

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

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ABSA International

60th Annual Biological Safety Conference

October 16, 2017

PROTECTING AND EMPOWERING CANADIANS
TO IMPROVE THEIR HEALTH

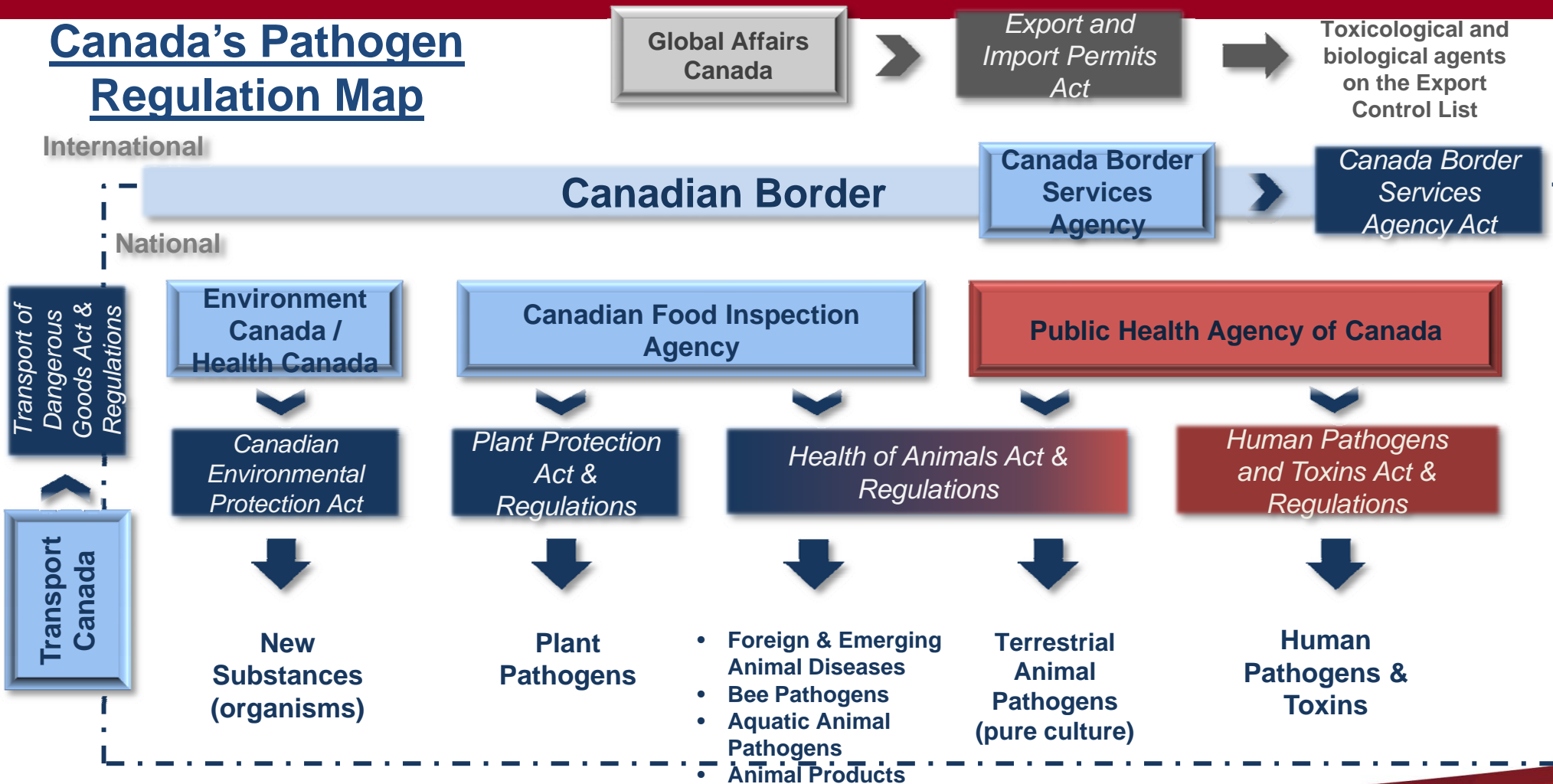


About the Centre for Biosecurity

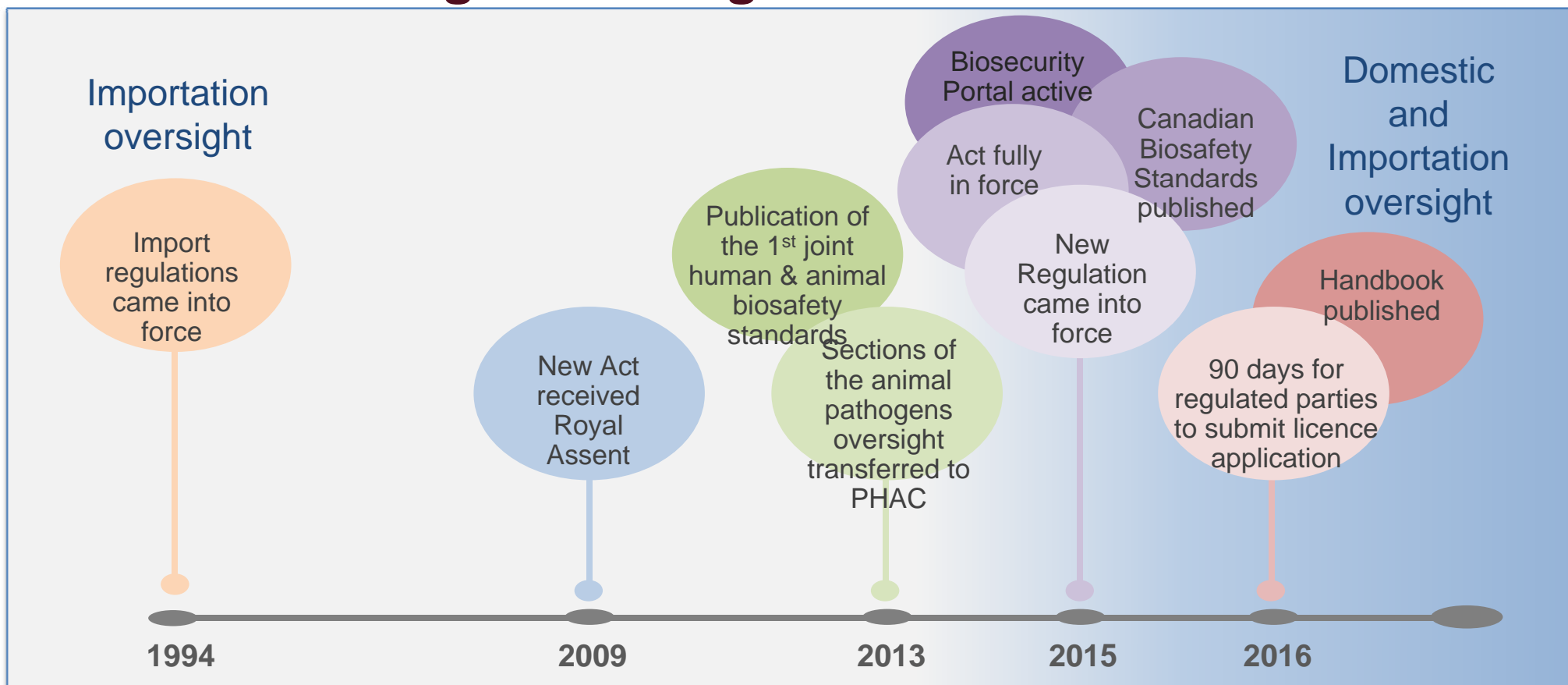
- The Public Health Agency of Canada's Centre for Biosecurity (PHAC-CB) is the **national authority for biosafety and biosecurity** of human pathogens and toxins.
- PHAC-CB is responsible for the administration and enforcement of the:
 - *Human Pathogens and Toxins Act* (HPTA).
 - *Human Pathogens and 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



Canada's Pathogen Oversight: Timeline



Managing the Transition

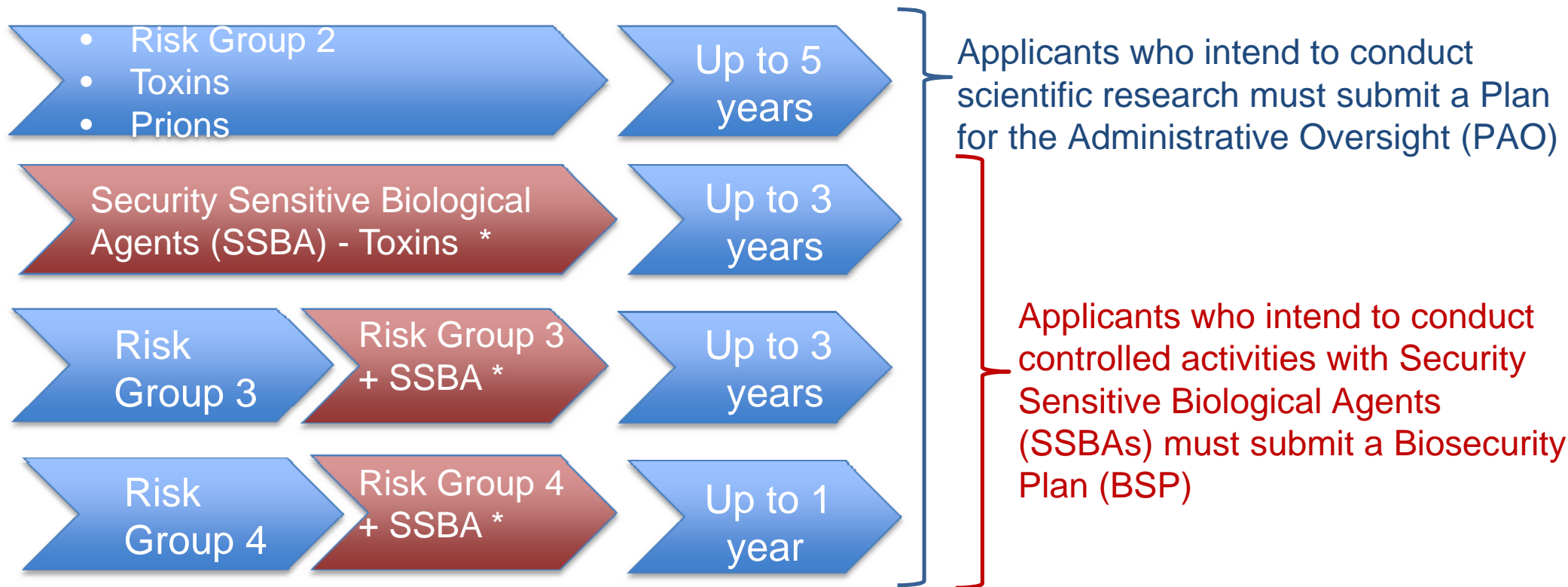
- “All-hands-on-deck” approach across the Centre for Biosecurity (CB).
- Development of tools and products to help regulated parties manage the transition. [Communication was crucial to success]
 - Townhall info session (general)
 - Targeted info sessions with the CB’s Directors
 - Newsletters
 - Targeted 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



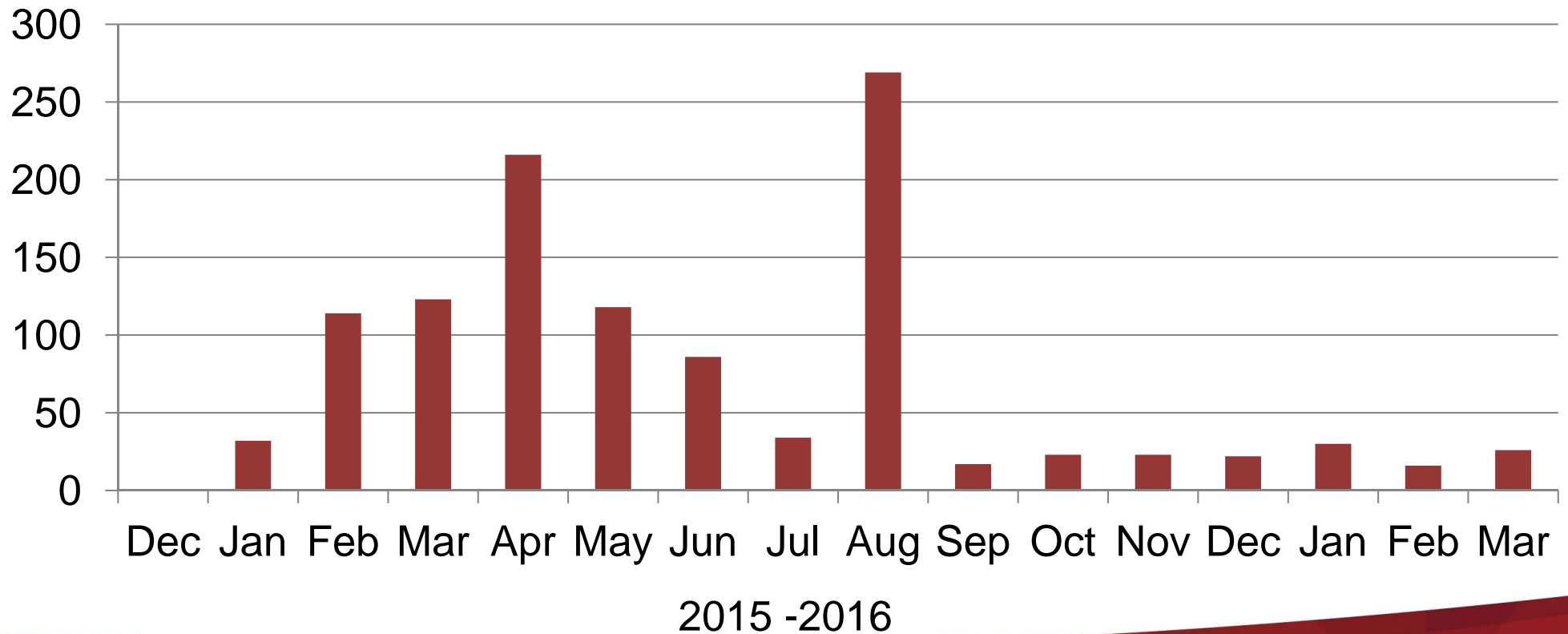
* HPTA Security Clearances are required for individuals who work with or have access to SSBAs

Issuing “Pathogen and Toxin Licences”

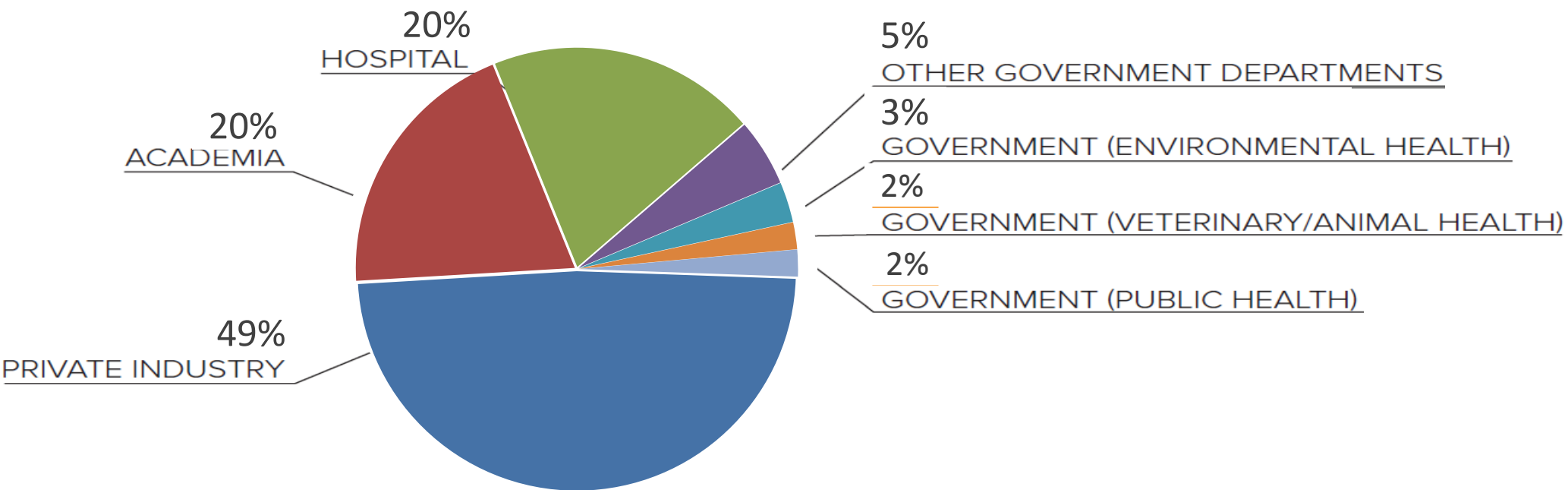
- 100% of licence applications received during the HPTR transition period (and who require a licence at this time) were processed by January 2017.
- Little over **1300** “Pathogen and Toxins Licences” issued since December 1, 2015.
- **962** Active Licences as of September 15th, 2017:
 - 93% are for 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)

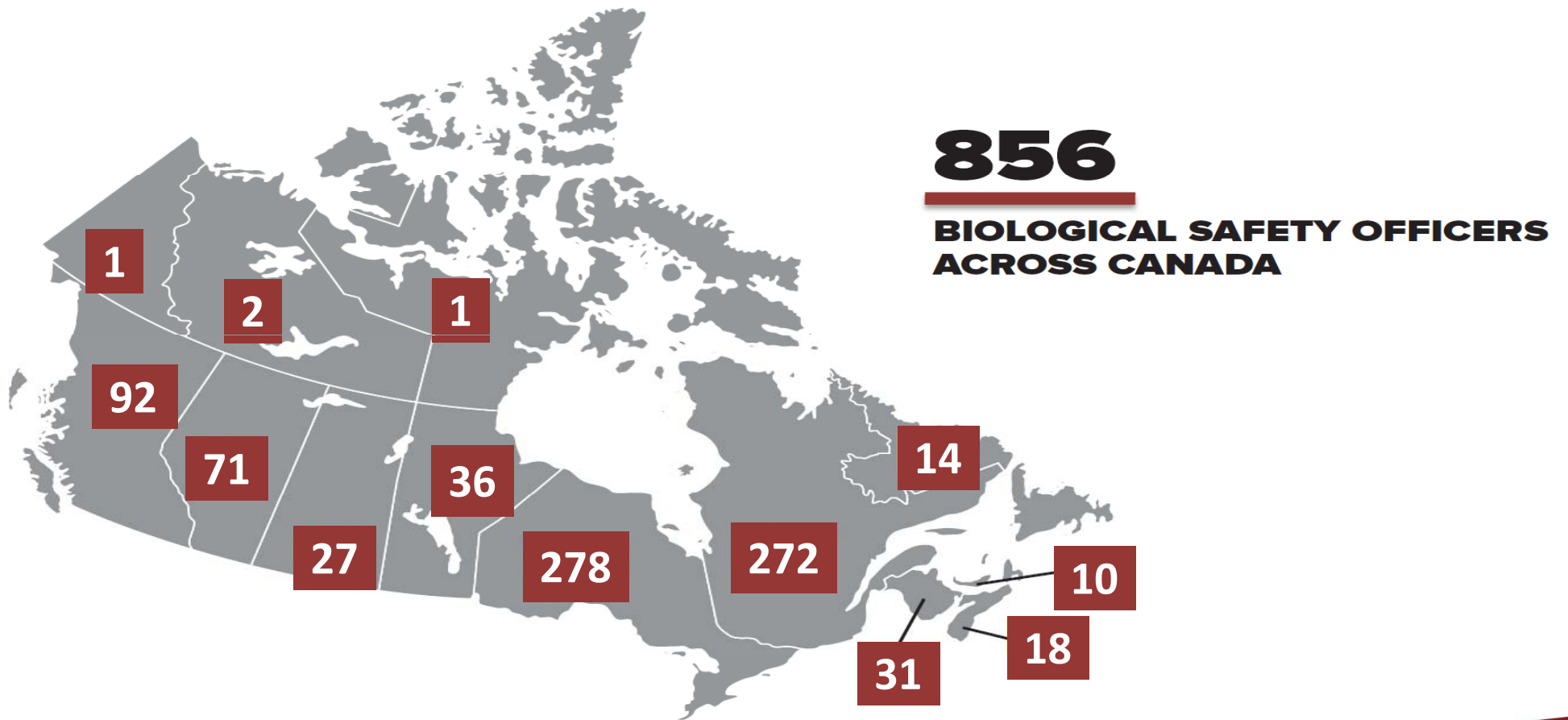
Licences Issued Per Month



Sector Profile Distribution



Biological Safety Officers Across Canada

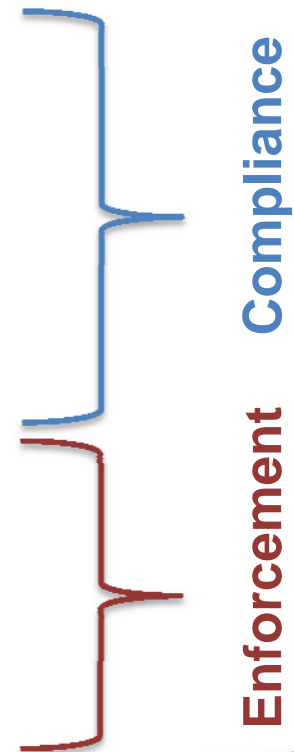


Activities Supporting Licence Issuance

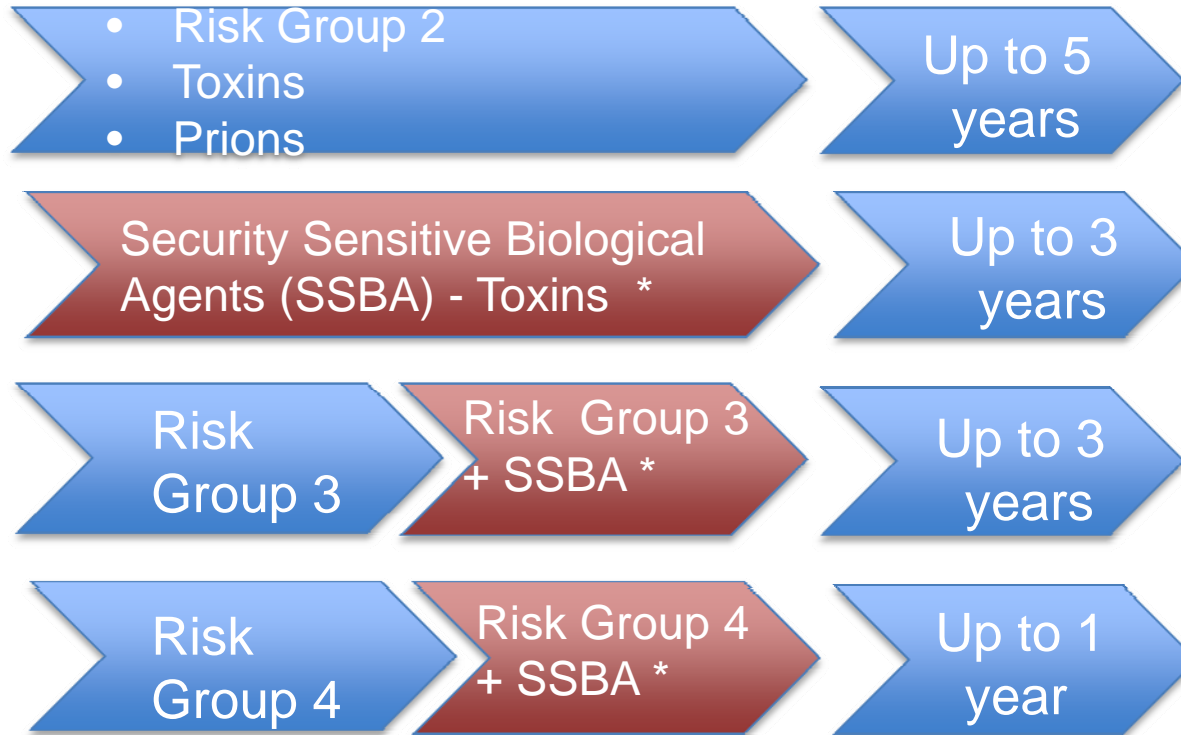
- 264 Plans for Administrative Oversight (PAOs) reviewed
 - To be submitted by licence applicants conducting scientific research
- 366 HPTA Security Clearances Issued
 - Required for individuals who work with or have access to Security Sensitive Biological Agents (SSBAs)
- 18 Biosecurity Plans reviewed
 - 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)**



Licensing



Inspection

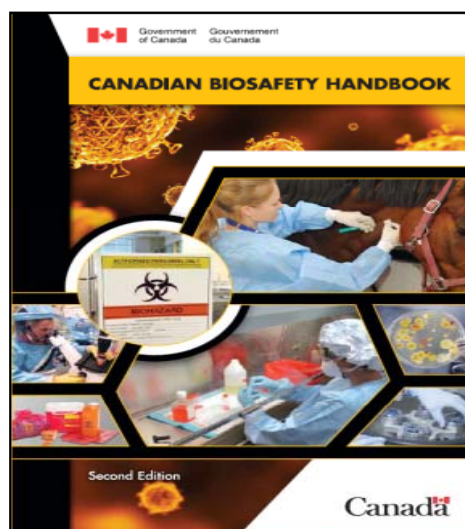
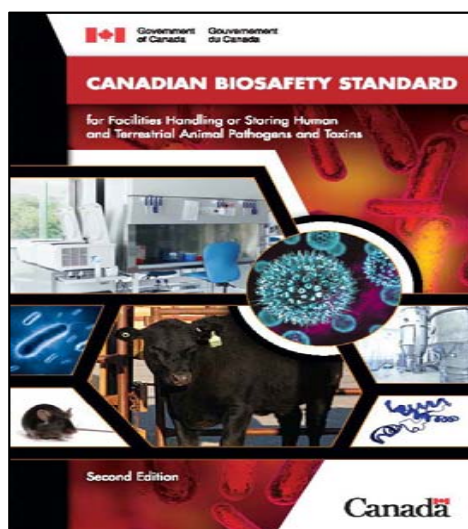


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	Compliant	Minor Non-Compliance	Major Non-Compliance	Serious & Imminent Non-Compliance
Compliance Level*	Legal Requirements:			
	Meets relevant minimal legal requirements	Meets most of the relevant legal requirements	Below the relevant minimum legal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

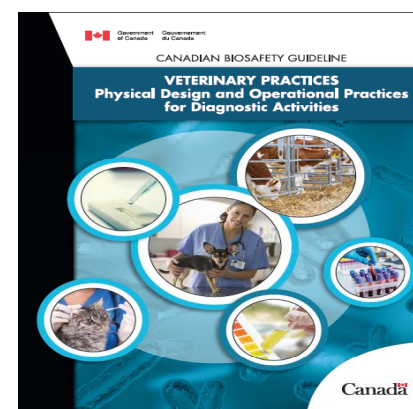
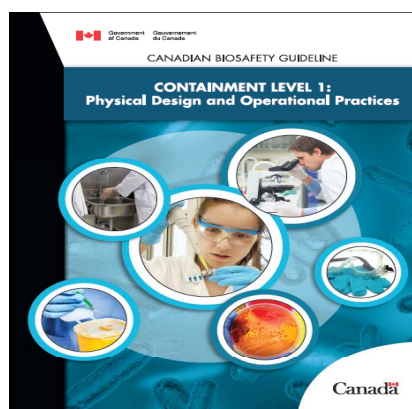
Canadian Biosafety Standard and Handbook

- 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)

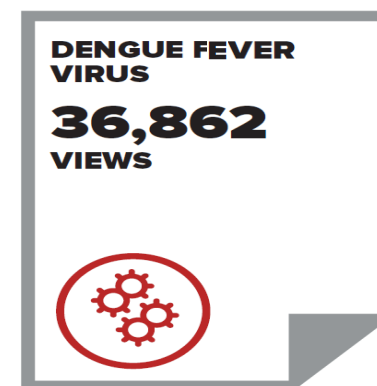
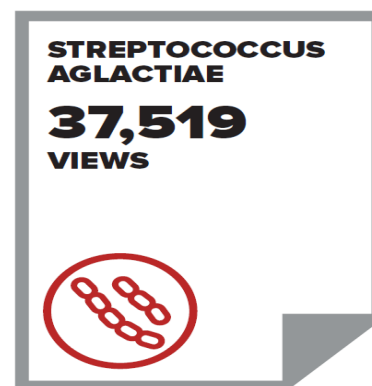
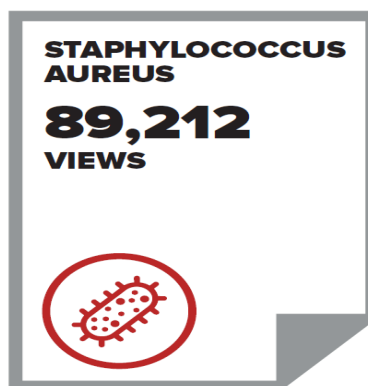


Pathogen Safety Data Sheets (PSDS)

- Access to information on hazards of various pathogens and how to work with them safely

- Most downloaded PSDS:

<https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html>



- PSDS website access by country



444,991 Hits



357,793 Hits



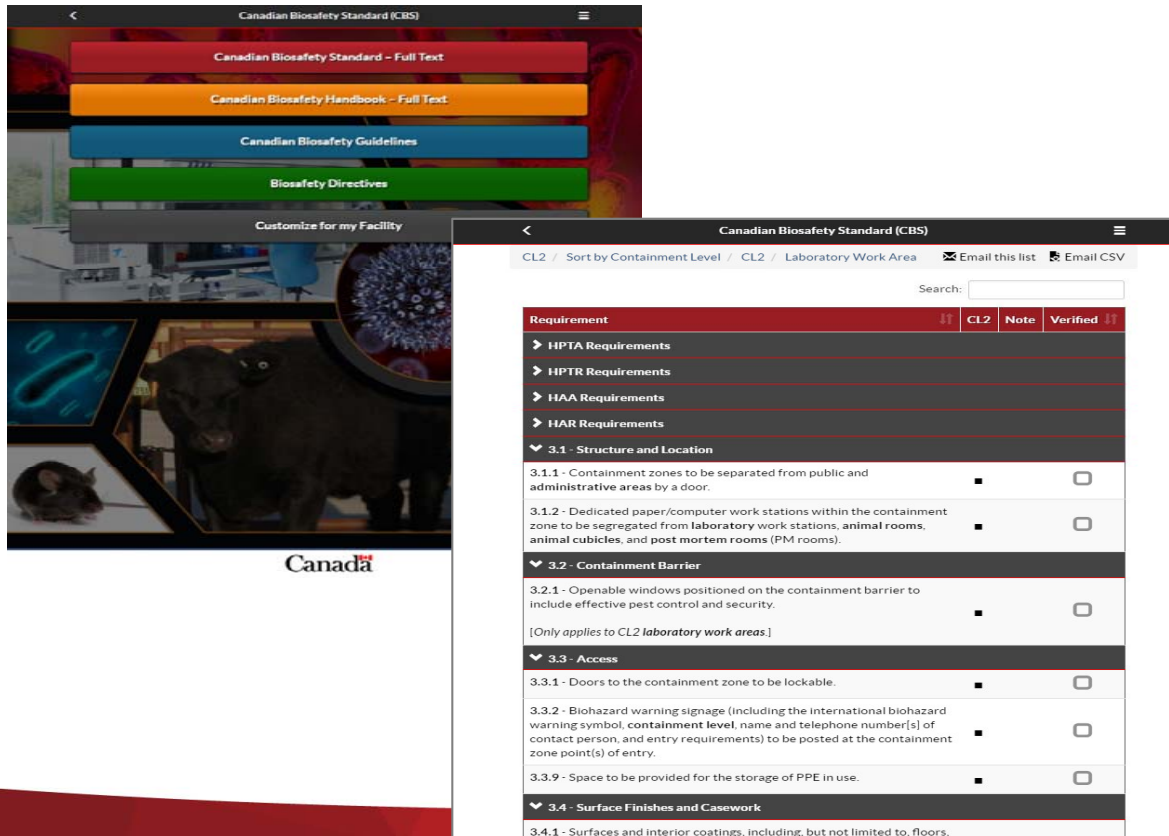
357,793 Hits



43,779 Hits

Cool Apps

- Canadian Biosafety Standards APP: over 2325 downloads



- Pathogen Safety Data Sheets App: Over 3760 downloads

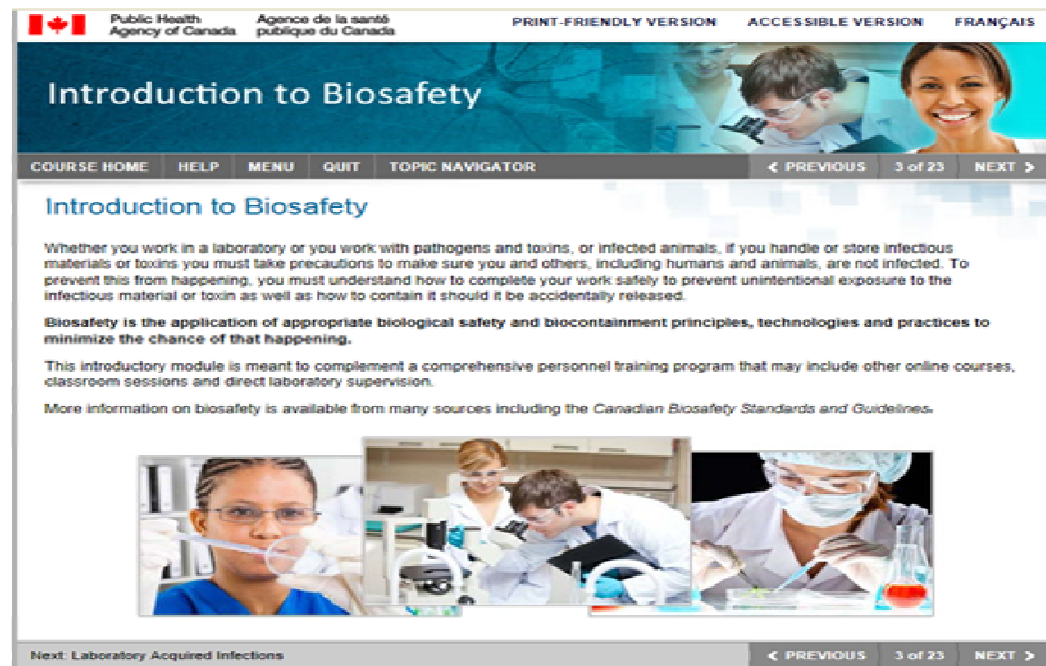


Canada

Both available through:
- Android App in Google Play
- Apple App via App Store

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





Public Health
Agency of Canada

Agence de la santé
publique du Canada

No.
L-ST-43878-15-YS-00

Public Health Agency of Canada
Pathogen and Toxin Licence

Centre for Biosecurity / Centre de la biosûreté

(Name of Organization)

100 Colonnade Road, Ottawa, Ontario, K1A 0K9

(Address)

Security Sensitive Biological Agent Toxin Licence under section 18 of the *Human Pathogens and Toxins Act*

AND

Risk Group 2 Terrestrial Animal Pathogen Permit under section 160 of the *Health of Animals Regulations*

(Risk group covered by the Licence)

Subject to the conditions annexed hereto

Validity Period: 2015-12-01 to 2018-12-01, *unless otherwise suspended, varied, or revoked.*
Date Issued: 2015-11-25
Issued to: Roman Montague
Biological Safety Officer: Juliet Capulet

To Reach Us

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<https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity.html>