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

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Canada's Biosecurity Oversight Strengthening Biosecurity Risk Assessment

ABSA 61st Annual Biological Safety Conference

October 16th, 2018

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PROTECTING AND EMPOWERING CANADIANS TO IMPROVE THEIR HEALTH

Objectives

- Introduce the Public Health Agency of Canada's Centre for Biosecurity
- Describe the Canadian Biosecurity Oversight Program Elements
- Introduce the Biosecurity Risk Assessment Methodology

About the Public Health Agency of Canada's Centre for biosecurity

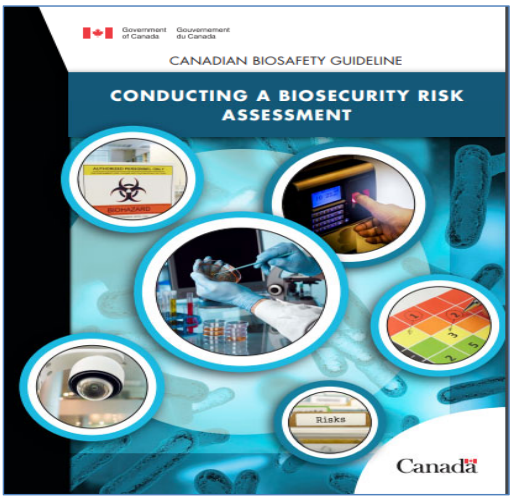
- National authority for biosafety and biosecurity of human pathogens and toxins
- WHO Collaboration Centre for Biosafety and Biosecurity
- Responsible for the administration and enforcement of the:
  - *Human Pathogens and Toxins Act* (HPTA);
  - *Human Pathogens and Toxins Regulations* (HPTR); and
  - sections of the *Health of Animals Act* (HAA) and the *Health of Animals Regulations* (HAR).
- Purpose of the HPTA: to establish a safety and security regime to protect the health and safety of the public against risks posed by human pathogens and toxins
- 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 obtain a valid "Pathogen and Toxin Licence"

Pillars of Biosecurity Oversight

- Biosecurity Risk Assessments
  - Required for all licence holders
  - Purpose is to identify and prioritize biosecurity risks, and to address those risks through the implementation of mitigation measures commensurate to the level of risk described in the Biosecurity Plan.
- Biosecurity Plan
  - Required for all licence holders
  - Purpose of a biosecurity plan is to prevent the loss, theft, misuse, diversion, or intentional release of biological assets and related facility assets. The plan describes the measures implemented to address the biosecurity risks identified in the Biosecurity Risk Assessment.
- HPTA Security Clearances
  - Human Pathogen and Toxins Act (HPTA) Security Clearance are required for all people who have access to a subset of high-risk biological agents (known as security sensitive biological agents or "SSBAs").
  - Purpose is to provide assurance that individuals who have access to SSBAs have been assessed to not pose a security or diversion risk as a result of their access.

Conducting a Biosecurity Risk Assessment Guideline

- Overview
  - This guideline describes best practices for conducting a biosecurity risk assessment in an organization where human or animal pathogens, toxins, or other regulated infectious material are handled or stored.
  - It allows for the evaluation of appropriate mitigation measures identified via the risk assessment process.
- Who is this guide for
  - Pathogen and Toxin Licence holders
  - Biological Safety Officers
  - Personnel in regulated facilities



Biosecurity Risk Assessment Steps

- Risk assessment methodology involves the following five steps:
  1. Develop an asset inventory
  2. Assess biosecurity event likelihood
  3. Assess biosecurity event consequences
  4. Analyze
  5. Determine risk tolerance
- The components within this guidelines are assessed using a scale of five values.

Component Value (Quantitative)	1	2	3	4	5
Component Value (Qualitative)	Very Low	Low	Medium	High	Very High

Preparation and Asset Inventory

- Preparation
  - Gathering documentation
  - Developing an understanding of the threat environment
  - Selecting the assessment team
  - Schedule

- Asset Inventory
  - Identifying assets

Asset Class	Asset Category	Asset Group	Component	SSBA	Risk Group	Quantity	State	Ease of Use	Location	Dual-Use Potential	Priority Value
Tangible	Biological	Virus	HIV	No	3	10 x 1ml tubes	Frozen	Difficult	Freezer A	No	Medium (3)
Intangible	Information	Inventory	Pathogen and Toxin Inventory	N/A	N/A	1	Electronic	N/A	N/A	N/A	High (4)
People	Employee	Scientist	Professor	N/A	N/A	20	N/A	N/A	N/A	Yes	Very High (5)

Likelihood

- Likelihood assessment involves:
  - Identification of biosecurity event
  - Identifying adversaries
    - determining their motive, means and capability
  - Identifying the targeted assets
  - Determining the frequency
    - Time and location
- A value of one to five is assigned for adversary motive, means and capability, and biosecurity event frequency in proximity and at a distance.
- The likelihood value is an average of the four elements, rounded to the nearest whole number.

Scenario	Biosecurity Event Category	Biosecurity Event Group	Adversary Class	Adversary Category	Adversary	Targeted Assets	Likelihood Assessment				
							Adversary Motive Value	Adversary Capabilities Frequency	(Proximity) Frequency	(Distance)	Likelihood Value
Intentional release of infected animal by animal rights group	Deliberate	Intentional release	Outsider	Activist	Animal Rights Group	Animal	Very High (5)	Very Low (1)	Low (2)	Medium (3)	Medium (3)

Consequence

- Consequence assessment involves:
  - Assessing the impact to public health, animal health and the organization
  - Assessing vulnerabilities and effectiveness of mitigation measures
    - Pre-biosecurity event and post-biosecurity event
- A value of one to five is assigned for the impact to public health, animal health, the organization, and for the vulnerability of pre- and post-biosecurity event.
- The consequence value is the product of the impact value multiplied by the vulnerability value.

Asset	Impact	Impact Value	Mitigation Measure	Vulnerability Value
Animals	High Public Health; High Animal Health; Medium to organization	High (4)	Access Control System	Very Low (1)
			Security Guards	Low (2)

Analyze Risk

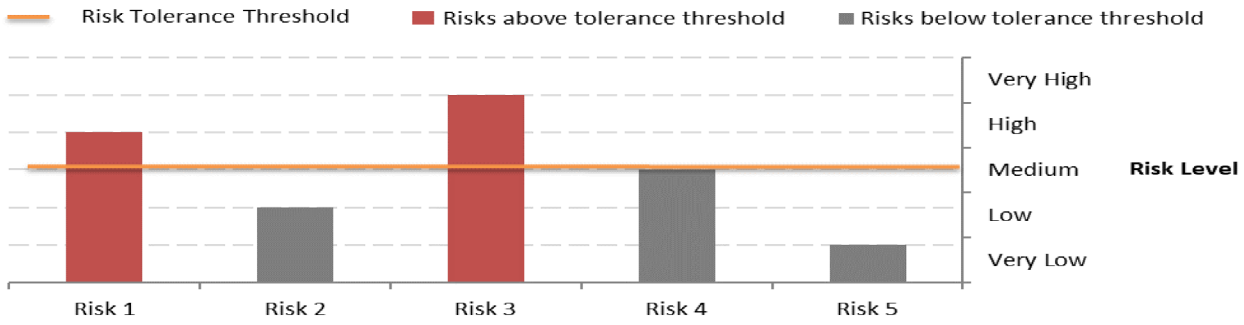
- Analyzing risk involves:
  - Risk calculation
  - Creating the risk register
- Risk is calculated by multiplying the likelihood value by the consequence value (i.e. impact and vulnerability).

Risk Range	1 – 4	5 – 18	19 – 34	35 – 74	75 – 125
Risk Level	Very Low	Low	Medium	High	Very High

ASSET	LIKELIHOOD			CONSEQUENCE				RISK LEVEL
	Biosecurity Event	Adversary	Likelihood Value	Impacts	Impact Value	Mitigation Measure	Vulnerability Value	
Animals	Release	Outsider, Activist	Medium (3)	High Public Health; High Animal Health; Medium to Organization	High (4)	Access Control System	Very Low (1)	Low (12)
						Security Guards	Low (2)	Medium (24)

Risk Tolerance

- Risk tolerance involves:
  - Determining the risk threshold
  - Accepting risk
  - Implementation of additional mitigation measures for unacceptable risks



Resources

Available on the Public Health Agency of Canada website

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

- Canadian Biosafety Guidelines
  - Developing a Comprehensive Biosecurity Plan
  - Conducting a Biosecurity Risk Assessment
  - In consultation: Dual-Use in Life Science Research.

- E-learning Portal
  - Free online training and resources on laboratory biosafety and biosecurity
  - Courses, videos, posters, interactive biocontainment tool
  - Upcoming courses:
    - Biosecurity Risk Assessment
    - Insider and Outsider Threat

Thank you

Public Health Agency of Canada
Centre for Biosecurity

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