Canadian Biosafety Standards and Guidelines

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Outline

• Overview of the regulation of pathogens in Canada.

• Introduction to the new Canadian Biosafety Standards and Guidelines (CBSG):
  - Overview
  - Current status

• Contact Information.
Regulatory Roles

- **Health of Animals Act & Regulations**
  > give the Canadian Food Inspection Agency (CFIA) the legislative authority to govern the importation of animal pathogens.

- **Human Pathogen Importation Regulations** and the new **Human Pathogens and Toxins Act**
  > give the Public Health Agency of Canada (PHAC) the legislative authority to govern human pathogens and toxins.
Regulatory Roles (cont’d)

- Duplication of some regulatory processes, since CFIA and PHAC have similar programs for:

  > issuance of import permits, and the

  > certification of laboratories importing these pathogens.
Overview

• CFIA and PHAC are currently in the process of developing a harmonized Canadian Biosafety Standards and Guidelines (CBSG) document that will apply to facilities handling:
  
  • human pathogens;

  • terrestrial animal pathogens;

  • prions; and

  • biological toxins.
Why Harmonize?

• Stakeholders have been encouraging the two agencies to work together to streamline and unify processes.

• Overlap in the regulations and associated programs exists for laboratories importing zoonotic pathogens.
Why Harmonize? (cont’d)

- Three documents need to be updated:

  - CFIA Containment Standards for Veterinary Facilities (1st ed. 1996);
  - CFIA Containment Standards for Laboratories, Animal Facilities and Post Mortem Rooms Handling Prion Disease Agents (1st ed. 2005); and
  - PHAC Laboratory Biosafety Guidelines (3rd ed. 2004).
Canadian Biosafety Standards and Guidelines

- Divided into two parts:
  - Part I - Standards
    - Technical document outlining the minimum requirements for the design, construction, commissioning and operation of containment facilities.
Canadian Biosafety Standards and Guidelines (cont’d)

> Part II - Guidelines

- Guidance document for the development of biosafety policies and programs in support of the requirements in the Standards.
Benefits to Regulated Parties

- Ease burden for regulatory compliance;

- Nationally streamline biosafety requirements and practices;

- Single reference document for facilities handling animal and human pathogens; and

- Continued collaboration between CFIA and PHAC to harmonize regulatory processes.
Current Status

- Work with PHAC started during summer 2010.

- Dissecting the current standards and guidelines and developing the seed document.
Current Status (cont’d)

- Expert Review Committee phase to start fall 2011.
- Public consultations to follow.
- Implementation phase to start fall 2012.
Contact Information

• Office of Biohazard Containment & Safety (CFIA)


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Contact Information (cont’d)

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