The Control of Human Pathogens in Canada

PUBLIC HEALTH AGENCY of CANADA
AGENCE DE LA SANTÉ PUBLIQUE du CANADA

Marianne Heisz
Chief, Importation and Regulatory Affairs
Office of Laboratory Security
Public Health Agency of Canada
Introduction

• Where Canada is today
  – The *Human Pathogens Importation Regulations*

• What Canada has presented
  – The Human Pathogens and Toxins Act: Bill C-54

• What Canada will propose
  – The regulatory framework
Where we are today

- **Human Pathogens**
  - **Importation Regulations**
    - Enacted 1994
    - Regulate the import of human pathogens
    - Risk groups 2-4
    - Definition of human pathogen
    - Refers to mandatory biosafety standard: the Laboratory Biosafety Guidelines
Human Pathogens Importation Regulations

Covers:
- Importation of risk groups 2-4
- Subsequent transfer of imported risk group 3-4

Risk Group 2
- Self attestation of meeting mandatory requirements of Laboratory Biosafety Guidelines
- Permit to import
- No prohibitions on subsequent transfer
Human Pathogens Importation Regulations

Risk groups 3-4
• Require certification by Public Health Agency of Canada (PHAC) inspectors
  – Certified as being compliant with the Laboratory Biosafety Guidelines
• Permit issued after certification
• Annual re-certifications
• Transfer of imported material requires approval
Gaps

- Only regulate imports
  - No oversight of domestically acquired pathogens
  - No requirement for security screening of personnel
  - No requirement for maintenance of inventories (specifically for risk group 2)
  - Only oversee transfer of risk group 3-4 materials, not risk group 2
  - No reporting requirements of inadvertent releases, production or lab acquired infections
  - Weak penalties
What Canada has presented: The Human Pathogens and Toxins Act, Bill C-54

- Tabled April 29, 2008
- Designed to address gaps of current Human Pathogens Importation Regulations
  - Cover imported and domestically acquired pathogens
  - Requires personnel security clearances
  - Requires maintenance of inventories
  - Oversight of all pathogen transfers
  - Requires reporting of inadvertent releases, production and laboratory acquired infections
  - Penalties commensurate with offenses
- Specific prohibitions: possess, transfer, store, dispose of, import, export a human pathogen of RG 2, 3 or 4 or toxin without a license
The Human Pathogens and Toxins Act: Bill C-54

- Approached from a public health perspective
  - “Good biosafety leads to good biosecurity”
- Not pathogen list based
- Uses risk group definitions plus lists
  - based on WHO definitions
- Covers all human pathogens in risk groups 2-4, plus toxins
  - Toxins are exclusively list based
The Details
Basic Requirements

• **Definitions (s. 3):**
  - Human pathogen is a pathogen listed on a schedule or falls into one of the 3 risk group definitions (i.e. RG 2, RG 3 or RG 4)
  - Toxins are defined only on a schedule

• **General duty of care. (s. 6)**

• **Prohibitions against undertaking controlled activities with a human pathogen, without a licence. (s. 7)**
  - Prohibited to: possess, transfer, store, dispose of, import, export a human pathogen of RG 2, 3 or 4 or toxin without a license

• **Prohibition to possess certain human pathogens such as smallpox. (s. 8)**
Reporting

• **Obligation to:**
  – inform of inadvertent release and/or production (s. 12)
  – report all laboratory acquired infections (s. 13)
  – Report missing pathogens (s. 14)

• **S. 12-15:** information submitted cannot be used in criminal proceedings.
Licencing

- Licences will be issued to facilities that work with human pathogens in RG2-4. (s. 18)

- Obligations for licence holder to inform others of conditions of licence. (s. 18(6))

- Licences can be varied, or suspended/revoked (s. 19 and 20)
  - Ability to do so in emergency situations (s. 22)

- Licence suspensions/revocations can be reviewed by a committee (s. 23)
  - Similar process of review as in the Human Pathogens Importation Regulations (HPIRs)
Access

• Requirement to maintain list of all persons accessing facilities. (s. 32)

• Requirement for authorized access pursuant to a security clearance (s. 33)
  – Security screening requirements to be specified in regulations

• Authorized access for visitors (s. 33(b))
  – Specifics may be outlined in regulations
Biological Safety Officer

• Requirement to designate a biological safety officer prior to licence issuance (s. 36)
  – Qualifications, powers and duties to be set out in regulations
Exemptions

• Prohibitions sections (s. 7, 8) do not apply for certain individuals (s. 37):
  – s. 37(a): inspectors;
  – s. 37(b) peace officers;
  – s. 37(c): anyone who “collects a sample for the purpose of laboratory analysis or diagnostic testing”;  
  – s. 37(d) in exigent circumstances
Inspectors

- Designation of inspectors. (s. 40)
- Powers of inspectors. (s. 41)
- Reasonable assistance to be provided to inspectors. (s. 41(4))
- Obstruction of inspectors. (s. 41(5))
- Measures may be ordered by inspectors in the event of serious and imminent danger. (s. 43)
Offences and Penalties

- **Basic Offence**: $250,000 or 3 months in jail or both (s. 53) Doubled on subsequent offences.

- **Offences related to s. 6 duty of care**: up to 2 years for negligence (s. 54); and up to 5 years for wanton or reckless disregard (s. 55)

- **Offences related to s. 7(1) and s. 18(7) “controlled activities” under licence**: up to $250,000 and/or three months on summary conviction (doubled on subsequent offences) or up to $500,000 and 6 months on indictment and up to $1 million or 2 years for subsequent offences. (s. 56)

- **Specific offences for s. 8 contraventions**: from minimum of $250,000 and three months to maximum of $1 million and 5 years (s. 57)

- **Intentional release/abandonment creating risk of harm**: maximum of 10 years jail (s. 58)
Implementation

Upon Royal Assent

- Transitional provisions (s. 70-71)
  - Until new regulations are enacted, the HPIRs will be in force, as well as select provisions of the Act.
  - Main provision: informing the Minister of possession of a RG 2, 3 or 4 pathogen within 90 days of Royal Assent.
Transition

• Laboratories certified under the *Human Pathogens Importation Regulations* (HPIR), will have a simplified transition to the new program.

• PHAC will make inspectors available to non-regulated laboratories that voluntarily request site visits to assess their compliance.

• PHAC will advise all laboratories prior to implementation of new requirements, which will take some years to fully implement.
Risk Groups

- The risk group categorization of the human pathogen defines how the pathogen will be controlled.

- Schedules of human pathogens (Schedules 2-4) are representative, not exhaustive lists.

- Schedule 1 lists all toxins covered by the Act.

- Schedule 5 lists all pathogens prohibited in Canada (i.e. Smallpox).

- The following tables show selected requirements for the schedules.
What Canada will propose
**Schedule 1**

<table>
<thead>
<tr>
<th>Description of Pathogens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxins</td>
</tr>
</tbody>
</table>

**Requirements:**
- Registration and licensing
- Self-Attestation
- Maintenance of an inventory - annual updates
- Spot/risk-based inspections
- Possible security clearance for select toxins
Schedule 2

<table>
<thead>
<tr>
<th>Description of Pathogens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk Group 2</td>
</tr>
</tbody>
</table>

**Requirements:**

- Registration and licensing;
- Maintenance of an inventory - must provide current inventory upon request;
- Yearly checklist submission
- Spot/risk-based inspections;
- There is no requirement for security screening.
Schedules 3 and 4

<table>
<thead>
<tr>
<th>Description of Pathogens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk Group 3 and 4</td>
</tr>
</tbody>
</table>

Requirements:
• As per Schedule 2 plus;
  – On-site visit by PHAC-OLS before license
• physical and operational documents and biosecurity plan
• Detailed inventory of pathogens: quantity, location and concentration
• Security clearances for anyone who could access RG 3-4 pathogens, but not for visitors.
• Regular reports of changes in inventories
• On-going inspections
Schedule 5

- No person in Canada is permitted to possess human pathogens in Schedule 5, regardless of level of containment or security clearance.
Registration process

• Internet-based

• Self-assessment tool will be developed/utilized
Possession and Handling

- Compliant with the mandatory successor document to the Laboratory Biosafety Guidelines.

- Possible supplementary conditions of licence.
Importation

• Permits for RG 2 pathogens would be granted on a yearly basis.

• Separate permit required for importing each RG 3 and 4 human pathogen.
Transfer

• Sending and receiving laboratories required to have a permit for transfer of any human pathogen or toxin.

• Automatically granted within 7 days of request, if PHAC does not refuse.

• Not required for intra-facility transfers.
Export

- Export of agents on the Export Control List would require authorization from DFAIT.

- PHAC would regulate the export for those pathogens not listed on Export Control List.

- Exporting lab required to attest that receiving lab properly accredited.
Resources

Office of Laboratory Security
Centre for Emergency Preparedness and Response
Public Health Agency of Canada
01 613 957 1779

The Human Pathogens and Toxins Act, Bill C-54:
http://www2.parl.gc.ca/HousePublications/Publication.aspx?Docid=3444972&file=4