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

Human Pathogens and Toxins Act:

Bill C-11

Public Health Agency of Canada | Agence de la santé publique du Canada

Canada

Gaps of the Current Regulatory Regime

- The *Human Pathogens Importation Regulations* (HPIR) were established in 1994 to provide mandatory oversight for only imported human pathogens or toxins.

- Under the Regulations, the 3,500 facilities which import these agents must:
  - obtain an importation permit for human pathogens of a Risk Group (RG) 2, 3 or 4;
  - allow mandatory inspection for facilities handling human pathogens of RG 3 or 4 to ensure that they comply with the Laboratory Biosafety Guidelines;
  - comply with these requirements in order to avoid the penalties defined by the Regulations, including a possible fine of $200 and/or an imprisonment of up to 3 months.

Gaps of the Current Regulatory Regime

- This regime cannot be expanded to cover domestically-acquired human pathogens and toxins.
- There are an estimated 4,000 laboratories that work with domestically acquired pathogens

The Act: Basics

- *Human Pathogens and Toxins Act* was tabled in Parliament February 9, 2009 (Bill C-11).
- Application: applies to all persons who carry on activities with a RG 2, 3 or 4 human pathogen (see schedules)
  - Non-exhaustive lists of pathogens
  - Application of Act based on risk group classification of agent in question.
- Will require regulations in order to bring the entire policy framework into effect – the specifics regarding security screening, inventories, and licencing will be in regulations, subject to consultations.
- Will replace the HPIR.

The Act: Prohibitions and Requirements

- General duty of care provisions.
- General prohibition to possess, transfer, store, dispose of, import, export a human pathogen of RG 2, 3 or 4 or toxin without a license.
- Absolute prohibition to possess listed pathogens (i.e. smallpox.)
- Requirement to report incidents that may have caused a laboratory acquired infection.
- Requirement to follow the widely-accepted Laboratory Biosafety Guidelines, as Canada's national biosafety standard.
- Provisions for significant penalties

The Act: On Royal Assent

- Upon Royal Assent, all facilities in Canada will be required to register with Office of Laboratory Security (OLS) - (basic information only).
- New facilities that commence operations between Royal Assent and promulgation of regulations will also have to register.
- Labs will have to appoint a contact person to facilitate contact with the OLS.

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.

Schedule 1

Description of Pathogens
Toxins

Requirements:

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

Schedule 2

Description of Pathogens
Risk Group 2

Requirements:

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

Schedules 3 and 4

Description of Pathogens
Risk Group 3 and 4

Requirements:

- As per Schedule 2 plus;
- Filing of inventory;
- Security clearances for personnel, but not for visitors.

Schedule 5

Description of Pathogens
Prohibited Pathogens and Toxins

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

Defined Exclusions from Application of Act

- Organisms in their natural environment.
- In a human suffering from a disease.
- Expelled from a person suffering from a disease.
- In a cadaver, body part or other human remains.
- A drug in dosage form.
- Controlled activity under the *Assisted Human Reproduction Act.*

Exemptions from Application of Act

- An inspector under this Act
- A peace officer
- Sample collection for a licensed facility
- Carrying out a function under any federal or provincial Act

Registration process

- Internet-based
- Self-assessment tool will be developed/utilized

Possible Licensing Process

To be Defined by Regulations following consultations

- All facilities handling RG 2-4 human pathogens will require licensing.

- RG 2
  - Checklist every year and inventory maintenance available upon request
  - Spot and risk inspections

Possible Licensing process: RG 3-4

To be Defined by Regulations following consultations

- 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

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.
- Not required for intra-facility transfers.

Export

- Export of agents on the Export Control List would require authorization from DFAIT.
- PHAC could regulate the export for those pathogens not listed on Export Control List.
- One option could be that an exporting lab could be required to show due diligence.

Disposal

- Laboratories would be required to notify PHAC of the nature of pathogens disposal.
- Laboratories responsible to ensure that a pathogen's disposal rendered it non-viable or non-functional.

Next Steps

- Consultations: Commencement of consultations on the regulations. Consultations are required in development of regulations.