



Human Pathogens and Toxins Act – Bill C-11



What is the Human Pathogens and Toxins Act?

Human pathogens and toxins pose a small but significant risk to human health and safety, either through accidental or deliberate release. In order to reduce these risks and to better protect the health and safety of the public, the House of Commons of Canada has passed the Human Pathogens and Toxins Act, <http://www2.parl.gc.ca/HousePublications/Publication.aspx?Docid=3865169&file=4> which contains prohibitions and requirements relating to a full range of laboratory activities. The new program and regulatory framework will be based on requirements of the Public Health Agency of Canada's Laboratory Biosafety Guidelines (LBGs). See <http://www.phac-aspc.gc.ca/ols-bsl/lbg-ldmbl/index-eng.php>.

The Human Pathogens and Toxins Act (HPTA) establishes legal prohibitions and authorities to govern human pathogens and toxins in Canada. It applies to pathogens in risk groups (RG) 2, 3, and 4 and all persons who work with them, and is designed to protect the health and safety of the public against the risks posed by human pathogens and toxins, while allowing science and research to progress. Fines will be levied against those not complying with the Act. Bill C-11, the Human Pathogen and Toxins Act (HPTA) received Royal Assent on June 23, 2009. Sections 70 and 71 and a number of other sections are already in force. This includes mandatory registration with the Public Health Agency of Canada (PHAC) and applies to all laboratories handling (RG) 2, 3 and 4, not just medical laboratories.

Within 90 days of obtaining Royal Assent, all laboratories in Canada are required to complete an online self-assessment which will permit the laboratory and the Public Health Agency of Canada to determine whether licensing is required.

The HPTA is being implemented in three phases; phase I is already in place as described above. Phase II will include meaningful consultation with stakeholders from all provinces and the drafting of regulations. This phase will be anchored in the Laboratory Biosafety Guidelines. Phase III is when the remainder of the Act and regulations will be brought into force by Orders in Council.

Key Elements of the HPTA Affecting Laboratories in Canada

- Application – Applies to all persons (unless exempted) who carry on activities with a risk group 2, 3, or 4 human pathogen.
- Definitions – “Human Pathogens” are defined in the HPTA based on risk group classification. Non-exhaustive lists of

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- human pathogens and a list of toxins have been provided.
- Regulations – Regulations are required to bring the policy framework into effect. The specifics regarding security screening, inventories and licencing will be in regulations subject to consultation.
- Importation – New regulations will replace the Human Pathogens Importation Regulations (HPIRs).
- Biological Safety Officers (BSO) – A BSO must be designated prior to the issue of a licence. There must be a BSO at all times. Qualifications and duties may be set out in regulations/guidelines following consultation with stakeholders.

Safe Laboratory Practice – Prohibitions under the Act

- General duty of care creating a prohibition against a failure to exercise caution.
- General prohibition to (among other things) possess, produce, store, dispose of, import, export a RG 2, 3, or 4 human pathogen or toxin without a licence.
- Prohibition against release of a human pathogen or toxin creating risk of harm.
- Absolute prohibition of certain pathogens, e.g. Smallpox.

Laboratory Requirements under the Act

- Maintenance and/or filing of an inventory of pathogens and toxins.
- Report incidents that may have caused a laboratory acquired infection.

- Follow the Laboratory Biosafety Guidelines as a biosafety standard.

Reporting

Licence holders and persons carrying on activities pursuant to a licence are obligated to report:

- Inadvertent release and/or production (not simple spills but releases from a facility).
- All laboratory acquired infections.
- Missing pathogen.
- Information submitted to the Minister pursuant to these sections cannot be used in criminal proceedings against the person reporting the information.

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Licensing

- Licences will be issued to facilities that work with human pathogens in RG 2-4.
- The licence holder is obligated to inform others of conditions of licence.
- Licences can be varied or suspended/revoked by the Minister, who has the ability to do so in emergency situations.
- Licence suspensions/revocations can be reviewed by a committee, similar to the process of review in the HPIRs.

Access

- Requirement to maintain list of all persons accessing facilities.
- Requirement for authorized access pursuant to a security clearance. No security clearance is required for persons accessing RG 2 human pathogens.
- Authorized access for visitors who must be accompanied by persons with security clearances.

Exemptions

- The HPTA does not apply to human

pathogens or toxins in the environment in which they naturally occur (e.g. a person with an illness; in a sneeze; in a cadaver; in water or a blood sample).

- Drugs authorized for sale under the Food and Drugs Act.
- Controlled activities under the Assisted Human reproduction Act.
- Activities that fall under the Transportation of Dangerous Goods Act.
- Certain prohibition sections do not apply to:
 - ◆ Inspectors
 - ◆ Peace Officers
 - ◆ Specimen collection for the purpose of laboratory analysis or diagnostic testing
 - ◆ Other regulatory exemptions

Future Appointment of Inspectors

The HPTA will outline a range of authorities related to inspections including:

- Powers of designation of inspectors
- Powers of inspectors
- Reasonable assistance to inspectors

- Obstruction of inspectors
- Measures may be ordered by inspectors in the event of serious and imminent danger

Offences and Penalties for Non Compliance

A scale of fines and prison terms will apply to offences related to RG 2, 3 & 4.

More information

For more information please visit the websites cited in the above literature. Comments may be submitted to the Office of Laboratory Security within the 90 day period. ❖

By mail, fax or email to:

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OSMT Annual General Meeting

The 47th Annual General Meeting

of the members of the Ontario Society of Medical Technologists will be held on

**Saturday,
November 14th, 2009**

**10:30 am – 12:00 noon at the
Novotel Toronto North York,
3 Park Home Avenue,
Toronto, ON M2N 6L3**

The agenda and 2008 Annual Report were mailed to members in the Summer 2009 issue of *Advocate* (AGM rescheduled from September 24th, 2009 in Sudbury)

RSVP by October 30th, 2009 by telephone 1-800-461-6768 or e-mail at osmt@osmt.org