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The *Human Pathogens and Toxins Act*
Potential Program and Regulatory Framework

***Caveat** - This document is intended for discussion purposes only, and should not be construed as a policy statement by the Government of Canada or the Public Health Agency of Canada.*

Purpose

This paper describes a potential program and regulatory framework which must be developed and implemented under the *Human Pathogens and Toxins Act* (HPTA). Such a framework describes the technical details and requirements that are needed to fully implement all aspects of the HPTA.

These technical details and requirements cannot be developed by the government in isolation. The Office of Laboratory Security of the Public Health Agency of Canada (OLS-PHAC) will lead extensive consultations with stakeholders in order to better ensure that the program and regulatory framework is developed in a way that works for everyone.

In exploring the potential details and requirements under this new framework, this paper will illustrate the different approaches intended for persons conducting controlled activities (i.e. possession, use, transfer, production, storage, etc. of human pathogens or toxins) including with Risk Group 2 (RG-2) human pathogens (e.g. dangerous human pathogens such as Salmonella) as opposed to the more dangerous Risk Group 3 (RG-3) human pathogens (e.g. very dangerous human pathogens such as SARS), or Risk Group 4 (RG-4) (e.g. extremely dangerous human pathogens such as Ebola), based on the relative risks associated with working with these agents. Simply put, the government intends to have a less stringent approach to facilities with RG-2 as opposed to RG-3 or -4 human pathogens. As well, this paper will be guided by the stated purpose of the proposed *Human Pathogens and Toxins Act*:

> *...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.*

Introduction

At present, laboratory biosafety guidelines are only mandatory for facilities that import human pathogens and toxins, while non-importing facilities operate under a voluntary regime. This means that an estimated 4,000 of the approximately 7,500 facilities in Canada which do not import these human pathogens operate with no mandatory biosafety guidelines in place. To better safeguard biosafety in Canada, it is important that all facilities handling human pathogens and toxins operate under to the same system of mandatory laboratory biosafety guidelines.

As well, Canada's international partners have moved forward to enhance biosecurity concerning human pathogens and toxins as a result of the events of 9/11, and subsequent events such as the anthrax attacks in the United States. Canada has no similar controls in place now, and we need new safeguards against the risks posed by dangerous human pathogens and toxins.

The proposed *Human Pathogen and Toxins Act* (HPTA) attempts to establish a universal system of biosafety based on the existing Laboratory Biosafety Guidelines (LBGs) and to establish a new system of biosecurity. The program and regulatory framework that is described below outlines some of the most basic technical details and requirements associated with the new legislation.

As noted, the government intends less stringent requirements for facilities conducting activities with RG-2 human pathogens than for those conducting activities with RG-3 or -4 human pathogens. For this reason, this paper discusses the requirements for facilities with RG-2 human pathogens, then it discusses the requirements for facilities with RG-3 or -4 human pathogens.

Risk Group 2 Requirements

The following is a brief summary of one possible approach to the application of the HPTA and the program and regulatory framework to persons conducting controlled activities with RG-2 human pathogens.

Licencing – Licences for persons carrying on controlled activities with RG-2 human pathogens would be simple, and could involve the completion of an on-line checklist and an attestation of compliance with the Laboratory Biosafety Guidelines.

A licence would be required by all persons conducting controlled activities with RG- 2 human pathogens. In order to apply for a licence authorizing controlled activities with RG-2 human pathogens, the person may only need to do the following:

- Complete a checklist application to be available online;
- Attest that they would be carrying on controlled activities only with respect to RG-2 human pathogens; and,
- Attest that they are in compliance with appropriate regulatory biosafety standards (based on the current third edition of the *Laboratory Biosafety Guidelines*).

Note that no fees are currently being considered for obtaining a licence.

Inventories – Inventory requirements for persons conducting controlled activities with RG-2 human pathogens could involve simply keeping a record of what human pathogens they possess, with this record being updated yearly and produced to OLS-PHAC only on demand.

It is likely that RG-2 laboratories would only be required to keep a record of which human pathogens they possess, without details like how much is possessed, its location, etc. It is also likely that there would be a requirement to produce a copy of this inventory only if requested by OLS-PHAC. There would be no requirement to file an inventory with OLS-PHAC, unless specifically requested. Note that there could be a phase-in period built into the program and regulatory framework to provide laboratories time to build-up the inventory database, if they do not already have one.

Security Screening – There is no intention to require security screening of persons accessing facilities that possess only RG-2 human pathogens.

Transfers – Persons conducting controlled activities with RG-2 human pathogens could work with OLS-PHAC to ensure, before transferring a human pathogen or toxin to another person within Canada and before receiving a transfer permit, that the person in question to whom the human pathogen is transferred is compliant with the LBGs.

It is important that human pathogens are handled safely at all times. To ensure that adequate biosafety guidelines are being followed, PHAC will seek to help any laboratory with RG-2 human pathogens that wants to transfer a human pathogen to another laboratory in Canada to ensure that the other recipient laboratory is following the *Laboratory Biosafety Guidelines*, before they transfer their human pathogen to them. This assistance could be rendered through the use of a PHAC-based registry system which would permit laboratories to submit requests for transfer permits to PHAC, which would automatically confirm whether a recipient laboratory has a licence. If they are licenced and if there is no indication that the proposed transferee is not compliant with the Act, the regulations or its licence, then issuing a transfer permit could be a simple matter.

Imports – The import permit system for RG-2 human pathogens would be essentially the same as it is at present.

Importation requirements for RG-2 human pathogens would be similar to the present system under the *Human Pathogens Importation Regulations*. That is, import permits would be provided for a specified human pathogen or toxin, or possibly group or type over a period of time, and it would not be necessary to seek a new permit for each separate import of the same RG-2 human pathogen. Import permits for RG -2 human pathogens would likely be granted on a yearly basis.

Exports – Persons conducting controlled activities with RG-2 human pathogens could be required, before exporting a human pathogen, to perform due diligence in order to assess whether the person who will receive the human pathogen is compliant with biosafety guidelines.

The export of human pathogens and toxins on the "Export Control List" of the Department of Foreign Affairs Canada (DFAIT) already requires DFAIT authorization. Should OLS-PHAC seek to authorize the export of human pathogens, it will not duplicate the efforts of DFAIT, and would not require authorization from the OLS-PHAC for human pathogens and toxins listed on the Export Control List.

It is important that human pathogens are handled safely at all times, and this includes human pathogens that are entering or leaving the country. Should PHAC want to play a role in the export of human pathogens, it could seek to require that exporters exercise due diligence before exporting a human pathogen or toxin, to ensure to the extent reasonably possible that the recipient laboratories in other countries follow biosafety guidelines.

One definition of "due diligence" is "*taking measures and exercising responsibility that a reasonable and prudent person would exercise in similar circumstances.*" In attempting to ensure that human pathogens are exported to a safe laboratory environment, due diligence could mean simply asking questions of the recipient laboratory including whether they are aware of

World Health Organization biosafety guidelines, and how those guidelines are applied. Any due diligence requirements would be developed as part of detailed consultations on the program and regulatory framework with stakeholders.

Laboratory Biosafety and Biosecurity – All licensees carrying on controlled activities with only RG -2 human pathogens would be required to follow the Laboratory Biosafety Guidelines (LBGs) as a mandatory regulatory standard.

The LBGs, which are basic laboratory biosafety guidelines and which have been in existence as a national standard for almost 20 years, would become a mandatory regulatory standard under the program and regulatory framework of the HPTA. In short, all persons conducting controlled activities with human pathogens or toxins in Canada will have to comply with these guidelines to ensure a common standard for biosafety across the entire country.

Biological Safety Officers – All licensees, including those whose licences cover activities with RG-2 human pathogens will be required to have a Biological Safety Officer (BSO).

The *Human Pathogens and Toxins Act* requires that every applicant for a licence have a BSO in place for the purpose of that licence. Licences could cover facilities with multiple, and in the cases of some universities, hundreds of laboratories. This implies that there need not be a separate BSO for every single laboratory. In some situations, there may be one BSO for a great many laboratories.

For the purposes of the program and regulatory framework, the key questions to answer concerning BSOs will be their qualifications and responsibilities. For persons conducting controlled activities with RG-2 human pathogens, a less stringent set of BSO qualifications and responsibilities could be set in place, perhaps through the use of voluntary guidelines. In other words, the qualifications and responsibilities of BSOs could be voluntary for these laboratories, as opposed to those conducting activities with RG-3 or -4 human pathogens. The qualifications and responsibilities for BSOs will be one of the key topics for consideration as part of the extensive consultations with stakeholders on the program and regulatory framework.

Disposal – Licensees conducting controlled activities with RG-2 human pathogens could be required to notify OLS-PHAC of the nature of their disposal of human pathogens.

Licensees could be required, either by regulation or perhaps as a condition of licence, to notify OLS-PHAC of the nature of the disposal of human pathogens. Licensees would be responsible to ensure that a human pathogen's or toxin's disposal rendered it non-viable or non-functional.

Compliance Inspections – All licensees conducting controlled activities with RG-2 human pathogens could be subject to spot and risk-based inspections.

Licensees with RG-2 human pathogens could be subject to risk-based and spot inspections by OLS-PHAC.

Risk Group 3 and 4 Requirements

The following list provides a brief summary of one possible approach to the application of the HPTA and the program and regulatory framework to persons carrying on controlled activities with RG-3 and -4 human pathogens or with toxins. Many of the program elements for persons carrying on controlled activities with more dangerous RG-3 and RG-4 human pathogens and/or toxins are similar to, but more stringent than what has been noted above for persons carrying on controlled activities with RG-2 human pathogens. The following discussion notes some of the most significant differences.

Licensing – Licences for persons carrying on controlled activities with RG -3 and/or -4 human pathogens or with toxins would likely involve applications in paper form (i.e. not on-line); a declaration that the applicants wishes to possesses RG- 3 and/or -4 human pathogens and/or toxins; pre-licence inspections; and a review of the applicant's biosecurity plan and other documentation.

Licencing requirements for persons who are conducting controlled activities with RG-3 or -4 human pathogens would be mandatory, and would be in the regulations portion of the program and regulatory framework. This reflects the more dangerous nature of RG-3 and -4 human pathogens as opposed to RG-2 human pathogens.

Applications for a licence relating to toxins or to RG-3 or -4 human pathogens would have to be made by way of a paper copy, as sensitive information relating to these categories of human pathogens and toxins should not be shared over the Internet. In the application, the applicant would have to declare that they wish to possess RG-3 or -4 human pathogens or toxins. As well, before a facility with toxins or RG-3 or -4 human pathogens could receive a licence, it would need to provide OLS-PHAC with a biosecurity plan and other relevant information. Finally, OLS-PHAC would undertake an on-site inspection before granting a licence.

As may be noted, these requirements are substantially more complex and detailed than what would be required of persons carrying on controlled activities with RG-2 human pathogens.

Inventories – Inventory requirements for persons carrying on controlled activities with RG-3 and -4 human pathogens would involve keeping a record of what human pathogens they possess, where they are kept, and how much is possessed, with this record being provided to OLS-PHAC yearly.

Inventory requirements for persons who are carrying on controlled activities with RG-3 or -4 human pathogens would also be mandatory, and would be reflected in the regulations portion of the program and regulatory framework, or as conditions of licence.

At the moment, OLS-PHAC intends that the conditions of the licence for all persons carrying on controlled activities with RG-3 and -4 human pathogens would most likely require that OLS-PHAC be provided with a complete inventory of human pathogens and toxins. As well, OLS-PHAC would require information relating to the quantity, concentration, location of, use and storage of each toxin or RG-3 or -4 human pathogen in the licensee's possession. Further, any changes in inventories of toxins or RG-3 or -4 human pathogens would have to be reported to

OLS-PHAC within a reasonable timeframe. Again, what is proposed here is much more detailed than what is proposed above for persons carrying on controlled activities with RG-2 human pathogens.

Security Screening – The intention is to require security screening of persons accessing facilities that possess RG-3 (or possibly a subset of RG -3s) and -4 human pathogens.

Security screening requirements are the key biosecurity aspect of the program and regulatory framework under the HPTA. The specifics for security screening would be set out in regulations, including conditions to be met for a security clearance; how the security clearances may be issued, and supervised; and the reconsideration of any decisions to not grant or to revoke or suspend a security clearance. Note that security screening may not apply to all RG-3 human pathogens, and the program and regulatory framework could include regulations that excluded the application of security screening requirements to a sub-set of RG -3 human pathogens (i.e. RG-3 human pathogens that would be harder to utilize in an intentional release, such as M. tuberculosis, the agent of tuberculosis.)

In general, any person working in a facility with RG-3 human pathogens to which security screening requirements applied, or with any RG-4 human pathogens or selected toxins, would be required to obtain a security clearance in order to continue to have access to those human pathogens (or select toxins.) This would apply even to non-scientific staff members who might have access by virtue of their administrative, custodial, or other kinds of support duties. Scientists and other workers who do not have security clearance might still be able gain access to these RG-3 or -4 human pathogens or select toxins if they were accompanied and supervised by another person who did have a security clearance. In addition, records would have to be kept of those persons who accessed facilities with these RG-3 or -4 human pathogens, and selected toxins. There are no fees being considered for obtaining security clearances.

Transfers – Persons carrying on controlled activities with RG-3 and -4 human pathogens could be required to ensure, before providing access to a human pathogen or toxin to another person, that the person in question is compliant with the LBGs.

As noted above, it is important that human pathogens are handled safely at all times. To make sure of this, OLS-PHAC will likely require that licensees that want to transfer RG-3 or 4 human pathogens to another laboratory make sure that the laboratory to which they want to transfer human pathogens is safe, before the transfer takes place.

For licensees proposing to transfer human pathogens within Canada, OLS-PHAC would require that the licensee that wants to transfer human pathogens ensure that the recipient laboratory is compliant with the Laboratory Biosafety Guidelines, before they receive authorization from OLS-PHAC to complete the transfer. There would be a requirement to notify OLS-PHAC if the human pathogens in question were or were not received within an identified time frame. This is consistent with the system currently in place for Risk Group 3 and 4 human pathogens imported under the *Human Pathogens Importation Regulations.*

Imports – The import permit system for RG-3 and -4 human pathogens would be essentially the same as it is at present.

Importation requirements would be in regulations, similar to the present system under the *Human Pathogens Importation Regulations*. Unlike with persons importing RG-2 human pathogens as noted above, a separate and discrete import permit would be required for each toxin or RG-3 or -4 human pathogen. Laboratories importing RG-3 or 4 human pathogens would be required to notify OLS-PHAC if the imported human pathogens were or were not received within an identified time frame. Based on an OLS-PHAC assessment of the circumstances, including the level of danger inherent in a given human pathogen that is proposed to be imported, special conditions might be attached to the import permit.

Exports – Persons conducting controlled activities with RG-2 human pathogens could be required, before exporting a human pathogen, to perform due diligence in order to assess whether the person who will receive the human pathogen is compliant with biosafety guidelines.

The export of human pathogens and toxins on the "Export Control List" of the Department of Foreign Affairs Canada (DFAIT) already requires DFAIT authorization. Should OLS-PHAC seek to authorize the export of human pathogens, it will not duplicate the efforts of DFAIT, and would not require authorization from the OLS-PHAC for human pathogens and toxins listed on the Export Control List.

It is important that human pathogens are handled safely at all times, and this includes human pathogens that are entering or leaving the country. Should PHAC seek to play a role in the export of human pathogens, it could seek to require that exporters exercise due diligence before exporting a human pathogen or toxin, to ensure to the extent reasonably possible that the recipient laboratories in other countries follow biosafety guidelines.

One definition of "due diligence" is "*taking measures and exercising responsibility that a reasonable and prudent person would exercise in similar circumstances.*" In attempting to ensure that human pathogens are exported to a safe laboratory environment, due diligence could mean simply asking questions of the recipient laboratory including whether they are aware of WHO biosafety guidelines, and how those guidelines are applied. Any due diligence requirements would be developed as part of detailed consultations on the program and regulatory framework with stakeholders.

Laboratory Biosafety and Security – All licensees carrying on controlled activities with RG-3 and -4 human pathogens would be required to follow the LBGs as a mandatory regulatory standard.

The LBGs, which are basic laboratory biosafety guidelines which have been in existence as a national standard for almost 20 years, would become a mandatory regulatory standard under the program and regulatory framework of the HPTA. In short, all persons conducting controlled activities with human pathogens in Canada will have to comply with these guidelines to ensure a common standard for biosafety across the entire country. In addition to being compliant with the *Laboratory Biosafety Guidelines*, the program and regulatory framework for the HPTA may require special possession and handling conditions for licensees with RG-3 and -4 human

pathogens, as a condition of licence. These conditions will be substantially more rigorous than for facilities in which controlled activities are occurring with RG-2 human pathogens.

Biological Safety Officers – All licensees, including those whose licences cover activities with RG -3 and 4 human pathogens will be required to have a BSO.

The *Human Pathogens and Toxins Act* requires that every applicant for a licence have a BSO in place for the purpose of that licence. Licences could cover facilities with multiple, and in the cases of some universities, hundreds of laboratories. This implies that there need not be a separate BSO for every single laboratory. In some situations, there may be one BSO for a great many laboratories.

For the program and regulatory framework, the key questions to answer concerning BSOs will be their qualifications and responsibilities. For persons conducting controlled activities with RG-3 or -4 human pathogens, a more stringent set of BSO qualifications and responsibilities could be set in place, perhaps through the use of mandatory regulations or conditions of licence. This could mean that the qualifications and responsibilities of BSOs could be mandatory for these laboratories, as opposed to those conducting activities with RG-2 human pathogens. The qualifications and responsibilities for BSOs will be one of the key topics for consideration as part of the extensive consultations with stakeholders on the programs and regulatory framework.

Disposal – Licensees carrying on controlled activities with RG-3 or -4 human pathogens will be required to notify OLS-PHAC of the nature of their disposal of human pathogens.

Licensees would be required, either by regulation or perhaps as a condition of licence, to notify OLS-PHAC of the nature of the disposal of human pathogens, as part of the annual or biannual update of inventories. Licensees would be responsible to ensure that a human pathogen's or toxin's disposal rendered it non-viable or non-functional.

Compliance Inspections – All licensees carrying on controlled activities with RG-3 and -4 human pathogens would be subject to regular, (i.e. yearly) inspections, which will be the norm.

Licensees with RG-3 or -4 human pathogens would be subject to regular (i.e. yearly), on-going inspections by OLS-PHAC. This is consistent with the current inspections approach of OLS-PHAC that puts emphasis on facilities in which controlled activities are undertaken with RG-3 and -4 human pathogens and selected toxins.