OVERVIEW OF THE HUMAN PATHOGENS AND TOXINS ACT (HPTA)

Purpose and Scope of the HPTA

The HPTA received Royal Assent on June 23, 2009. The purpose of the Act is to establish a safety and security regime to protect the health and safety of the public against risks posed by human pathogens and toxins. The HPTA applies to persons conducting specified activities with human pathogens and toxins. “Person” includes a corporation, individual, organization, partnership or public body.

The HPTA does not apply to:

- a human pathogen or toxin in an environment in which it naturally occurs, as long as it has not been cultivated or intentionally collected or extracted;
- a drug in dosage form whose sale is permitted under the Food and Drugs Act or a human pathogen or toxin contained in such a drug;
- any activity that is a controlled activity within the meaning of the Assisted Human Reproduction Act.

Policy Rationale for the HPTA

**Strengthens Biosafety:** The HPTA strengthens Canada’s existing controls over human pathogens and toxins by establishing minimum biosafety and biosecurity requirements in order to reduce risks to public health and safety.

**Establishes Domestic Accountability:** The HPTA enables Canada to address growing international concerns around proper handling, use and misuse of human pathogens and toxins. Specifically, the HPTA moves beyond current import controls to address risks associated with domestically acquired human pathogens and toxins.

**Supports International Commitments:** The HPTA helps Canada support its international commitments, including the United Nations Biological and Toxin Weapons Convention (BTWC), the WHO Polio Eradication Strategy and the International Health Regulations.

HPTA Basic Biosafety Scheme

Prior to Royal Assent of the HPTA, federal oversight for the biosafety of human pathogens and toxins was grounded in the 1994 Human Pathogens Importation
Regulations (HPIR). The HPIR makes the Laboratory Biosafety Guidelines (LBGs: 3rd ed., 2004) mandatory for facilities importing human pathogens and toxins in RG 2, 3, and 4. The intent is to repeal the HPIR once the new HPTA regulations are developed and in place.

With Royal Assent, select sections of the HPTA came into force to create a basic biosafety scheme. These include

- a requirement for every person responsible for activities involving toxins listed in Schedule 1 of the Act or Risk Group 2, 3 or 4 human pathogens to be registered with PHAC;
- a ban on activities conducted with human pathogens and toxins listed in Schedule 5 (currently limited to smallpox) and an obligation to inform PHAC of an inadvertent production of Schedule 5 human pathogens and toxins; and
- a duty to take all reasonable precautions to protect the health and safety of the public when knowingly dealing with human pathogens and toxins. To help meet this current obligation, compliance with the Laboratory Biosafety Guidelines (LBGs: 3rd ed., 2004) is recommended.

Most offence and penalty provisions are now in force, in addition to inspection powers that may be used for the purposes of verifying compliance or preventing non-compliance with the Act. HPTA inspection powers are consistent with other federal legislation.

Administration

The HPTA is administered by the Public Health Agency of Canada (PHAC) through the Pathogen Regulation Directorate (PRD). PRD was formerly known as the Office of Laboratory Security (OLS).

New HPTA Program and Regulatory Framework

Several foundational sections of the HPTA relating to licences, facility access, security clearances, biological safety officers, and information collection cannot come into force until a new program and regulatory framework is developed. Key pillars of this framework include the Canadian Biosafety Standards and Guidelines (CBSG), regulations, and a licensing regime. PHAC will be consulting thoroughly with interested parties to inform the development of this new framework.

Canadian Biosafety Standards and Guidelines (CBSG)

The cornerstone of the new HPTA program and regulatory framework is the Laboratory Biosafety Guidelines (LBGs: 3rd ed., 2004). An updated version of the LBGs is an integral component to the regulatory package that will support the full implementation of the HPTA. In an effort to streamline biosafety requirements for Canadian stakeholders, PHAC and the Canadian Food Inspection Agency (CFIA) are currently developing the harmonized Canadian Biosafety Standards and Guidelines (CBSG). This document will combine

The development of the CBSG will occur in phases and will include an expert review and consultation phase starting in 2011. The CBSG project is expected to be completed in 2013.

**HPTA Regulations**

The HPTA allows the Governor in Council (the Governor General acting on the advice of the Federal Cabinet) to make regulations in relation to human pathogens and toxins. Under the HPTA, specific authority is given to make regulations respecting matters such as:

- Containment levels;
- Decontamination;
- Licensing;
- Facility specifications;
- Facility access;
- Security clearances;
- The qualifications of biological safety officers;
- The maintenance of inventories;
- The collection, use and disclosure of personal and confidential business information.

When making regulations, the Governor in Council is required to consider the varying levels of risk posed by human pathogens and toxins. This risk-based approach would mean that requirements for activities involving Risk Group 2 human pathogens would generally be less stringent than requirements for activities involving Risk Group 3 or 4 human pathogens.

Regulations developed under the HPTA will also be subject to Parliamentary oversight. In most cases, proposed regulations developed under the HPTA must be tabled before each House of Parliament before they are made. This provides an additional layer of oversight and scrutiny to the proposed regulations.

Like other federal departments and agencies, PHAC must adhere to principles and requirements outlined in the Cabinet Directive on Streamlining Regulation (CDSR). This modernized Government of Canada regulatory policy includes a comprehensive management approach with specific requirements for the development, implementation, evaluation and review of regulations.

The CDSR supports the Government’s commitment to protect and advance the public interest in health, safety and security, the quality of
the environment, and the social and economic well-being of Canadians through a more effective, efficient and accountable regulatory system.

HPTA Consultations

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Under the CDSR, federal departments and agencies have a responsibility to be inclusive, transparent, and cooperative when consulting Canadians on regulatory proposals. This is to ensure the greatest overall benefit to Canadians. The HPTA Consultation Plan sets out PHAC’s commitment to engage stakeholders and interested parities, its principles and its way forward in several phases. The consultations are designed to allow each phase to build towards a program and regulatory framework that takes into consideration the input of stakeholders and interested parties, and allow a variety of engagement opportunities.

PHAC continues to encourage all interested parties to participate in HPTA consultations. For more information and updates, please visit us at www.publichealth.gc.ca/pathogens. You may also reach us directly at:

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Full Implementation of the HPTA

Full Implementation of the HPTA will take a number of years. Sufficient time is required to develop the new HPTA program and regulatory framework, including ample time for thorough and meaningful consultations.

Once the consultation process is complete and the new HPTA program and regulatory framework is developed, the remaining sections of the HPTA can be brought into force. The target date for full implementation is 2015.