Implementation of the *Human Pathogens and Toxins Act*: The First Year

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About the Centre for Biosecurity

- The Public Health Agency of Canada’s Centre for Biosecurity (PHAC-CB) is the national authority for biosafety and biosecurity of human pathogens and toxins.

- PHAC-CB is responsible for the administration and enforcement of the:
  - *Human Pathogens and Toxins Act* (HPTA).
  - *Human Pathogens and Toxins Regulations* (HPTR).
  - and sections of the *Health of Animals Act* (HAA) and the *Health of Animals Regulations* (HAR).

- The purpose of the HPTA and HPTR is to establish a safety and security regime that will protect the health and safety of the public against risks posed by human pathogens and toxins.

- Under the Act and Regulations, a risk-based licensing framework was designed to improve federal oversight of human pathogens and toxins in Canada.

- Anyone conducting controlled activities with human pathogens and toxins must have a “Pathogen and Toxin Licence”.
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Canada’s Pathogen Regulation Map

Global Affairs Canada
Export and Import Permits Act
Toxicological and biological agents on the Export Control List

Canada Border Services Agency Act

Canadian Border Services Agency

Environment Canada / Health Canada

Canadian Food Inspection Agency

Plant Protection Act & Regulations

Health of Animals Act & Regulations

Human Pathogens and Toxins Act & Regulations

New Substances (organisms)

Plant Pathogens

• Foreign & Emerging Animal Diseases
• Bee Pathogens
• Aquatic Animal Pathogens
• Animal Products

Terrestrial Animal Pathogens (pure culture)

Human Pathogens & Toxins

Transport of Dangerous Goods Act & Regulations

Transport Canada

International

National

Public Health Agency of Canada

Environment Canada

Canadian Environmental Protection Act

Canadian Food Inspection Agency

Plant Protection Act & Regulations

Health of Animals Act & Regulations

Human Pathogens and Toxins Act & Regulations

Public Health Agency of Canada
Canada’s Pathogen Oversight: Timeline

1994
- Importation oversight
  - Import regulations came into force

2009
- New Act received Royal Assent

2013
- Publication of the 1st joint human & animal biosafety standards
- Sections of the animal pathogens oversight transferred to PHAC

2015
- New Regulation came into force
- Act fully in force
- Canadian Biosafety Standards published

2016
- Biosecurity Portal active
- Handbook published
- 90 days for regulated parties to submit licence application

2019
- New Act received Royal Assent
- Sections of the animal pathogens oversight transferred to PHAC

2021
- Importation oversight
Managing the Transition

• “All-hands-on-deck” approach across the Centre for Biosecurity (CB).
• Development of tools and products to help regulated parties manage the transition. [Communication was crucial to success]
  - Townhall info session (general)
  - Targeted info sessions with the CB’s Directors
  - Newsletters
  - Targeted e-blasts
  - Development of Frequently asked questions
  - Development of pictograms, WebExs, and instruction manual for help with the Biosecurity Portal and technical questions
• Surge plan established
One Portal for All

- PHAC launched its Biosecurity Portal on December 1, 2015.

- The Biosecurity Portal is a secure electronic system designed to provide stakeholders and regulated parties with a secure platform to interact with PHAC.

- Access to the Biosecurity Portal is only granted to stakeholders after PHAC performs a verification process.

A total of 893 applications were received through the Biosecurity Portal by the deadline of the 29th of February 2016.
Risk-Based Approach for Licensing

- Risk Group 2
  - Toxins
  - Prions
  - Security Sensitive Biological Agents (SSBA) - Toxins *
  - Up to 5 years

- Risk Group 3
  - Risk Group 3 + SSBA *
  - Up to 3 years

- Risk Group 4
  - Risk Group 4 + SSBA *
  - Up to 1 year

* HPTA Security Clearances are required for individuals who work with or have access to SSBAs

Applicants who intend to conduct scientific research must submit a Plan for the Administrative Oversight (PAO)

Applicants who intend to conduct controlled activities with Security Sensitive Biological Agents (SSBAs) must submit a Biosecurity Plan (BSP)
Issuing “Pathogen and Toxin Licences”

• 100% of licence applications received during the HPTR transition period (and who require a licence at this time) were processed by January 2017.

• Little over 1300 “Pathogen and Toxins Licences” issued since December 1, 2015.

• 962 Active Licences as of September 15th, 2017:
  – 93% are for risk group 2 pathogens, prions, and SSBA toxins below the trigger quantity
  – 6% are for risk group 3 + SSBA pathogens
  – <1% are for risk group 4 + SSBA pathogens
  – <1% are for SSBA toxins
Issuing “Pathogen and Toxin Licences” (cont’d)

Licences Issued Per Month

2015-2016
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**Sector Profile Distribution**

- **49%** Private Industry
- **20%** Hospital
- **20%** Academia
- **5%** Other Government Departments
- **3%** Government (Environmental Health)
- **2%** Government (Veterinary/Animal Health)
- **2%** Government (Public Health)
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Biological Safety Officers Across Canada

856
BIOLOGICAL SAFETY OFFICERS ACROSS CANADA

[Map showing the distribution of biological safety officers across Canada with numbers indicating the count in each region.]
Activities Supporting Licence Issuance

- 264 Plans for Administrative Oversight (PAOs) reviewed
  - To be submitted by licence applicants conducting scientific research
- 366 HPTA Security Clearances Issued
  - Required for individuals who work with or have access to Security Sensitive Biological Agents (SSBAs)
- 18 Biosecurity Plans reviewed
  - Required by all facilities
  - To be submitted by licence applicants conducting controlled activities with SSBAs
- 200+ calls responded to per month
Compliance Monitoring, Verification, and Enforcement

- **Risk-based** approach to compliance monitoring, verification, and enforcement.

- **Promotion activities**
  - Guidance documents
  - Training course and material, etc.

- **Compliance monitoring and verification activities include**
  - On-site inspections
  - Targeted document reviews
  - Border audits, etc.

- **Regulatory Enforcement**
  - Non Compliance Letters
  - Suspend, vary, revoke a licence
  - Seizure, detention, refuse entry of material into Canada, etc.

- **Penal Enforcement (Warrant, Investigation and Prosecution)**
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### Licensing

- **Risk Group 2**
  - Toxins
  - Prions
  - Security Sensitive Biological Agents (SSBA) - Toxins *

- **Risk Group 3**
  - Risk Group 3 + SSBA *

- **Risk Group 4**
  - Risk Group 4 + SSBA *

### Inspection

- **Risk-Based**
  - Minimum once per 3 years

- **Up to 5 years**
  - Minimum once per 3 years

- **Up to 3 years**
  - Minimum once per 3 years

- **Up to 1 year**
  - Minimum annually
# Implementation of the *Human Pathogens and Toxins Act: The First Year*

<table>
<thead>
<tr>
<th>Compliance Level</th>
<th>Compliant</th>
<th>Minor Non-Compliance</th>
<th>Major Non-Compliance</th>
<th>Serious &amp; Imminent Non-Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal Requirements</td>
<td>Meets relevant minimal legal requirements</td>
<td>Meets most of the relevant legal requirements</td>
<td>Below the relevant minimum legal requirements</td>
<td>Unacceptably below relevant minimum legal requirements</td>
</tr>
<tr>
<td>Biosafety and Biosecurity Requirements</td>
<td>All requirements met</td>
<td>Most requirements are met</td>
<td>Several minor, entity wide minor (systemic) and/or major requirements are not met</td>
<td>Most or major requirements are not met</td>
</tr>
<tr>
<td>Degree of Compliance</td>
<td>Compliance observed</td>
<td>Minor and easily remedied</td>
<td>Significant</td>
<td>Extreme</td>
</tr>
<tr>
<td>Management Response</td>
<td>Competent and demonstrates adequate identification of principle risks, implementation of necessary control measures, confirmation that these are used effectively, and subject to review</td>
<td>Committed to improve standards and recognises essential relevant components of effective safety and security management</td>
<td>Committed to take remedial action but limited recognition of the essential relevant components of effective safety and security</td>
<td>Inadequate commitment to take remedial action and fails to recognise issues relevant to effective safety and security</td>
</tr>
<tr>
<td>Initial Enforcement Activities</td>
<td>No activity, Some recommendations may be appropriate</td>
<td>Minor non-compliances identified in the inspection report along with timelines for corrections</td>
<td>Notice of Non-Compliance and possible additional enforcement activities</td>
<td>Inspector Order, additional enforcement activities and/or prosecution</td>
</tr>
</tbody>
</table>
Canadian Biosafety Standard and Handbook

• The Centre for Biosecurity verifies compliance with the appropriate legislation and applicable requirements of the Canadian Biosafety Standard (CBS).

• The Canadian Biosafety Handbook (CBH) provides essential guidance on how to meet the requirements described in the CBS.
Canadian Biosafety Guidelines

- Developing a Comprehensive Biosecurity Plan
- Containment Level 1: Physical Design and Operational Practices (future release)
- Veterinary Clinics: Physical Design and Operational Practices for Diagnostic Activities (future release)
Pathogen Safety Data Sheets (PSDS)

- Access to information on hazards of various pathogens and how to work with them safely
- Most downloaded PSDS:
  - STAPHYLOCOCCUS AUREUS
    - 89,212 VIEWS
  - STREPTOCOCCUS AGALACTIAE
    - 37,519 VIEWS
  - DENGUE FEVER VIRUS
    - 36,862 VIEWS

- PSDS website access by country
  - 444,991 Hits
  - 357,793 Hits
  - 357,793 Hits
  - 43,779 Hits
Cool Apps

- Canadian Biosafety Standards APP: over 2325 downloads
- Pathogen Safety Data Sheets App: Over 3760 downloads

Both available through:
- Android App in Google Play
- Apple App via App Store
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**E-Learning Portal**

- Free online training and resources on laboratory biosafety and biosecurity
- 20 courses and videos
- Courses updated and expanded in February 2017
- **4200+** Registered Users of the E-Learning Portal
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