



## Human Pathogens and Toxins Act (HPTA)

---

### Implementation of the Human Pathogens and Toxins Act (HPTA)

---

The new legislative framework will be implemented in three phases:

**Upon Royal Assent June 23, 2009:**

Phase I. Basic scheme brought into force on Royal Assent

**The Path Forward:**

Phase II. Meaningful consultation with stakeholders and drafting of regulations

Phase III. Remainder of Act and regulations brought into force by Orders in Council.

---

### Upon Royal Assent June 23, 2009: Phase I

---

On Royal Assent, the following **obligations and prohibitions** (and their related penalties) will come into force:

- An **obligation to take reasonable precautions** (a "duty of care") to protect the health and safety of the public when knowingly dealing with human pathogens or toxins (Section 6).
- An **obligation to advise the Minister**, within 90 days, of the risk groups of **human pathogens or toxins in a person's possession, and their location**. An obligation to designate a person with the appropriate safety training as a contact. This information must be updated annually (Section 70).
  - The same obligations will be imposed on people acquiring pathogens or toxins after coming into force of Act, but they must do so within 30 days.
- A **ban on** any activity with pathogens or toxins listed in Schedule 5. Only **smallpox** is currently listed (Section 8).
  - If in possession of smallpox, you must notify the Minister within 30 days and dispose of materials as instructed by the Minister (Section 71).
- A **prohibition on knowingly communicating false or misleading information to the Minister** (Section 17).
- A **prohibition on knowingly obstructing or** making false or **misleading** statements to **inspectors** (Section 41(6)).
- A **prohibition on intentionally releasing human pathogens or toxins** causing risk to the health or safety of the public (Section 58).
- All related offences and penalties (Sections 53-58).

The Minister will be able to appoint inspectors to administer and enforce the basic elements of the Act, such as to inspect places or conveyances, seize and detain materials, or order persons to take measures to reduce or eliminate serious or imminent dangers (sections 40 to 52). As well, the power of the Governor in Council to make regulations in relation to human pathogens and toxins will also come into effect.

## The Path Forward: Phase II

---

This second phase will require extensive consultations with affected stakeholders in order to develop the program and regulatory framework. The consultations will engage on such matters as:

- **Licences:** what specific procedures will be required for the different risk groups of human pathogens, or toxins
- **Security screening:** for whom and for what RG3 and RG4 human pathogens and toxins
- **Inventories:** what level of detail and content would be required for which human pathogens and toxins
- **Transfers, Imports and Exports:** what would be the basic steps to follow for different risk groups of human pathogens or toxins
- **Biological Safety Officers:** what specific qualifications and training will be required, and what will be their duties and functions.

The work of this second phase will be anchored in the existing *Laboratory Biosafety Guidelines* (LBGs). There are two ways of achieving this end:

- Make stand-alone regulations,
- Further refine the existing guidelines and incorporate them by reference into a regulation.

## Phase III

---

The final phase will bring into force the remaining parts of the Act and the associated regulations, by Orders in Council.

This includes:

- **Prohibition to engage in controlled activities**, such as possessing, producing, storing, transferring, importing/exporting or disposing of human pathogens or toxins, **without a licence** (sections 7 and 56)
- The **entire licensing scheme**, including requirements to keep a list of persons authorized to access the facilities, to obtain security clearances, and to appoint biological safety officers (sections 18 to 36)
- **Obligation to report an inadvertent release, or an incident** that has or may have **caused disease, or missing human pathogen or toxin**, to the Minister (sections 12(1), 13 to 16).

As the regulatory framework will contain a wide range of mandatory requirements, such as the necessity to obtain a licence and report on inventories, stakeholders will be given a reasonable period of time to comply with the regulations. After that, the legislative and regulatory framework will be entirely in force.

The current *Human Pathogens Importation Regulations*  will continue to apply until they are repealed in this third and final phase.

---

Date Modified: 2009-06-24