Legislative Summary **LS-630E**

BILL C-11: HUMAN PATHOGENS AND TOXINS ACT

David Johansen
Legal and Legislative Affairs Division

Sonya Norris
Marlisa Tiedemann
Social Affairs Division

24 February 2009
Revised 16 July 2009

Library of Parliament

Bibliothèque du Parlement

Parliamentary Information and Research Service

LEGISLATIVE HISTORY OF BILL C-11

HOUSE OF COMMONS		SENATE	
Bill Stage	**Date**	**Bill Stage**	**Date**
First Reading:	9 February 2009	First Reading:	6 May 2009
Second Reading:	23 February 2009	Second Reading:	2 June 2009
Committee Report:	2 April 2009	Committee Report:	**22 June 2009**
Report Stage:	27 April 2009	Report Stage:	
Third Reading:	5 May 2009	Third Reading:	**23 June 2009**

Royal Assent: **23 June 2009**

Statutes of Canada **2009, c. 24**

N.B. Any substantive changes in this Legislative Summary that have been made since the preceding issue are indicated in **bold print.**

Legislative history by Michel Bédard

CE DOCUMENT EST AUSSI PUBLIÉ EN FRANÇAIS

CONTENTS

CANADA
LIBRARY OF PARLIAMENT
BIBLIOTHÈQUE DU PARLEMENT

BILL C-11: HUMAN PATHOGENS AND TOXINS ACT*

BACKGROUND

Bill C-11, An Act to promote safety and security with respect to human pathogens and toxins (the Human Pathogens and Toxins Act), was introduced in the House of Commons by the Minister of Health, the Honourable Leona Aglukkaq, on 9 February 2009. It was first introduced during the 2nd Session of the 39th Parliament as Bill C-54. That bill died on the *Order Paper* with the dissolution of Parliament on 7 September 2008. There are slight differences between the two bills.

The intent of the bill is to promote safety and security with respect to human pathogens and toxins, including listed micro-organisms, nucleic acids, proteins, or toxins, by requiring everyone who conducts activities involving these human pathogens or toxins to take all reasonable measures to protect the health and safety of the public. Departmental background information provided for Bill C-11 defines human pathogens as micro-organisms capable of causing disease in humans, such as salmonella and influenza. Toxins can be produced by or derived from such micro-organisms and these too are capable of causing disease in humans.

Currently, there are two sets of regulations that control the importation and storage of some pathogens and toxins for use in laboratories. The *Human Pathogens Importation Regulations*, made under the *Department of Health Act*, mandate that laboratories that *import* pathogens that belong to any of Risk Groups 2, 3 or 4 (as defined in the bill) comply with the *Laboratory Biosafety Guidelines* (the *Guidelines*). The *Guidelines* is a technical document produced by the Office of Laboratory Security at the Public Health Agency of Canada that is intended for those who design, operate or work in laboratories in which human pathogens are manipulated for diagnostic, research or development purposes. The *New Substances*

---

* Notice: For clarity of exposition, the legislative proposals set out in the bill described in this Legislative Summary are stated as if they had already been adopted or were in force. It is important to note, however, that bills may be amended during their consideration by the House of Commons and Senate, and have no force or effect unless and until they are passed by both houses of Parliament, receive Royal Assent, and come into force.

Notification Regulations (Organisms), made under the *Canadian Environmental Protection Act, 1999*, also reference the *Guidelines* as mandatory for laboratories working with pathogens from Risk Groups 2, 3 and 4, but are limited to containment requirements.

Bill C-11 expands on the existing legislative framework by covering more varieties of organisms and including those that are domestically acquired. (The *Guidelines* are not currently mandatory for laboratories that acquire human pathogens and toxins from domestic sources.) It was originally tabled with the observation that it would bring Canada into line with other developed nations with respect to keeping track of the human pathogens and toxins used within the country's laboratories. In the United States, legislation requires the safe and secure possession, storage, transfer and disposal of those human, plant and animal pathogens and toxins that have been identified as requiring special oversight, having been deemed a threat to public health. Among U.S. laws pertaining to this issue, Public Law 107-188, the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, in particular Title II entitled *Enhancing Controls on Dangerous Biological Agents and Toxins*, is comparable to Bill C-11. All entities intending to possess, use or transfer any of the select agents must register with the Secretary of Health and Human Services and are subject to a security risk assessment. Before registration is granted, the facility must also meet biosafety requirements that are commensurate with the risk that the select agent or toxin poses, and must establish security measures that provide graded protection in accordance with the threat that the agent or toxin poses.

In the United Kingdom, the *Anti-Terrorism, Crime and Security Act 2001* (in particular Part 7 and Schedule 5) is intended to protect the more dangerous pathogens and toxins from compromise by terrorists. The Act was extended in May 2007 to include animal pathogens. Under this legislation, sites holding or intending to hold those agents listed in Schedule 5 must inform the Home Office, which in turn arranges, via the National Counter Terrorism Security Office, for a site visit similar to the site visits required in the United States.

DESCRIPTION AND ANALYSIS

A. Short Title, Purpose, and Interpretation and Application

The bill's short title is the Human Pathogens and Toxins Act (clause 1).

The purpose of the bill is to establish a safety and security regime to protect the health and safety of the public against the risks posed by human pathogens and toxins (clause 2).

Definitions for purposes of the bill are set out in clause 3(1). They include definitions for "human pathogen," each of "Risk Groups" 2, 3 and 4, and "toxin":

- A "human pathogen" is defined to mean a micro-organism, nucleic acid or protein that:
  (a) is listed in any of Schedules 2 to 4 or in Part 2 of Schedule 5; or
  (b) is not listed in any of the Schedules but falls into one of Risk Groups 2, 3 or 4.
- "Risk Groups" 2, 3 and 4 are generally defined in terms of the levels of risk that a category of human pathogens poses to the health of individuals and to the public.
- A "toxin" is defined to mean a substance that is listed in Schedule 1 or in Part 1 of Schedule 5.

Clause 4 lists certain exclusions from the Act.

B. Obligation and Prohibitions

Clause 6 imposes an obligation on every person who knowingly conducts any activity referred to in clause 7 involving a human pathogen or toxin to take all reasonable precautions to protect the health and safety of the public against the risks posed by the activity.

Clause 3 defines a "controlled activity" for purposes of the Act to mean an activity referred to in clause 7(1). The following controlled activities that are knowingly conducted in relation to a human pathogen or toxin and that are set out in clause 7(1) must be authorized through a licence issued by the Minister of Health pursuant to clause 18: possessing, handling or using; producing; storing; permitting access to; transferring; importing or exporting; releasing or otherwise abandoning; and disposing. Clause 7(2) excepts from clause 7(1) any activity to which the *Transportation of Dangerous Goods Act, 1992* applies, as well as the export of human pathogens or toxins authorized under the *Export and Import Permits Act*.

Clause 8 provides that, notwithstanding clause 7, no person is permitted to conduct any activity listed in that clause in relation to a human pathogen or toxin listed in Schedule 5 (regarding prohibited human pathogens and toxins).

According to clause 37, the prohibitions in clauses 7(1) and 8 do not apply to: a) an inspector or analyst carrying out his or her functions under the bill; b) a peace officer carrying out his or her functions under any federal or provincial Act or a person providing assistance to that officer; c) any person who, in the course of his or her employment, outside a facility in which controlled activities are authorized, collects a sample for the purpose of laboratory analysis or diagnostic testing; or d) in exigent circumstances, any person carrying out his or her functions under any federal or provincial Act.

C. Schedules to the Bill

The bill contains five schedules as follows:

- Schedule 1 – Toxins
- Schedule 2 – Risk Group 2 Human Pathogens
- Schedule 3 – Risk Group 3 Human Pathogens
- Schedule 4 – Risk Group 4 Human Pathogens
- Schedule 5 – Prohibited Human Pathogens and Toxins
  - Part 1 – Toxins
  - Part 2 – Human Pathogens

If the Minister is of the opinion that a substance is produced by, or derived from, a micro-organism and is able to cause disease in a human, the Minister may, by regulation, add it to Schedule 1 (clause 9(1)).

If the Minister is of the opinion that a micro-organism, nucleic acid or protein is able to cause disease in a human, the Minister may, by regulation, add it to one of Schedules 2, 3 or 4, depending on which Risk Group the Minister is of the opinion that it falls into (clause 9(2)).

The Minister may, by regulation, delete a substance from Schedule 1 if the Minister is of the opinion that it is not produced by, or derived from, a micro-organism or is not able to cause disease in a human. Similarly, the Minister may, by regulation, remove a micro-organism, nucleic acid or protein from any of Schedules 2 to 4 if the Minister is of the opinion that it does not fall into the risk group to which that Schedule relates (clause 9(3)). Clauses 9(4) and 9(5) introduce a requirement for the Minister to consult an advisory committee, which will make its advice public.

The Governor in Council may, by regulation, on the Minister's recommendation, a) add a substance to Part 1 of Schedule 5 if the Governor in Council is of the opinion that: 1) it is produced by, or derived from, a micro-organism and is able to cause disease in a human, and 2) all activities referred to in clause 7 should be prohibited in relation to it; b) add a micro-organism, nucleic acid or protein to Part 2 of Schedule 5 if the Governor in Council is of the opinion that: 1) it is able to cause disease in a human, and 2) all activities referred to in section 7 should be prohibited in relation to it; or c) delete a substance, micro-organism, nucleic acid or protein from any of Schedules 1 to 4 if the Governor in Council adds it to Schedule 5 (clause 10(1)).

According to clause 10(2) the Governor in Council may, by regulation, on the Minister's recommendation, delete a substance, micro-organism, nucleic acid or protein from Schedule 5 if the Governor in Council believes it is in the public interest to allow one or more of the activities referred to in section 7 to be authorized (by a licence issued under clause 18) in relation to that substance, etc. Clauses 10(3) and (4) introduce a requirement for the Minister to consult an advisory committee, which will make its advice public.

Within 30 days after the publication of a regulation made under section 9, every person who, as a result of the regulation, no longer has lawful possession of a human pathogen or toxin must: a) dispose of it in accordance with the regulations; b) transfer it to a facility where controlled activities in relation to it are authorized; or c) obtain from the Minister a licence, or a variation of the conditions of that person's existing licence, authorizing possession of it (clause 11(1)).

Within 14 days after the publication of a regulation made under clause 10(1), every person who, as a result of the regulation, no longer has lawful possession of a human pathogen or toxin must dispose of it in accordance with the regulations (clause 11(2)).

Clause 11(3) stipulates that no person contravenes clause 7(1) or clause 8 by reason only that he or she possesses a human pathogen or toxin in the circumstances described in clauses 11(1) or (2) if that person transfers or disposes of it in accordance with either of those clauses.

D. Obligation to Inform the Minister

According to clause 12(1), if a licence holder has reason to believe that a human pathogen or toxin has been released inadvertently from a facility in the course of an activity otherwise authorized by the licence, the licence holder is obligated to inform the Minister of the release without delay, and to provide the Minister with the information specified in clause 12(3) that is under the licence holder's control.

Clause 12(2) provides that if a person is in possession of a human pathogen or toxin in contravention of either of clauses 7(1) or 8 as a result of the inadvertent production of that human pathogen or toxin in the course of an activity that is otherwise lawful, the person must follow the procedure spelled out in clause 12(2). Clause 12(4) stipulates that no person contravenes clauses 7(1) or 8 by reason only that he or she possesses a human pathogen or toxin in the circumstances described in clause 12(2) if that person transfers or disposes of it in accordance with that provision.

Clauses 13 and 14 set out the respective procedures to be followed in informing the Minister if a licence holder has reason to believe that an incident involving a human pathogen or toxin that is in the licence holder's possession has, or may have, caused disease in an individual, or has been stolen or is otherwise missing.

If a person conducting activities under the authority of a licence has reason to believe that any of the incidents described in clauses 12(1), 12(2), 13 or 14 has occurred, the person must, without delay, inform the licence holder (clause 15).

According to clause 16, no information provided under clauses 12 to 15 by a licence holder may be used or received against that person in any criminal proceedings that are subsequently instituted against him or her, other than with respect to a contravention of clause 17.

It is an offence for a person to knowingly communicate to the Minister false or misleading information in relation to a matter under the bill (clause 17).

E. Licences

The Minister may, in accordance with the regulations, issue a licence authorizing any controlled activity (referred to in clause 7) in any facility if the Minister believes that the conduct of the activity poses no undue risk to the health or safety of the public (clause 18(1)). An application for a licence must be filed with the Minister in the form specified by the Minister (clause 18(2)). If the Minister refuses to issue a licence, he or she must notify the applicant in writing of the reasons for the refusal (clause 18(3)). A licence authorizes the controlled activities specified in it and is subject to any conditions the Minister considers appropriate to protect the health and safety of the public (clause 18(4)). A licence must set out the information prescribed in clause 18(5). The licence holder must inform all persons conducting the controlled activities authorized by the licence of its conditions (clause 18(6)) and they must comply with them (clause 18(7)).

The Minister may, on his or her own initiative or on the application of the licence holder, vary the licence conditions if the Minister believes that the variation poses no undue risk to the health or safety of the public (clause 19(1)). The Minister may vary the licence conditions on his or her own initiative only if the Minister first gives the licence holder a reasonable opportunity to make representations (clause 19(2)). In varying the licence conditions, the Minister may specify in writing any measures to be taken to protect the health and safety of the public that the variation in conditions may necessitate (clause 19(3)).

Clause 20 permits the Minster to suspend or revoke a licence under specified circumstances and sets out the procedure to be followed by the licence holder in such a case.

The Minister must notify a licence holder by registered mail of any decision made regarding the variation or revocation of a licence, and must give reasons for the decision in the notice and advise the licence holder of his or her right to request a review of the decision (clauses 21(1)-(2)). The Minister's decision normally takes effect 31 days after the notice is received (clause 21(3)).

If the Minister is of the opinion that there is a serious and imminent danger to the health or safety of the public, the Minister must notify the licence holder orally of the decision to suspend or revoke his or her licence (clause 22(1)). The decision takes effect at that time and the licence holder is advised that it is effective immediately (clause 22(2)). The Minister is not required to give the licence holder an opportunity to make representations in respect of the decision (clause 22(3)). The Minister must send the notice referred to in clause 21(1) within five days after the day on which the licence holder is notified orally of the decision (clause 22(4)).

According to clause 23(1), the person whose licence is affected by the decision may, within 30 days after the notice is received, request in writing, stating his or her reasons, that the Minister refer the decision to a committee for review. Clause 23(2) provides that a request for review suspends the application of the decision, unless the Minister notified the licence holder orally of the decision under the circumstances described in clause 22(1). When a request for a review is made, the Minister may specify in writing any measures to be taken to protect the health and safety of the public pending the Minister's final decision (clause 23(3)).

A person whose licence is affected by the decision shall ensure that any measures specified by the Minister under clauses 19(3), 20(3) or 23(3) are implemented (clause 24(1)). No person contravenes either of clauses 7(1) or 8 by reason only that he or she has implemented those measures (clause 24(2)).

Clause 25 concerns the composition of the committee to which the Minister refers the decision for review. Clause 26 sets out the factors to be considered by the committee in its review. Clause 27 provides for the confidentiality of the information submitted to committee members as part of the review. Within 60 days after the referral of a decision to a committee, or within any longer period that the Minister may allow, the committee must report its findings and recommendations to the Minister and to the person who requested the review (clause 28).

Within 60 days after receiving a committee's report, the Minister must, taking into account the committee's findings and recommendations, reconsider the decision in respect of which the report was made and send his or her final decision by registered mail to the person who requested the review (clause 29(1)). The Minister's final decision takes effect on the day after it is received (clause 29(2)).

A person whose licence is suspended or revoked must, without delay, inform all persons conducting controlled activities authorized by it of its suspension or revocation (clause 30(1)). That person must also return the licence by registered mail to the Minister as soon as feasible after the Minister's decision takes effect or, if the decision is reviewed, as soon as feasible after the Minister's final decision takes effect (clause 30(2)).

F. Access to Facility to Which Licence Applies

A licence holder must establish, maintain, and provide to the Minister upon request, a list of all persons authorized by the licence holder to access the facility to which the licence applies, including persons holding a security clearance for that facility and visitors (clause 31).

If a licence holder decides to prohibit the holder of a security clearance from having access to the facility to which the licence applies, the licence holder must, without delay, inform the Minister in writing of that decision (clause 32).

G. Security Clearances

According to clause 33, no person is permitted to enter the part of a facility in which controlled activities are authorized in relation to prescribed Risk Groups 3 or 4 human pathogens, or prescribed toxins, unless he or she holds a security clearance issued by the Minister in accordance with clause 34 for that part of the facility, or unless he or she is accompanied by a person who holds a security clearance for that part of the facility.

If the Minister refuses to issue a security clearance or suspends or revokes it, the individual concerned has 30 days after the notice is received to request in writing that the Minister reconsider the decision (clause 35(1)). Clause 35(2) specifies the information that must be set out in the request. The Minister must provide a reasonable opportunity for the individual concerned to make representations (clause 35(3)). Within a reasonable time after representations have been made or an opportunity to do so has been given, the Minister must reconsider the

decision (in accordance with the regulations) and confirm or vary it (clause 35(4)). The Minister must notify the individual concerned in writing of the decision made following the reconsideration (clause 35(5)).

H. Biological Safety Officers

An applicant must, before a licence authorizing a controlled activity can be issued under clause 18, designate an individual as a biological safety officer for the requested licence. The individual designated may also be the applicant (clause 36(1)). The biological safety officer must meet the qualifications set out in the regulations (clause 36(3)). The biological safety officer may exercise the powers and must carry out the functions set out in the regulations (clause 36(5)). If an individual ceases to act as a biological safety officer, the licence holder must, without delay, designate another individual and inform the Minister of the new designation (clause 36(6)).

I. Information Requested by the Minister

Clause 38(1) specifies that the Minister may order an applicant for a licence, a licence holder or a biological safety officer to provide to the Minister information under that person's control, including personal information and confidential business information that the Minister believes, on reasonable grounds, is relevant to the administration of the bill. Clause 38(2) sets out certain information that may be required by the Minister under clause 38(1). The relevant person must provide the Minister with the information, in accordance with any conditions that the Minister may specify (clause 38(3)). Notwithstanding clauses 38(1)-(3), the Minister of National Defence may refuse to disclose information the disclosure of which could reasonably be expected to be injurious to the defence or security of Canada or of a state allied or associated with Canada (clause 38(4)).

The Minister may, in certain specified cases, and without the consent of the person to whom the information relates, disclose personal information and confidential business information obtained under the bill, to named parties (clause 39(1)). Persons receiving such information are generally required to give the Minister their written agreement that they will maintain its confidentiality**,** unless they are required by law to disclose that information (clause 39(2)).

J. Administration and Enforcement

The Minister may designate any individual (or class of individuals) as an inspector for purposes of the administration and enforcement of the bill (clause 40(1)) and must provide them with a certificate of designation which, on entering any place or conveyance under clause 41(1), they must produce to the person in charge, if requested to do so (clause 40(2)).

Clause 41(1) permits an inspector to enter places or conveyances for the purpose of verifying compliance or preventing non-compliance with the bill. The extensive powers of an inspector who has entered a place or conveyance are enumerated in clauses 41(2) and 41(3). Notwithstanding those enumerated powers, the Minister of National Defence may refuse to disclose any information the disclosure of which could reasonably be expected to be injurious to the defence or security of Canada or of a state allied or associated with Canada (clause 41(4)). The owner or person in charge of a place or conveyance that is entered by an inspector carrying out his or her functions, and every person in that place or conveyance, must give the inspector all reasonable assistance and provide the inspector with any information he or she may reasonably require (clause 41(5)).

It is an offence for person to knowingly obstruct, or make a false or misleading statement either orally or in writing to, an inspector who is carrying out his or her functions (clause 41(6)).

Clause 42(1) prohibits an inspector from entering a dwelling-house without the occupant's consent, except under the authority of a warrant issued by a justice of the peace, on *ex parte* (without notice) application, under clause 42(2). In executing the warrant, the inspector named in it may not use force unless accompanied by a peace officer and unless the use of force is specifically authorized in the warrant (clause 42(3)). If an inspector believes that it would not be practical to appear personally to make an application for the warrant, the warrant may be issued by telephone or other means of telecommunication on application submitted by any one of those means (clause 42(4)).

If, upon inspection, an inspector believes that a controlled activity is conducted in a manner that poses a serious and imminent danger to the health or safety of the public, the inspector may order the licence holder, or any other person in the place or conveyance, to carry out any measure that the inspector considers necessary to reduce or eliminate the danger (clause 43(1)). The person ordered by the inspector to carry out the measure must comply

(clause 43(2)). An inspector who orders a measure to be carried out must withdraw the order if he or she is satisfied that the controlled activity is no longer conducted in a manner that poses a serious and imminent danger to the health or safety of the public (clause 43(3)). An inspector must, without delay, refer any decision to make or withdraw an order to the Minister for review. After review, the Minister may amend, replace or rescind the order if the Minister is of the opinion that it is necessary to do so (clause 43(4)). The referral of the decision to the Minister does not suspend the application of the decision (clause 43(5)). If the licence holder or any other person ordered to carry out a measure fails to comply with the order, the inspector may carry out the measure or require another person to do so (clause 43(6)) and, in that case, must advise the person who failed to comply with the order that the measure was carried out (clause 43(7)). No person is required to carry out a measure ordered by an inspector if doing so would expose that person to a danger as defined in section 122(1) of the *Canada Labour Code* (clause 43(8)). A licence holder (or, if no licence has been issued in respect of the controlled activity, the person who is responsible for the conduct of the controlled activity) must bear the cost of carrying out any measure ordered by an inspector (clause 43(9)).

An inspector may order that a thing seized under the bill be kept or stored in the place where it was seized, or that it be removed to any other appropriate place (clause 44(1)). Except with the inspector's authority, no person may remove, alter or interfere with the seized thing (clause 44(2)).

An inspector who seizes a thing under the bill must release it if he or she is satisfied that the applicable provisions of the bill have been complied with (clause 45).

Clause 46(1) permits the owner of a seized thing, or the person in possession at the time of seizure, on reasonable notice in writing to the Minister, to apply to a provincial court judge within 60 days of seizure for an order of restoration. The judge may order that the seized thing be restored immediately to the applicant if the judge is satisfied that the requirements set out in clause 46(2) have been met. According to clause 46(4), the judge may not make an order for restoration if the seized thing has been forfeited by consent under clause 47(2).

If no application is made for restoration within 60 days of the thing's seizure, or if an application has been made but no order of restoration was made after the application was heard, the seized thing is forfeited to the federal Crown (clause 47(1)). Similarly, if an inspector has seized a thing and its owner, or the person in possession of it at the time of seizure, consents in writing to its forfeiture, the thing is forfeited to the federal Crown (clause 47(2)). Subject to

clause 48, the Minister may dispose of a seized thing that is forfeited to the federal Crown in any manner that the Minister directs (clause 47(3)).

The Minister must make reasonable efforts to preserve any thing seized under the bill pending its disposition (clause 48). The owner of the thing seized, or the person in possession of it at the time of its seizure, must bear any associated seizure, storage, transfer, preservation or disposition costs (clause 49).

The Minister may designate any individual (or class of individuals) as an analyst for the administration and enforcement of the bill (clause 50). An inspector may submit to an analyst, for analysis or examination, any thing seized or taken by the inspector (clause 51(1)) and, in such a case, the analyst may issue a certificate or report setting out the results of the analysis or examination (clause 51(2)).

An analyst's certificate (or report) is admissible in evidence in any prosecution for an offence under the bill if it meets the requirements specified in clause 52(1). The party against whom a certificate or report is produced may, with leave of the court, require the analyst's attendance for the purpose of cross-examination (clause 52(2)). No certificate or report can be admitted in evidence unless, prior to the trial, the party intending to produce it has given reasonable notice of that intention, together with a copy of the certificate or report, to the party against whom it is intended to be produced (clause 52(3)).

K. Offences and Punishment

The bill sets out offences and penalties for breaches of specific provisions of the bill, namely: clause 6 (penalties in clauses 54 and 55); clauses 7(1) and 18(7) (penalties in clause 56); and clause 8 (penalties in clause 57); as well as for the intentional release of a human pathogen or toxin in contravention of the bill (penalty in clause 58) and for breaches of any other provision of the bill (penalties in clause 53).

Clause 59 provides that a person who establishes that he or she exercised due diligence to prevent the commission of an offence under the bill may not be convicted of that offence, except in respect of certain enumerated provisions.

Clause 60 specifies where the trial may be held.

If the offence is committed or continued on more than one day, the person who committed the offence is liable to be convicted for a separate offence for each day on which it is committed or continued (clause 61).

Summary conviction proceedings for an offence under the bill may be instituted no later than two years after the day on which the subject matter of the proceedings becomes known to the Minister (clause 62(1)).

If a person other than an individual (for example, a corporation) is convicted of an offence under the bill, any of its directors, officers, etc., who directed, authorized, assented to, acquiesced in or participated in the commission of the offence is a party to and guilty of the offence and liable to the punishment provided for the offence (clause 63).

In the prosecution for an offence under the bill, it is sufficient proof of the offence to establish that it was committed by the accused's employee acting within the scope of his or her employment, or the accused's agent acting within the scope of his or her authority, whether or not the employee or agent is identified or prosecuted for the offence, unless the accused establishes that: a) the offence was committed without the accused's knowledge or consent; and b) the accused exercised all due diligence to prevent its commission (clause 64).

L. Debts

Clause 65 specifies that the following constitute debts due to the federal Crown and may be recovered as such in any court of competent jurisdiction: a) an amount that a person is directed to pay under an order made by a court under the bill; b) the costs incurred in the seizure, storage, transfer, preservation or disposition under the bill of any human pathogen, toxin or other thing; and c) the costs incurred in carrying out a measure under clause 43(6).

M. Regulatory Powers

Clause 66(1) grants the Governor in Council extensive powers to make regulations in relation to human pathogens and toxins, including regulations regarding the matters specifically enumerated in that clause. The varying levels of risk posed by the pathogen or toxin must be taken into account when making regulations. A regulation may establish classes of persons, facilities, activities, human pathogens and toxins, and distinguish among those classes (clause 66(2)).

Clause 66.1 pertains to the parliamentary scrutiny of regulations. Subject to the exceptions set out in clause 66.2, clause 66.1 requires the Minister to lay proposed regulations before both houses of Parliament. Such regulations must be referred to the appropriate committee of each house. Once they have been laid before Parliament, the proposed regulations may not be passed before the earliest of the following deadlines has expired:

- 30 sitting days after the regulations have been laid before Parliament;
- 160 calendar days after the regulations have been laid before Parliament; or
- the day after both committees have reported their findings.

The Minister must take into account any committee report submitted. If the regulations do not incorporate a recommendation made one or the other committee, the Minister must lay before the house to which that committee is attached a statement of the reasons for not incorporating it. Any proposed regulation laid before Parliament need not be laid before Parliament again, whether it has been altered or not.

Clause 66.2, however, allows regulations not to be laid before Parliament if the Minister is of the opinion either that the change to an existing regulation is immaterial or insubstantial, or that the regulation must be made immediately to protect the health or safety of any person. In such cases, the Minister must lay an explanatory statement before each house of Parliament.

Clause 67(1) authorizes the Minister to make an interim order containing any provision that may be contained in a regulation under clause 66 if the Minister is of the opinion that prompt measures are required to address a serious and imminent danger to the health or safety of the public. Clause 67(2) specifies that the interim order has effect from the day on which it is made and ceases to have effect on the earliest of the days specified therein. For purposes of the bill, any reference to regulations made under the bill is deemed to include interim orders, and a reference to a regulation made under a specified provision of the bill is deemed to include a reference to the portion of an interim order containing any provision that may be contained in a regulation made under the specified provision (clause 67(4)). A copy of each interim order must be tabled in each house of Parliament within 15 days after the day on which it is made (clause 67(5)); if the house is not sitting at the time, the interim order may instead be sent to the Clerk of the House (clause 67(6)).

A regulation may incorporate by reference the following documents:

- documents that are produced by a person or body other than the Minister, including: a) an organization established for the purpose of writing standards, including an organization accredited by the Standards Council of Canada; b) an industrial or trade organization; or c) a government (clause 68(1));

- documents that the Minister reproduces or translates from documents that are produced by a person or body other than the Minister (clause 68(2));

- documents that the Minister produces jointly with another government for the purpose of harmonizing the regulation with other laws (clause 68(3)); and

- technical or explanatory documents that the Minister produces (clause 68(4)).

A document may be incorporated by reference as amended from time to time (clause 68(5)). As well, clauses 68(1)-(5) do not limit any authority to make regulations incorporating documents by reference that exists apart from those provisions (clause 68(7)).

If a provision of a regulation incorporates a document by reference, then no person can be convicted of an offence for the contravention of that provision, unless it is proved that at the time of the alleged contravention: a) the document was reasonably accessible to the person; b) reasonable steps had been taken to ensure that the document was accessible to persons likely to be affected by the regulation; or c) the document had been published in the *Canada Gazette* (clause 69).

N. Transitional Provisions and Coming Into Force

The bill includes transitional provisions (clauses 70-71).

Specified provisions of the bill come into force on a day or days to be fixed by order of the Governor in Council (clause 72).

COMMENTARY

Prior to its referral to the House of Commons Standing Committee on Health, Bill C-11 elicited virtually no commentary. However, during its study of the bill, the committee heard from a number of stakeholders, many of whom expressed concerns. While several witnesses voiced support for the bill, many others said that it was overly broad and suggested that it be amended so as to limit the number of pathogens for which licensing would be required.

They explained that the pathogens listed in the appendices of the bill represented widely differing health risks. All witnesses agreed that the pathogens listed in Risk Groups 3 and 4 largely represent significant risks to health and that licensure of these pathogens is justifiable from a public health perspective. They said, however, that, while a few of the pathogens listed in Risk Group 2 could be a threat to public health, overall, the pathogens in this group pose a much reduced health risk, and frequently either pose no threat to public health if released into the environment or no health risk at all.

In response to some of the concerns raised, the Health Committee amended the preamble of the bill to include an acknowledgement that pathogens pose varying levels of risk. In addition, the committee amended the bill so that security clearances would no longer be required for work with Risk Group 2 pathogens (clause 33), but it did not remove the licensure requirement for Risk Group 2 pathogens. The Public Health Agency of Canada tabled its proposal for implementation of this legislation and assured members that the intent was not to require licensure for work with Risk Group 2 pathogens, but only to require registration with the Agency. The offences and punishment provisions of the bill were also amended to reflect a distinction between Risk Group 2 and the higher Risk Groups (clauses 53 and 56). Finally, the Health Committee amended the regulation-making provisions of the bill to require that proposed regulations be laid before both houses of Parliament, which must report the regulations back within a specific time frame (clauses 66.1 and 66.2).

During the Standing Senate Committee on Social Affairs, Science and Technology's review of the bill, witnesses raised issues similar to those discussed during the Health Committee's review of the bill. The Senate Committee reported the bill back to the Senate without amendment but with a number of observations, as well as the following recommendations:[(1)]

1. **That the Public Health Agency of Canada ensure that the provinces, territories and stakeholders are given the opportunity to participate in the development of Bill C-11 regulations in a meaningful way. Consultations should be carried out as expeditiously as possible, but not at the expense of a thorough and open discussion.**

---

(1) Standing Senate Committee on Social Affairs, Science and Technology, *Ninth Report*, 22 June 2009, http://www.parl.gc.ca/40/2/parlbus/commbus/senate/com-e/soci-e/rep-e/rep09jun09-e.htm.

2. **That the role of the advisory committee referred to in clauses 9(4) and 10(3) be expanded to include advising the Minister with respect to the general implementation of the bill.**

3. **That PHAC expand the role of the advisory committee referred to in clauses 9(4) and 10(3) of Bill C-11 to include providing the Minister with advice in relation to the qualification and training of inspectors.**

4. **That PHAC ensure that the need to enter into a written confidentiality agreement after information has been disclosed under clause 39(1)(*b*) is addressed in regulations.**