119] *Criminal Code,* R.S.C. (Revised Statues of Canada) 1985, c. C-46 [hereinafter *Criminal Code*].

[120] SOR/98-462 (Statutory Orders and Regulations).

[121] *Criminal Code*, s. 87.

4.2.3.6. Conclusion

The above Acts are administered by different institutions. The Minister of the Environment and the Minister of Health regulate the CEPA, the Minister of Transport has authority over the *Transportation of Dangerous Goods Act*, the Export Controls Division of the Department of Foreign Affairs and International Trade (DFAIT) together with Customs agents implement the IEPA, the Minister of Health administers the *Hazardous Products Act*, and the Department of Justice is responsible generally[122] for the *Criminal Code*. Furthermore, it is evident that these Acts regulate much more than what is relevant to the National Authority. Still, the identification of these institutions and their implementation mechanisms, for the purposes of supporting the BTWC, will contribute to the overall effectiveness of the Canadian National Authority.

4.2.4. Conclusion

The preceding section has examined the extent to which the subject matter of the Protocol is already regulated by existing domestic legislation. For example, the FDA and the HAA are similar insofar as they attempt to restrict the conditions under which an outbreak of disease might occur. They are, however, different from the Protocol insofar as their purposes are different, as both the HAA and the FDA focus on vectors and assume that they will be used for peaceful purposes.[123] Conversely, the BTWC and the Protocol target specifically the purposes of use and prohibit the development, production, stockpiling, or otherwise acquisition or retention of microbial or other biological agents, toxins whatever their origin or method of production, of types and in quantities that have no prophylactic, protective or other peaceful purpose, together with weapons, equipment, or means of delivery,[124] including the prohibition of natural or legal persons undertaking activities prohibited by the BTWC.[125]

These laws provide considerable insight into the possible means of regulating the industries to be affected by the Protocol. They also show the work that remains to be done in order to ensure that any new piece of legislation regarding the creation of the National Authority adequately links the spectrum of activities governed by the Protocol. The existing domestic implementory mechanisms, as will be seen later, offer a good example of the manner by which compliance can be ensured, as well as the degree of coordination which the National Authority must achieve in order to discharge its duties.

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[122] In Canada, the provinces are responsible for the administration of justice. The RCMP, as well as regional police, enforce the Code.

[123] Or purposes not prohibited by the BTWC.

[124] BTWC, Article I.

[125] See Protocol at Article X.

4.3. The Impact on Related Industries and the Protection of Confidential Business Information

The protection of confidential business information[126] is an issue of the foremost importance, both for the States Parties participating in the negotiation of the Protocol and those industries that will be subjected to declarations and inspections of varying degrees and kind. The *Ad Hoc* Group is well aware of this sensitivity and the protection of such information is an explicit part of their mandate, which in particular states that "[m]easures should be formulated and implemented in a manner designed to protect sensitive commercial proprietary information and legitimate national security needs."[127] Protection of CBI constitutes a particular challenge to the State Party and to the prospective National Authority. The issue is addressed in specifically in this section.

The need for particular protection for commercial business information stems from two sources: the nature of the business information itself and the particularities of the potentially affected industries. CBI, and particularly trade secrets, are volatile things. Their viability or commercial usefulness depends on their secrecy. Once these secrets are within the public domain or known by competitors, their value is lost. The critical position of CBI is summarised by Barry Kellman, who states that

> "Protection of CBI is critical to the industries that are most likely to be subject to arms control verification. The same technologies that are used in sophisticated weaponry also have important commercial applications; the control of these dual-use technologies demands regulation of highly competitive, leading-edge industries that have invested massively in research and development. In order to recoup their investment and make a profit, it is essential that these firms retain some measure of confidentiality with respect to their technical knowledge. The revelation of CBI can enable a competitor to obtain, at minimal cost, information that its originator acquired through an enormous investment of time and money, thereby erasing the competitive advantage created by that initial investment in research and development."[128]

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[126] The term "confidential business information" is used analogously to "commercial proprietary information"; however, the former term is preferred in this report [hereinafter CBI].

[127] United Nations, Special Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, BWC/SPCONF/1, Geneva, 19-30 September 1994, as cited in M.R. Dando, *The Strengthened BTWC Protocol: Implications for the Biotechnology and Pharmaceutical Industry*, Department of Peace Studies, University of Bradford, UK, online: University of Bradford homepage, http://www.brad.ac.uk/acad/sbtwc/briefing/bw-briefing.htm (last modified: 2 August 1999) at para 1.

[128] B. Kellman, D.S. Gualtieri & E.A. Tanzman, "Disarmament and Disclosure: How Arms Control Verification Can Proceed Without Threatening Confidential Business Information" (1995) 36 Harvard International Law Journal at 36, 71 and 73. See also footnote 5 where they define CBI as: "business related information that gives its holder a commercial advantage because it is not widely known to its competitors or the general public. CBI can consist of technical or non-technical forms of information, including: formulas, patterns, compilations, programs, devices,

Because of the fact that the viability of many firms may depend on the possession of a few secrets, the sensitivity to inspections and declarations can be quite high. The concern for commercial proprietary information in other fora such as NAFTA, the CWC, and START is considerable and several conventions have attempted to regulate the subject matter generally.[129] Furthermore, on a policy level, the argument can be put as follows: States Parties that would normally support arms control measures can find themselves in opposition to verification provisions because of the potential breach of CBI that such provisions could entail. For these reasons, and on grounds of fairness to the relevant industries, it is therefore desirable to address this issue head-on so as to avoid a potentially flawed treaty negotiation process or, at best, reticence on the part of a State Party.[130]

The issue is further complicated by the state of the industries most likely to be affected *viz.* the biotechnology and pharmaceutical industries. Although it is not within the scope of this chapter to deal with the development of the industry, the subject deserves some attention. According to a report by Graham S. Pearson,[131] in the past two decades the science and business of biotechnology has burgeoned. Particularly, such growth has occurred in the area of such medical products as antibiotics, vaccines, and other medicines.[132] Moreover, emerging applications in the energy, chemical, waste treatment, and agro-food sectors offer considerable economic promise. For example, in the United States, sales for US research-based pharmaceutical companies increased from $ 4.5 billion to $ 11.7 billion in 1980, and $ 38.6 billion in 1990. Estimates were in the order of $ 66 billion for 1997.[133]

As reported by G.S. Pearson, new technologies have been identified in the area of biotechnology, including the sequencing of genes and proteins, genetic engineering, fused cell techniques, protein engineering, and fermentation of cell cultures permitting the growth of large

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methods, techniques, drawings, processes, financial data, price codes, customer lists, economic studies, cost reports, and bookkeeping methods."

[129] These include the *Berne Convention for the Protection of Literary and Artistic Works* of 1886, 9 September 1886, 828 U.S.T. (United States Treaties and Other International Agreements) 221; the *Universal Copyright Convention*, 24 July 1971 25 U.S.T. 1341; and the *Paris Convention for the Protection of Industrial Property*, 20 March 1893, 21 U.S.T. 1583. Both the World Intellectual Property Organisation and the World Trade Organisation deal with the protection of types of CBI.

[130] *Supra* note 128 at 76.

[131] G. S. Pearson, "The Threat of Deliberate Disease in the 21st Century", Department of Peace Studies, University of Bradford, UK, online: University of Bradford Homepage <http://www.brad.ac.uk/acad/sbtwc/briefing/bw-briefing.htm> (last modified: 2 August 1999).

[132] *Ibid.* at 15.

[133] *Supra* note 131 at 15-16 citing Table 11 in *PhRMA Annual Survey: 1997* (Washington D.C.: Pharmaceutical Research and Manufacturers of America, 1997) at 66.

amounts of microbial or animal or plant cells.[134] These great advances, however, have a darker side in that they can also be used for purposes prohibited by Article I of the BTWC.

The need for a viable verification mechanism must then balance the requirement for the protection of the confidentiality of commercial proprietary information with the need to address national security interests. Given the potentially devastating effects of biological weapons, the verification mechanism must be rigorous enough to ensure that prohibited activities are not taking place, while still protecting the CBI of relevant industries. To that end, it will be necessary in the following sections to examine the provisions regarding confidentiality in the Protocol, as well as the actual potential requirements on the part of the relevant industries which may be affected by its terms.

4.3.1. Measures Protecting Confidential Business Information in the Protocol

The Protocol places a strong emphasis on the prevention of potential loss of information resulting from disclosure either in a declaration or in any investigation activity. Article IV of the Protocol is the principal article pertaining to the protection of confidentiality.

Paragraph 1 of Article IV, *in fine*, states that the Organisation shall take every precaution to protect the confidentiality of information related to civil and military activities and facilities in the implementation of the Protocol. Paragraph 2 further requires States Parties to treat as confidential and afford special handling to information and data that it received in confidence from the Organisation in connection with the implementation of the Protocol. Additionally, paragraph 3 provides that each State Party shall have the right to take measures as it deems necessary to protect confidential information, in accordance with the provisions of the Protocol. Paragraphs 4 *et seq.* go on to define the rights and duties of the Organisation, particularly the Technical Secretariat, in relation to information acquired from States Parties or other legal or moral persons. In particular, they allow the Director-General to impose appropriate disciplinary measures on employees who violate their obligations of confidentiality. In case of a serious breach, immunities may be waived. Finally, in paragraph 7, a State Party which considers that it has been affected by a breach of confidentiality or that its legal persons have suffered damages through such a breach may resolve their disputes in accordance with Article XII. This could include referral to the Confidentiality Commission in accordance with paragraph 8 of annex E, section IV.

While Article IV outlines the general requirements for the protection of confidentiality, the substantive measures are found primarily in annex E of the Protocol. Generally, this annex provides for the following: 1) general principles for the handling of confidential information; 2) conditions of staff employment relating to the protection of confidential information; 3) measures to protect confidential information in the course of, or as the result of, on-site activity; and 4) procedures in

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[134] *Ibid,* at 16.

case of breaches or alleged breaches of confidentiality.

In particular, the Annex provides that a State Party may classify information as confidential, in which case access to such information will be severely restricted. The Annex further provides for a code of conduct for employees, principles for the protection of sensitive information and the protection of samples. Finally, in certain cases a waiver of immunity can be obtained.

4.3.2. Specific Measures for the Safeguarding of CBI

Although Article III addresses mainly compliance measures, several methods are available to the State Party in order to safeguard confidential information. Depending on the nature of the activity, these measures may include restricting the visit to a limited time frame, restricting activities to the purpose of the visit, and developing procedures for managed access. It is foreseeable that for most types of visits, the principle of managed access will apply.

Managed access involves specific measures in order to ensure the safeguarding of information. For example, during visits, the State Party could have the right to the:

> "(a) Removal of sensitive papers from office spaces;
> (b) Shrouding of sensitive displays, stores, and equipment;
> (c) Shrouding sensitive pieces of equipment, such as computer or electronic systems;
> (d) Logging off of computer systems and turning off data indicating devices;
> (e) Using random selective access techniques whereby the team is requested to select a given percentage or number of buildings of their choice to investigate; the same principle can apply to the interior and content of sensitive buildings or documents;
> (f) In exceptional cases, limiting the number of team members who have access to certain parts of a facility; and limiting the viewing angle; the reasons for such limitations shall be stated;
> (g) Limiting the time team members may spend in any area or building, while allowing the team to fulfil its mandate; and limiting the viewing angle; the reasons for such limitations shall be stated;
> (h) The visited State Party may at any time during the visit identify products and processes in which it has a proprietary interest in order to help the team respect the visited State Party's right to safeguard proprietary information. It may request that if a specific piece of information is released to the team, it should be accorded the most stringent protection measures by the Organization."

However, the more intrusive the visit, such as the type of visit required during an investigation, the more these measures could find themselves directly at odds with the purpose and mandate of the type of visit. For example, the protection of national security data which, if revealed, would uncover an offensive biological weapons programme would clearly not fall within the scope of legitimate protection from visiting teams. The potential revelation of a trade secret, conversely, would deserve protection. Defining these boundaries will be a challenge for the Protocol, since a

State Party can, ultimately, prevent the efforts of an inspection team and so frustrate the inspection process. Defining what constitutes the national interest is a delicate issue; however, this issue must be addressed if the verification mechanism is to have any credibility.

It is clear from this discussion that any type of visit must reveal some type of information and that such revelations could conceivably lead to a breach of confidentiality provisions. Additionally, the success of the Protocol will involve some measure of intrusiveness into the affairs of the States Party. At the very least there exists a risk to the CBI of an industry affected by the Protocol. Measures exist in the Protocol for the protection of information, much like those in effect for the CWC.[135] Still, even with a highly professionalised inspectorate with loyalty to the prospective *OPBTW*, investigations, will pose a particular problem with respect to confidentiality, given their intrusive nature.[136] The State Party, when providing access to relevant industries, must be aware of the concern that exists within these highly competitive industries and take the appropriate measures provided for under the Protocol to ensure that breaches of confidentiality do not occur.

4.3.3. Post Breach Remedies

The accountability of personnel who disclose CBI is tenuous. Most of the Protocol's provisions regarding confidentiality deal with the prevention of disclosure. As such, there is very little regarding actual indemnification of an injured party. Rules regarding the breach of confidentiality can be found in annex D of the Protocol. The Director General can waive the immunity conferred on the members of the OPBTW by virtue of Article IX of the Protocol. As well, the Director-General's immunity can be waived by the Executive-Council. These cases are extreme measures, provided for in cases where it would impede the course of justice to maintain immunity of the individual in question. The annex further provides that investigators are to be held liable to physical and juridical persons, according to the relevant rules of international law, for any intentional or accidental damage resulting from unlawful actions on their part, including the disclosure of confidential information. Article IV provides, further, that without prejudice to the privileges and immunities to be accorded pursuant to the Protocol, the Organisation, Director-General and staff members of the Technical Secretariat shall be liable to natural or legal persons for damage. An alternate phrasing requires the Director-General to impose liability. Finally, a State Party which considers that it has been adversely affected by a breach of confidentiality or that its natural or legal persons have suffered damage may seek to settle the dispute in accordance with provisions set forth in Article XII.

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[135] For a comprehensive review of such measures, see *supra* note 128.

[136] *Ibid.* at 98.

These provisions are, at best, confusing since the granting of immunity prevents most recourse. The legal subgroup for the Federation of American Scientists, or FAS, has presented the dilemma as follows:

> "The first question that arises is how they square with the granting of immunity to the OPBTW and its staff accorded elsewhere in the B[T]WC Protocol. The immunity provisions of the B[T]WC Protocol require that the immunity to jurisdiction and immunity to execution of judgment be waived before an individual would be subject to full liability. Liability in national legal systems cannot attach to the OPBTW or any other member of its staff for alleged violations of confidentiality rules without express waivers of immunity. If the immunity protections did not exist, there would be no need to impose liability on entities or individuals in the B[T]WC Protocol because such liability would attach by operation of general international law."[137]

Moreover, as emphasised by the FAS working group, not granting diplomatic immunity for officials and staff of the OPBTWC is unrealistic since immunity is necessary for the effectiveness of the compliance regime. As well, weakening the principle of immunity would undermine the regime as the staff might be reluctant to enforce the Protocol.[138]

The FAS recommends the establishment of a compensatory regime at the international or national level in order to bolster remedies available in case of loss sustained pursuant to a breach of confidentiality. Such a remedy is available in some circumstances. In Canada, for example under the *Health of Animals Act* and the *Plant Protection Act*, compensation can be paid for loss out of the Consolidated Revenue Fund.[139] This solution is an attractive remedy if the State Party wishes to foster compliance on the part of the industry with the BTWC. The provision of a fund for industries whose secrets have been divulged as a result of a disclosure could further strengthen cooperation with regard to visits and inspections on the part of industry. This type of remedy could be included in the implementation legislation for Canada, but also should be provided for in the Protocol.

4.3.4. CBI Concerns Regarding Declarations

The Protocol, as discussed in a previous section, provides for a number of declarations. Under the current language of the Protocol, triggers for declarations are not set in stone. However, those industries which will be subject to declaration can be reasonably foreseen.

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[137] D.P. Fiddler *et al.*, "Working Paper of the Legal Subgroup on the Protection of Confidential Information" Federation of American Scientists, online: <http://www.fas.org/bwc/paper/full_legal.htm> (last modified: 6 January 1998) at 8.

[138] *Ibid.* at 4.

[139] See as well *supra* note 128 at 122.

Under the initial declarations described in section D of Article III, past offensive or defensive activities as stated by the Protocol should not reveal any difficulties regarding CBI;[140] neither should the reporting of national legislation and regulation. Under the annual declarations ten categories are distinguished: 1) current defensive programmes; 2) vaccine production facilities; 3) maximum biological containment facilities; 4) high biological containment facilities; 5) work with listed agents and/or toxins; 6) other production facilities; 7) other facilities; 8) transfers; 9) declarations on the implementation of Article X of the Convention; and 10) outbreaks of diseases. The specific data to be reported is prescribed in annex B. In general, the reporting requirements are not unduly onerous and pertain to the equipment used, the size and capacity of such equipment, the source of funding, the toxins used and quantities thereof, the purpose of use, and so forth.[141]

It is obvious from the requirements for reporting that the risks for disclosure of CBI are very slight since the information to be provided does not require an in-depth description of the processes undertaken. Nevertheless, it is possible that the revelation of seemingly benign information could cause significant damage; this must be examined in further detail. More onerous requirements, however, exist under other Canadian legislation such as the *Food and Drugs Act* and the *Canadian Environmental Protection Act*. The latter Act is of particular interest because of the reporting requirements for any new substance under the *New Substances Notification Regulations*, especially in schedule XV of the regulations. Moreover, under the CEPA at section 31 a request for a masked name may be made if the publication of "the explicit chemical or biological name of a substance would result in the release of confidential business information in contravention of section 20", in which case "the substance shall be identified by a name determined in the prescribed manner".[142] Such a solution may be desirable, but given the reporting requirement, it may also be excessive.

Finally, as reported by Malcom Dando, an analysis of surveys made by developed countries has shown that each country would have to declare little more than ten facilities. An Austrian/UK submission to the EU seminar for industry in May 1998 confirmed these findings. On a world scale, this would entail the declaration of roughly 1600 to 3200 facilities.[143] If there were to be 100 visits per year, of which 30 would be for biological defence facilities and past biological weapons facilities, the remaining visits could be spread out so that the burden on any one state would not be great.[144] This argument that declarations need not be unduly difficult is not entirely convincing in

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[140] Although they may present a problem for national security and some of these programmes may be undertaken in conjunction with the private sector.

[141] For more detail, refer to appendix B of the Protocol.

[142] S. 31, CEPA.

[143] *Supra* note 131 at 6.

[144] *Ibid.* at 12

that it does not specifically address disclosure of information; however, it does allay fears of widespread intrusive visits and inspections.

4.3.5. Conclusion

The protection of CBI is critical to a proper balancing of interests, as well as the success of the verification mechanism. Various measures exist in the Protocol as it currently stands, but these could be strengthened, especially given the need for immunity and the need for proper compensation should a breach occur. The information to be submitted is not unduly onerous and it is unlikely that a serious breach of confidentiality could occur through the submission of declarations. However, further work must be done in assessing the specific risks associated with the declaration of even minimal amounts of information. This is why it is critical that a working relationship be established between the National Authority (or those responsible for creating it), and relevant heads of industry. Moreover, at the domestic and the international levels, serious thought should be given to including a comprehensive compensation mechanism together with the possibility of a masking system for confidential information. Additionally, when the National Authority is created, it will be important for the latter mechanism to represent the concerns of the relevant industry when they are undergoing inspections or visits.

In light of the two preceding sections, a useful role for a National Authority for the Protocol to the BTWC can be carved out. While the function of the authority need not be all encompassing, it must be able to coordinate a whole range of activities. This theme is covered in the following section.

4.4. Acts Relevant to the Creation of a National Authority

4.4.1. The CWCIA and the CNTBTIA

Two federal acts of parliament provide explicitly for the creation of a National Authority: The *Chemical Weapons Convention Implementation Act* and the *Comprehensive Nuclear Test-Ban Treaty Implementation Act*.[145] Both Acts create National Authorities to ensure that duties imposed by, respectively, the *Chemical Weapons Convention* and the *Comprehensive Nuclear Test-Ban Treaty* are properly discharged. The CWCIA and the CNTBTIA define the role of the National Authority different ways. In the CNTBTIA, the National Authority is defined as follows:

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[145] 1998, S.C. (Statutes of Canada) 1998, c.32 [not in force]. The *Comprehensive Nuclear Test-Ban Treaty Implementation Act* is hereinafter referred to as the CNTBIA.

"National Authority

9. (1) The Minister may designate any person or class of persons to be the National Authority for Canada.

Designation and activities of representatives

(2) The Minister may
(a) designate persons or classes of persons to act as representatives of the National Authority; and
(b) authorize, for the purpose of this Act, activities of those representatives or their access to certain places, including their access to places controlled by the Government of Canada, subject to any conditions that the Minister considers appropriate.

Certificates

(3) The Minister shall furnish a representative with a certificate of the representative's designation that indicates the activities or access, including any conditions on them, that the Minister authorizes.

Identification required

(4) A representative who enters a place shall, on the request of a person in possession or control of the place, show the certificate to the person.

Duties and functions of National Authority

10. The National Authority

(a) may, subject to section 12, establish or designate facilities and laboratories and, if necessary, operate, maintain, equip and upgrade them to permit the performance of verification measures as part of the International Monitoring System by means of
(i) radionuclide monitoring,
(ii) seismological monitoring,
(iii) hydroacoustic monitoring, and
(iv) infrasound monitoring;
(b) shall communicate data obtained from its verification measures to the International Data Centre of the Technical Secretariat of the Organization;
(c) may establish or designate facilities under the name of the National Data Centre for the exchange of data with the International Data Centre of the Technical Secretariat of the Organization;
(d) shall participate with States Parties to the Treaty in consultation and clarification processes;
(e) shall facilitate and provide support for and assist in the conduct of on-site inspections by inspectors;
(f) shall cooperate with the Organization in confidence-building measures;
(g) shall receive notices given under section 8;

(h) shall cooperate with persons engaged in the mining or other relevant industries in order to encourage them to provide the National Authority with information about chemical explosions that might register with the International Monitoring System and to facilitate that reporting; and
(i) shall cooperate with the Organization and report to it regarding Canadian compliance with the Treaty.

Delegation by National Authority

11. The National Authority may delegate any of its powers, duties and functions conferred by or under this Act to one or more persons who shall exercise those powers and perform those duties and functions, subject to any terms and conditions that the National Authority specifies.

Minister of Health

12. (1) The Minister of Health shall establish or designate facilities and laboratories and, if necessary, operate, maintain, equip and upgrade them to perform analyses of samples from radionuclide monitoring stations.

Minister of Natural Resources

(2) The Minister of Natural Resources shall establish or designate facilities and, if necessary, operate, maintain, equip and upgrade them to perform verification measures as part of the International Monitoring System by means of seismological, hydroacoustic and infrasound monitoring."

In the CNTBTIA, the role of the National Authority is tightly defined insofar as the relevant activities are circumscribed. Moreover, given the nature of the treaty, the Act provides for coordination of activities with the Minister of Natural Resources and the Minister of Health. The National Authority for the CNTBT is administered by the Nuclear Non-Proliferation and Disarmament Implementation Agency (IDN) of DFAIT.

The National Authority for the CWC is similarly housed within IDN. However, the role and scope of the National Authority is less circumscribed. The relevant sections pertaining to the National Authority for the CWC reads as follows:

"NATIONAL AUTHORITY

National Authority

3. (1) For the purposes of implementing Canada's obligations under the Convention and of giving effect to paragraph 4 of Article VII of the Convention, the Minister may designate any portion of the public service of Canada to be the National Authority for Canada.

Representatives

(2) For the purposes of implementing Canada's obligations under the Convention, the Minister
(a) may designate persons or classes of persons to act as representatives of the National Authority; and
(b) shall furnish every representative of the National Authority with a certificate of designation.

Contents of certificate

(3) A certificate of designation must indicate the places or classes of places that the holder of the certificate is authorized to have access to for the purposes of this Act and any conditions applicable to the holder's activities under the certificate that the Minister considers advisable for those purposes.

Identification required

(4) Every holder of a certificate of designation shall, on request of the person in charge of a place to be entered by the holder under this Act, show the certificate to that person.

PURPOSE OF ACT

Implementation of Convention

4. The purpose of this Act is to implement Canada's obligations under the Convention."

While the Act goes on to provide measures in which to implement the obligations under the CWC, it does not further delimit the role of the National Authority. Without a clear delineation of their specific tasks, this loose definition puts members of the National Authority in the undesirable situation of having to define their own role. Moreover, such a situation creates the risk of a National Authority assuming obligations for which is not qualified or for which other institutions are better qualified. For example, as seen in the survey of the legislation, the Minister of Health would be better suited to deal with issues of health and safety relevant to the Protocol. Equally, during international visits or inspections, the use of laboratories and personnel may be necessary. A reference to such cooperation (such as in the CNTBTIA) could contribute to furthering mutually beneficial interaction and the proper delegation of responsibilities.

Although the distinction may exist only in the legislative documents, it is perhaps important nevertheless to delineate the scope of a prospective BTWC National Authority in a tighter fashion, similar to the listing of activities contained in the CNTBT in section 10.

4.4.2. Duties to be Performed by the Prospective National Authority for the BTWC

At this point it is necessary to recall the obligations imposed on the State Party so as to better gauge and appreciate the future role to be played by the National Authority. Generally, the requirements of the Protocol parallel those imposed under the CWC, except that the Protocol does not ban a whole class of substances. Like the CWC, the Protocol focuses on the purpose to which substances are put and forbids a range of activities enabling the prohibited purpose, namely weaponisation in all its aspects.

As analysed earlier, Articles I, III, VII, and X establish the primary obligations of the State Party. The degree to which a National Authority must assume all of these obligations depends necessarily on the nature of the obligations. A loose idea can be formed as to the role of the National Authority based on a reading of the relevant articles.

First, Article X requires that each State Party "shall designate or set up a National Authority and shall so inform the Organization upon entry into force of this Protocol for it. The National Authority shall serve as the national focal point for liaison with the Organization and with other States Parties."[146] While this paragraph suggests but one aspect of what the National Authority must do, it does underscore the need for the National Authority to be informed, at the very least, of the State Party's undertakings regarding the Protocol. It also highlights the coordinative role that the National Authority must play.

Second, Article I's general prohibition can not be fully assumed by the National Authority; nor is this particularly desirable. Other members of Canada's federal institutions are fully empowered to ensure that these obligations are met. These institutions include especially the RCMP, CSIS and the Export Controls Division of DFAIT. Nevertheless, this does not mean that a National Authority would not interact with these institutions. A properly empowered National Authority must be aware of efforts made to fulfill obligations under Article I and, indeed, must encourage and be kept informed by the relevant institutions.

Third, Article III explains the compliance measures to be taken by the State Party. This is where the National Authority can play its most significant role. Article III stipulates all the verification and compliance measures available to the BTWC, together with the primary obligations to be assumed by the National Authority. These include: 1) the dissemination and collection of information *vis-à-vis* the relevant institutions and industries affected by the Protocol; 2) the coordination of inspections with the Technical Inspectorate, and; 3) the submission of declarations, reports, and legislation.

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[146] Protocol at Article X, para 3.

Fourth, Article VII requires that States Parties cooperate in the area of scientific and technological exchanges for peaceful purposes, as well as on the issue of technical cooperation. As liaison for the State Party and the Organisation, the National Authority can play a pivotal role in ensuring that peaceful exchanges[147] do take place. Additionally, since the National Authority will be at the forefront of issues relating to the Protocol, it will be useful in assisting various domestic interests to cooperate at the international level. In this regard, it would not be undesirable for the National Authority to have a budget that provides for such undertakings.

Fifth, Article X covers the National Implementation Measures to be taken under the Protocol. In this respect, the National Authority must ensure that the proper enabling legislation is enacted. The proper drafting of legislation and regulations, to be done in conjunction with the Minister of Justice, is critical for the success of a National Authority. As seen in the previous sections of this chapter, many legislative documents cover some of the subject matter relevant to the Protocol, but very few directly address the purpose of the use of agents, toxins, and equipment. For this reason, these Acts alone are insufficient in terms of implementing the Protocol.

In seeking to delineate the activities to be performed by a new National Authority, it is useful to consider the performance and structure of its close relative, the CWC National Authority. The experiences of the CWC National Authority will, hopefully, enable a new similar institution to avoid its pitfalls and capitalise on its successes.

4.5. Lessons Learned from the CWC National Authority

The National Authority for the CWC, housed in IDN at the Department of Foreign Affairs and International Trade, was created in order to fulfill Canada's obligation under the Convention. The Convention was signed in January 13, 1993, and came into force on April 29, 1997. The legislation creating Canada's National Authority was assented to on 13 July 1995, but has not yet entered into force due to the lack of regulations. The stated activities of the National Authority are as follows:

> "The Canadian National Authority seeks to ensure the effective implementation of Canada's CWC obligations, while also seeking to minimize its regulatory impact. Its principal current activities include:
>
> - preparing and forwarding periodic Declarations to the OPCW;
> - providing advance notifications of transfers of Schedule 1 chemicals;
> - supporting the conduct of inspections;
> - supporting Canada's Delegation to the OPCW;
> - liasing (*sic*) with the OPCW and other States Parties;

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[147] This term requires further definition within the Protocol. It is usually defined negatively as a purpose not prohibited.

- undertaking domestic outreach activities to ensure awareness of the Convention's objectives and obligations;
- consulting with domestic stakeholders on declarations and licensing regulations, and inspections modalities;
- continuing to define Canada's contributions in the event of the use of, or threat of the use of, chemical weapons."[148]

The success of National Authority has been partial. The fact that regulations to the CWCIA remain to be completed, something which is necessary to ensure the entry into force of the Act, is of considerable concern. As such, should an investigation be launched, under certain circumstances a facility could refuse entry to a prospective international investigation team, something which would place Canada in default of its international obligations. As much as the initial drafting of the Implementation Act has dragged on, so too has the drafting of the relevant regulations.[149] The significance of this failure cannot be overstated and it unfortunately tarnishes the relative success of the CWC National Authority.

4.5.1. Current CWC National Authority Issues

4.5.1.1. Composition

Because Canada has a very small declarable industry under the Convention, the size of its National Authority is proportionally small. The members of the National Authority include a National Coordinator, a Senior Advisor on Industry Issues, a Head, Industry Operations, an Advisor for Inspections, part of a Rotational Secretary, and scientific and informatics advisors on contract. The current size constitutes an important downgrade in numbers of personnel from the original plan, which foresaw at least two more scientific or technical-related positions and more senior members, especially at the level of National Coordinator.[150] The view has been expressed that the National Coordinator should be fully devoted to CWC issues, and be non-rotational.[151] This view is perhaps due to the fact that since its inception, the post has changed three times. This view is not universally shared and it has been expressed that dedication to the job constitutes a more sound criterion.[152] It would also be desirable to have a position where a junior political officer might gain experience with

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[148] Canadian National Authority, "Chemical Weapons Convention and Canada", online: http://www.dfait-maeci.gc.ca/nndi-agency/cwc/english/obligation.html (last modified: 31 October 1998).

[149] Interview 2 (3 August 1999) and interview 1 (14 June 1999).

[150] *Ibid.*

[151] *Ibid.*

[152] Letter 1 (16 August 1999) and Letter 2 (29 July 1999).

regard to both the political and technical aspects of the CWC. Moreover, members of the National Authority have stated that the rank of Coordinator could be greater so that National Authority issues could be better represented, particularly *vis-à-vis* private sector representatives.[153] It was stressed that it is essential not to overlook or underestimate the correct staffing level that will be required for the Permanent Delegation to the BTWC Organisation. The CWC experience has shown that in the early stages, two individuals (one with policy experience and the other with an industry/technical background) are desirable. This will also be the case for supporting Canadian membership on bodies such as the Executive Council.

The issue of downsizing is of considerable importance, particularly in light of the need for a well-trained administrator and contract inspection escorts, together with contracted sources during declaration periods.

4.5.1.2. Subject Matter

The work done by the National Authority has been considerable. The creation of declaration formats and the identification of targeted industries has been an area where the National Authority has succeeded despite initial difficulties, a success due in very large part to the dedicated efforts and technical expertise of the Head, Industry Operations. This is one of the principal obligations under the CWC, together with the coordination of inspections. The latter responsibilities have also been successfully carried out, even though, at present, Canada has only one eligible facility under the CWC. However, the lack of promulgated legislation has created a situation where, despite these successes, most declarations have depended and still depend on the good faith of the industries. As of yet there have been no industry inspections, the execution of which, as stated above, is problematic without legislation in force.

With regard to the informational role of the National Authority, there are a number of important lessons that can be learned. The need to identify likely candidates for declaration and inform them of their responsibilities under the CWC was one of the primary initial tasks for the National Authority. This considerable task was difficult and carried out in a piecemeal fashion, principally because of the absence of qualified staff members with a chemical industry knowledge. This has since been rectified. It was also difficult to locate and identify all users, government as well as private sector, of scheduled chemicals for the purposes of identifying those who needed to complete declarations. This effort was very much aided by coordinative efforts through Industry Canada and Revenue Canada with regards to the identification of relevant parties and the distribution of declaration forms, something which further demonstrated the need for a good interdepartmental network. Nevertheless, once the forms were received, some industries neglected to fill them out, believing that they dealt solely with chemical weapons. This was clearly a shortcoming in the early stages of implementation; however, this is a problem generally shared by a number of other National Authorities, all of whom have found it a very challenging task to explain the CWC and identify all

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[153] It was suggested that this appointment should be at the "EX" level.

those who may be affected. This experience also points to the need for ongoing domestic informational and outreach activities. At present, as previously stated, there is only one Canadian facility (part of the Department of National Defence) eligible for an annual inspection. However, the increased inspection burden on the National Authority, including that of the administration and accompanying of the OPCW inspection team, will increase the demands on the National Authority and its personnel with the progressive implementation of the CWC.

One very important problem faced by the National Authority was the delay caused by the inappropriate drafting of the original legislation. This resulted in whole year being wasted until the current version was finally properly drafted. Since then, a variety of circumstances have meant that the required regulations for declarations and licensing of users of certain chemicals have not been completed. The lesson here is to obtain dedicated and competent legal personnel in order to ensure that these essential tasks can be completed without the same unacceptable delay experienced by the CWC National Authority.

In terms of the implementation of the CWC, the most important lesson learned is that if issues are left unresolved at the end of the negotiations, as they were for the CWC in 1993, the chances of resolving them recede dramatically. After four years of preparatory committees and two years after entry into force, a number of important policy issues regarding the CWC still have not been agreed upon multilaterally. This is causing problems regarding the equitable and effective implementation of the Convention, and is a strong argument for competent and sufficient representation at the international level.

To sum up, the lessons learned from the CWC National Authority experience are that considerable attention, based on expert advice from knowledgeable individuals, is required in determining the staffing requirements of a National Authority, and that care is then needed to ensure that these resources do not disappear. It must also be recognised that additional resources, whether engaged on a full-time or contract basis, are required during the initial phases of the life of the National Authority for the Convention. Equally, specific knowledge and expertise regarding the BTWC are required on the part of the members of the National Authority. The staffing and initial experiences of the CWC National Authority constitute a clarion call for the future BTWC Protocol National Authority.

The CWC calls for many other potential duties to be assumed by the National Authority. The idea of a National Authority constituting a focal point suggests something more than simply submitting declarations and satisfying inspection teams. It must also be able to provide guidance on issues facing the BTWC, including the defining of relationships between domestic legislation, actors and various multilateral fora or arrangements, the promotion of industry exchanges and the undertaking of close consultations with industry, as well as the provision of a forum for the expression of industry concerns. It must also seek to coordinate its activities and information with

such governmental institutions as the Export Controls Division of DFAIT, the RCMP, and CSIS.[154] In essence, although a National Authority may not itself need to carry out many of the tasks related to the implementation of the Convention, it must play a pivotal role in ensuring that the relevant government institutions, as well as the private sector, are aware of the obligations that Canada has undertaken, and ensure that they are being carried out. It has been a challenge for the National Authority with regard to the CWC and the CTBT to maintain a high political profile, and it will be so for the BTWC Protocol as well. From a DFAIT perspective, many of the relevant issues, as well as the prospective clients, lie outside the Department's traditional purview. The experience with the CWC suggests that there is little interest in the BTWC in most other departments. It will be up to the National Authority to foster such interest. Regardless of where the National Authority is located, an Oversight or Steering Committee comprised of mixed government and private sector representation can play an important part in this respect.

On a multilateral level, experience has shown that Canada can play an effective role, even with limited resources, if it is represented by individuals possessing both expertise and devotion to the tasks at hand. Canada's good fortune in this respect with regard to the Permanent Delegation has meant that Canada has been able to play a strong role on a number of important issues related to the implementation of the BTWC. However, this should be planned for in the BTWC National Authority, and not simply left to chance.[155]

4.6. Creating the BTWC National Authority

As seen previously, the Protocol imposes a range of duties on each State Party. The National Authority need not assume all these duties, but must ensure or at least foster compliance with the Protocol. Over and above the specific duties of the National Authority which, as seen herein, involve implementation of the terms of Article III, the balance of the work to be done will involve a massive coordination and information effort.

4.6.1. Coordination and Information

The question of coordination of activities will depend necessarily on what tasks the National Authority assumes. The OPCW has recommended the following tasks for States Parties to the CWC:

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[154] The CWC National Authority has conducted outreach programmes, but has not addressed the topic of enforcement.

[155] Letter 1, *supra* note 152.

> "[T]he preparation and submission of declarations under Articles III and VI;
> the enactment of new legislation or the revision of existing legislation to facilitate the enforcement of the Convention;
> preparations for receiving inspections, including approval of the list of inspectors;
> the issuing of multiple entry visas for inspectors;
> providing aircraft clearances;
> designating points of entry and exit, etc.;
> supplying information about the national programme related to protective purposes;
> deciding on the option for the provision of assistance under Article X; and
> facilitating the exchange of scientific and technological information in the field of chemicals for purposes not prohibited by the Convention, etc.
>
> In order to be able to discharge these tasks a National Authority will require the active assistance of a number of national bodies specialising in specific areas."[156]

These tasks should not be any different under the Protocol. Further, the cited paragraph underscores the need for active assistance from other national bodies. The specific tasks faced by the National Authority for the BTWC are developed in the following section.

4.6.1.1. Coordination with National Bodies

As examined in the survey of legislation, the subject matter of the Protocol is regulated in many fashions and for various purposes. Most of the legislation covered shows a marked concern for the potential spread of disease. In this respect, considerable coordination with Health Canada, the national body responsible for implementation of health-oriented acts, will be necessary. Equally, the way it ensures compliance with the acts for which it is responsible can provide an important analogy for the National Authority.

4.6.1.1.1 Health Canada

The general mandate of Health Canada is to help the people of Canada maintain and improve their health.[157] This goal is achieved in many ways, one of which is through the Health Intelligence Network, which collaborates with other levels of government and the health care system in order to prevent, research, and control outbreaks of disease in Canada and around the world. Equally, the Health Protection Branch assesses the safety, effectiveness and quality of drugs and medical devices.[158] It operates what it terms "risk management activities" which involve, among other things,

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[156] OPCW, "National Bodies which Could Support and Assist the National Authority", online: OPCW Homepage <http://www.opcw.org/natadv/nabodies.htm> (last modified: 22 April 1998).

[157] Health Canada, "About Health Canada", online: Health Canada Homepage http://www.hc-sc.gc.ca/english/about.htm (last modified: 13 August 1999).

[158] *Ibid.*

recalling hazardous products, seizing or refusing certain specified imported goods and generally keeping the public informed of health issues.[159] Also, the Policy and Consultation Branch, in particular, manages Canada's relationship with the World Health Organisation, the Pan American Health Organisation, and other international bodies with the interest in the health area. As well, it participates in the exchange of information and scientists.[160]

Health Canada provides an important example for two reasons: 1) its illustrates how compliance can be promoted through an information and not only an enforcement process; and 2) it covers some of the duties expressed in Article VII of the Protocol.

4.6.1.1.2. Agriculture and Agri-Food Canada and the Canadian Food Inspection Agency

The Canadian Food Inspection Agency (CFIA) is another important compliance mechanism; it reports to Parliament through the Minister of Agriculture and Agri-Food.[161] The CFIA represents a consolidation of the delivery of inspection and quarantine services previously provided for by four other Federal institutions. Its efforts to ensure compliance involve systematic inspection programmes for animals and plants. The CFIA, for example, controls import activities so as to prevent exotic diseases and pest from entering Canada. This is achieved through inspection, testing, and certification of horticultural, livestock, forestry, biological, and other food commodities before their release into Canada.[162] The CFIA constitutes another complex compliance mechanism in that it goes beyond requirements and provisions for enforcement to include a considerable commitment to supporting research and informing relevant domestic actors.

The previous two compliance instruments illustrate how the acts for which they are responsible are implemented. The National Authority for the BTWC can learn from these two mechanisms by seeing exactly how cooperation can be achieved. Given that both Health Canada and the CFIA deal to a certain extent with similar subject matter, it will be necessary for the National Authority to maintain an active relationship with both bodies. The activities to be assumed by the National Authority are contained in the following section.

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[159] *Ibid.*

[160] *Ibid.*

[161] Canadian Food Inspection Agency, "Reorganizing the Federal Food Inspection System in Canada", online: CFIA.Homepage http://www.cfia-acia.agr.ca/english/backgr.html (last modified: 9 March 1999).

[162] *Ibid.*

4.6.1.1. The Domestic Level

Articles I and X of the Protocol outline the range of activities prohibited to States Parties. To ensure the effectiveness of the Protocol, legislation will be necessary in order to give focus to its mandate. The National Authority can play a pivotal role in coordinating the quick implementation of legislation to that effect, in conjunction with relevant personnel at the Department of Justice. As a preliminary matter, this duty should be discharged as soon as practicable.

Coordination with the Export Controls Division of DFAIT will be crucial in satisfying one of the most sensitive obligations of the Protocol, i.e. the transfer of listed pathogens and equipment.[163] This duty is one that involves consultation rather than direct involvement of the National Authority since the Export Controls Division of DFAIT already controls the export of sensitive products. Nevertheless, with the ratification of the Protocol, some of the requirements for sensitive transfers may be different, as seen in the CWC. Both bodies can contribute in this respect by providing one another with a constant flow of information. Moreover, the National Authority could contribute to efforts made by the Export Controls Division in training customs officers.[164]

The obligations under Article III will constitute the bulk of the work to be performed by the National Authority. At the initial stages, identifying declarable industries will be a key task. This is where the expertise of the team members will come into play, and where a great degree of coordination will be necessary. Cooperation with the Department of National Defence will be critical with regards to the submission of the initial declarations regarding past offensive and defensive activities, as well as for annual declarations regarding current defensive activities. Additionally, the Department of National Defence conducts extensive research in the area of biological defence and operates research branches dedicated to discovering advanced protection and detection mechanisms.[165] The Department of National Defence already cooperates with Health Canada in this area. Inspections, visits and declaration will be facilitated if the National Authority is constantly in contact with these branches. Completion of the initial declaration will be greatly facilitated if communication can be established with the Policy and Consultation Branch of Health Canada and the Defence Research and Development Branch of the Department of National Defence.

During the initial phases of the establishment of the National Authority, Health Canada, Agriculture Canada, and Industry Canada will be able to assist in identifying relevant vaccine production facilities, maximum and high biological facilities, and facilities that work with listed

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[163] Annex A.

[164] Interview 3 (2 July 1999).

[165] Interview 4 (29 July 1999) and National Defence, *Outline of Program: June 1999* by Defence Research and Development Branch (Ottawa: 1999).

toxins or other production facilities with relevant equipment, given the fact that these departments possess the relevant expertise and work with the private sector facilities on an active basis.

Of particular importance will be the challenge of addressing the issue of prospective visits as provided for under Article III of the Protocol. The National Authority's duties in this respect will more or less mirror the duties of the current CWC National Authority, with, perhaps, the added issue of those industry concerns particular to the Protocol. In this respect, when hosting an inspection, the National Authority will have to ensure that it properly represents the interests of the State Party. Heightened cooperation with government institutions will be necessary in this area, especially where speedy and efficient measures will have to be taken when hosting an inspection team. A range of such measures can be foreseen; they will likely include the arranging of required visas and ensuring entry and exit into Canada, providing accommodation and transportation for the inspection team, the setting up of meetings, and the provision of relevant facilities such as laboratories should 'in-country' sampling be necessary. Finally, in order to guarantee the effectiveness of the verification mechanism, the members of the National Authority will be required to possess an excellent knowledge of the inspection mechanism so that it does not frustrate the spirit of the Protocol, while remaining sensitive to the various interests at stake.[166]

To facilitate the routine and the yearly tasks of the National Authority, it is strongly recommended that a computerized database be established, much like the current system devised for the CWC National Authority. This process has eased the burden of declarations for both the National Authority and the relevant industries. Furthermore, again in order to facilitate compliance, considerable effort should be made to create and maintain a web site that can provide pertinent information to the public. Equally, compliance can be further encouraged through outreach programmes across Canada outlining the obligations of relevant industries and offering assistance in filling out declarations. Finally, a yearly report detailing the activities performed by the National Authority would be desirable as a compendious up-to-date source of activities performed in Canada relating to the BTWC.

4.6.1.2. International Measures

The success of the National Authority will, in large part, depend on the effectiveness with which it performs its duties to the OPBTW and the way it is perceived by the international community. This is why the submission of a yearly report summarising the activities of the National Authority would contribute positively to this process. The timely and accurate submission of declarations and the hosting of inspection teams will also be an important cornerstone of the National Authority's success. Moreover, active participation as provided for under Articles VI and VII of the Protocol would further contribute to the National Authority's effectiveness. Again, coordination by the National Authority in creating horizontal links among domestic agencies and

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[166] Article III as well as the relevant annexes contain a series of mechanisms that list the duties and obligations in this respect.

other National Authorities will be particularly useful. This is also an area where the National Authority can play an important outreach and informational role. It is clear that many States Parties will not have the resources that Canada possesses. Therefore, in the spirit of the Protocol, an efficient and well-established National Authority can both serve as a model and contribute to the overall success of the verification process by assisting other States Parties in developing their National Authorities.

Along these same lines, the delegation to the Protocol to the BTWC can also constitute an important resource. It is clear from the preceding discussion that the delegation must have some experience in matters relating to the Protocol, so as to properly represent Canada's interests. Furthermore, a well-qualified delegation will not only be able to contribute actively to the development of the verification process, but will underscore Canada's seriousness and dedication to this process. Finally, from an international perspective, Canada is a wealthy country and will therefore be expected to be prepared when implementing the Convention. The establishment of an efficient National Authority for the BTWC will be expected of Canada. Although it is possible to fulfill many of the "paper" obligations in an *ad hoc* fashion, this may constitute bad policy on a multilateral level.

4.6.2. Composition and Structure

Three members of the National Authority for the CWC and the Alternate Representative to the OPCW provided valuable insight into the future composition of the National Authority for the Protocol. As may be predicted from the previous section, there was consensus on the need for adequate staffing levels, with individuals' attention preferably fully devoted to BTWC matters. The structure suggested comprised a minimum of at least five full-time members, including a National Coordinator, a Senior Scientific/Technical Advisor, a Head, Industry Operations, a Junior Scientific/Technical Advisor, and an Administrator. At startup, this would be complemented by at least three other persons to help establish the initial structure for the BTWC National Authority. A further issue to be addressed would be whether there should be a co-location of the CWC and the BTWC National Authorities, and, if so, the extent to which certain administrative functions could be shared. However, it would be important for each National Authority to maintain its separate identity.

It was further suggested that an oversight committee be created to survey the works of the National Authority, and that the National Authority be made accountable to this committee so that it would be possible to ensure that the National Authority's duties were being carried out.[167] This type of committee would be desirable in order to oversee activities: it would be a forum for discussion of the orientation of the National Authority. It would be composed of senior members

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[167] Interview 1, *supra note* 149.

from relevant departments, and would have to meet several time per year during the early stages of the National Authority, and then once a year.

The experience of the CWC National Authority should not to be ignored. In general, the prospective National Authority should resemble its CWC counterpart. Moreover, the input of its members can help to avoid the difficulties experienced by the CWC National Authority. As such, a proper role for the National Authority can be developed from a review of the relevant legislation and an analysis of the confidentiality issues heretofore mentioned, in tandem with input from the oversight committee.

A well as the staffing requirement, it has also been suggested that an additional junior political officer position be integrated into this effort so that a a junior officer might gain the specific knowledge necessary to take up a position as a delegate to the Organisation. Such an officer could be assigned to both National Authorities in order to assist him/her in developing a wider experience with both CWC and BTWC matters.

As regards qualifications for the positions, it is clear that given the small size of the National Authority, the individual members must be highly qualified and fully dedicated to the task of running the body. With respect to the technical composition of the authority, serious consideration should be given to membership from Health Canada and Agriculture and Agri-Food Canada. As seen in the legislation surveyed earlier, both institutions play a critical role in dealing with the subject matter of the Protocol. Moreover, both institutions have access to qualified inspectors through the Canadian Food Inspection Agency. The role played by Health Canada, in particular, cannot be duplicated by DFAIT, if the National Authority is to be seated in the latter department. Equally, Industry Canada should be consulted in order to assess the number of industries in Canada which could be affected by the Convention and Protocol. Just as the CWC National Authority has benefited from an individual with industry knowledge, representation on the technical level from Industry Canada might be desirable given the particularities of the industry involved. So, with the particular declaration requirements of the Protocol[168], which bridge both health matters and technical/industrial matters, a representative from each institution would be needed to fill the post of junior and senior technical advisors.

The primary requirement for the National Coordinator will be a thorough knowledge of the Protocol and the Convention, non-proliferation and disarmament policy, relevant multilateral institutions, and the ability to assist in establishing an effective mechanism capable of ensuring the proper discharge of the obligations that Canada has assumed under the Protocol. It has also been suggested that the Coordinator should enjoy a rank appropriate to the task of representing the interests of the National Authority *vis-à-vis* other institutions (both government and private sector).

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[168] See the Protocol appendices and Article III.

The position of Head, Industry Operations is of crucial importance. Since the primary "visible" obligation of the Protocol mirrors that of the CWC (i.e. the submission and distribution of declarations), this undertaking will only be successful where managed by a highly qualified individual. It has been stated that the successes of the CWC National Authority have pivoted around this member. Similarly, the position will be as important for the BTWC National Authority. The Protocol contains appendices which outline the content of the submissions to be made, so the individual's responsibilities, in this respect, will be somewhat reduced. The Head, Industry Operations for the CWC National Authority has stated that with proper computer qualifications the job is not unduly onerous, although it would be important during the nascent period of the BTWC National Authority to have contracted personnel to assist in the development of this infrastructure, particularly with regard to the development of computer databases and electronic declaration questionnaires and formats.

Finally, filling the position of Administrator is also an important task in that it is necessary to identify a person capable of coordinating activities and providing support to the members of the National Authority. Contracted personnel may be required during peak periods and inspections or visits.

A properly staffed National Authority can go a long way in ensuring the effective implementation of the Protocol. Where such requirements are however not met, the National Authority will be hard pressed to fulfill even the most basic of tasks. Similarly, as previously mentioned, at least two persons should be delegated as representatives to the BTWC. An oversight committee, staffed by senior members of government institutions such as DFAIT, Health Canada, Industry Canada and the Department of National Defence, together with private sector and/or academic representatives where appropriate, should oversee the work of the new National Authority. Moreover, the production of a yearly report would also contribute greatly to the success of the National Authority and would constitute an important informational resource, both at the national and international levels.

4.6.3. Conclusion

This section has highlighted the need to plan for the creation of a National Authority for the Protocol to the BTWC. It has also reflected upon some of the lessons from the creation of the CWC National Authority. This section has stated that a National Authority can play a key role in coordinating activities and informing relevant persons, legal and moral, of their duties under the Protocol. Moreover, a well-organised National Authority can ensure that the obligations undertaken by the State Party are being fulfilled.

At the international level, it is clear that Canada could be more prepared for the duties that may be assumed under the Protocol. For example, the Australian Safeguards and Non-Proliferation Office (ASNO) has conducted a survey of the Australian biotechnology industry in order to identify

the industries likely to be affected by the Protocol.[169] This type of trial run demonstrates the seriousness with which certain States Parties are taking the verification mechanism, together with their desire to identify early on those domestic hurdles which they must overcome. This same type of effort has been made by the Swiss, who reported to the *Ad Hoc* Group the results of a trial inspection of a vaccine production facility.[170] Although the particular findings are outside the scope of this paper, the fact that active measures are being taken on the part of some states to ascertain the practical aspects of the verification mechanism is of significance. Similar Canadian efforts to prepare for a National Authority could not only represent sound planing and preparation at the domestic level, but also could serve as a further example to the international community and the salience of this issue-area.

Finally, with respect to the creation and functioning of a new National Authority for the BTWC, several interviews were conducted with relevant members from, particularly, Health Canada, the Department of National Defence, and the Export Controls Division at DFAIT. It is clear from these interviews that the outbreak of disease, whether from the use of a biological weapon or some other vector, is of particular concern. It is equally clear that the establishment of relationship between these organisations will be crucial to the success of the National Authority insofar as the latter could draw on the significant expertise that lies in those institutions and provide a forum for the discussion of biological and toxin weapons. As well, many of the institutions mentioned here provide good examples of compliance mechanisms that combine enforcement and promotion of compliance.

4.7. Conclusion

The Protocol imposes a wide range of obligations on the States Parties. The National Authority that will be created pursuant to the Protocol will face many challenges, the first of which will be to ensure that the verification mechanism is properly implemented within the State Party. To that end, several measures must be taken; they will include informing the relevant industries of their obligations, collecting the proper declarations, and assisting potential international inspections. However, as mentioned previously, this is not the only role that the National Authority must play. In order to ensure that obligations are being met, the National Authority should coordinate with those institutions within government which possess both the capacity and expertise to deal with the subject matter at hand. Export controls are a good example. The National Authority need not assume all responsibility for export controls since the job is already being done within the Export Controls

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[169] Australian Safeguards and Non-Proliferation Office, *Survey of the Australian Biotechnology Industry* (summer 1999).

[170] Ad Hoc Group of the States Parties to the *BTWC*, *Working Paper Submitted by Switzerland: Report on the Trial Inspection Based on a Random Visit to a Vaccine Production Facility*, BWC/AD HOC GROUP/WP.371 (Geneva:10 June 1999).

Division. However, since the National Authority will have the most knowledge regarding the scope of the Protocol, constant dialogue and cooperation will be necessary between these two branches.

A seen in part 4.2, considerable legislation exists as to the regulation of the subject matter of the Protocol. The concern for the outbreak of disease demonstrates in part the seriousness of the tasks faced by the National Authority. It also informs the National Authority as to the measures that are available in Canadian society to prevent and remedy a potential outbreak, including the governmental bodies that can contribute to the National Authority's mandate. Finally, as addressed in part 4.3 of this report, several legitimate concerns exist with respect to the protection of commercial proprietary information. Although the declarations are not unduly onerous and the potentially affected industries are already highly regulated, there exists a risk of disclosure which could result in significant loss, despite efforts made in the Protocol to protect CBI. As such, it may be desirable to set up a mechanism to indemnify victims for loss of information.

Finally, the establishment of a National Authority for the Protocol to the BTWC is a task that need not be overly complicated. The lessons learned from the creation of the CWC National Authority, coupled with the analysis provided herein, can provide some insight into the duties to be assumed by the prospective National Authority.

5. CONCLUSION

Setting up a National Authority for the BTWC need not be an unduly onerous task. If Canada is going to play an active role in the implementation of the Protocol, serious consideration should be given to the various challenges outlined in this report. As demonstrated in the conclusion to the previous section, some States Parties are already assessing their industries and carrying out mock visits. Planning for a National Authority not only constitutes sound management practice, but it can also provide a further example of commitment to the international community and so underscore Canada's dedication to an effective verification mechanism for the BTWC.

Within Canada, many challenges exist with respect to the implementation of the Protocol. On a purely legal level, some concern remains as to the constitutionality of regulating business activities by the Federal Parliament. Nevertheless, it has been argued that legislation enacted pursuant to the Protocol would be upheld as a proper use of the federal parliament's criminal law power. More significant concerns reside in the types of visits provided for under the Protocol and their potential infringement on the *Charter* provision guaranteeing against unreasonable searches and seizures. In some cases, a full warrant may be required to undertake such an investigation.

The protection of commercially sensitive information is a priority for the State Party and there are insufficient provisions in the Protocol to remedy loss suffered from revelation of, for example, a trade secret. Given the state of the industries most likely to be affected by the inspection mechanism, the loss of a trade secret could spell disaster for, as an example, a cutting-edge biotechnology company. However, this concern must not be overstated, as many of the reporting

requirements generally require a reporting of activities rather than in-depth probing into the biological processes and firms' trade secrets. Moreover, there are many provisions in the Protocol providing for the maintenance of confidentiality. Furthermore, the State Party can manage the access of the inspection team to sensitive areas during visits and investigations. Finally, the industries most likely to be affected are already quite heavily regulated and, as seen in some of the legislation surveyed, more stringent inspection and reporting mechanisms are already in place. Nevertheless, it may be desirable for the State Party to provide for a mechanism of recovery for loss should a breach of confidentiality occur.

A National Authority for the BTWC must be able to implement the compliance regime as outlined in Article III of the Protocol. The dissemination and gathering of declarations will constitute a primary task to this end. The National Authority must also assist in the visit and inspection aspects of Article III. In view of this, proper composition and delineation of tasks have been emphasised by this report. The National Authority should endeavor to play an active, as opposed to reactive, role in this regard. The National Authority must maintain relationships with other Federal institutions, such as Health Canada and the Department of National Defence, that have an interest in the subject matter relevant to the Protocol. Moreover, not only must the National Authority enforce the parts of the Protocol for which it is responsible, but it must also foster compliance by undertaking outreach programmes and providing relevant and up-to-date information via important media sources like the internet. Finally, as a focal point for activities relevant to the Protocol, the National Authority for Canada must play an important role at the international level, given Canada's privileged position in the international community (particularly in the area of disarmament).

To conclude, any legislation that is enacted in order to implement the Protocol will have to take into account the issues raised by this study. Although the success of implementation will not ultimately turn on the legislation passed, a comprehensive and well- drafted document can constitute a good starting point. Over and above the general prohibitions mandated by the Protocol and related penal measures, the legislation should, first, contain an outline of the tasks to be performed by the National Authority, as can be seen in the CNTBTIA. Second, adequate warrant provisions should be included so as to reflect the current requirements for search and seizure. Third, provisions for delegation of some authority to the Minister of Health may be desirable. Fourth, the requirement for an annual report should be contained in the legislation. Finally, provisions to provide for compensation could be included in case of loss incurred pursuant to a disclosure of confidential information. These provisions will reflect the specificity of the Protocol and contribute to its goal: that of an effective domestic verification mechanism.