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# Canadian Biosafety Standards and Guidelines

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# Outline

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- Overview of the regulation of pathogens in Canada.
- Introduction to the new *Canadian Biosafety Standards and Guidelines* (CBSG):
  - Overview
  - Current status
- Contact Information.



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## Regulatory Roles

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- *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.



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## Regulatory Roles (cont'd)

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- 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.



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# Overview

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- 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.



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## Why Harmonize?

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- 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.



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## Why Harmonize? (cont'd)

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- Three documents need to be updated:
  - > CFIA *Containment Standards for Veterinary Facilities* (1<sup>st</sup> ed. 1996);
  - > CFIA *Containment Standards for Laboratories, Animal Facilities and Post Mortem Rooms Handling Prion Disease Agents* (1<sup>st</sup> ed. 2005); and
  - > PHAC *Laboratory Biosafety Guidelines* (3<sup>rd</sup> ed. 2004).



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## *Canadian Biosafety Standards and Guidelines*

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- Divided into two parts:
  - > Part I - Standards
    - Technical document outlining the minimum requirements for the design, construction, commissioning and operation of containment facilities.



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## *Canadian Biosafety Standards and Guidelines* (cont'd)

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### > Part II - Guidelines

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



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## Benefits to Regulated Parties

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- 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

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- Work with PHAC started during summer 2010.
- Dissecting the current standards and guidelines and developing the seed document.



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## Current Status (cont'd)

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



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## Contact Information

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- Office of Biohazard Containment & Safety (CFIA)
  - > <http://www.inspection.gc.ca/english/sci/bio/bioe.shtml>
  - > [standardsnormes@inspection.gc.ca](mailto:standardsnormes@inspection.gc.ca)
  - > 613-773-6530



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## Contact Information (cont'd)

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- Pathogen Regulation Directorate (PHAC)
  - > <http://www.phac-aspc.gc.ca/ols-bsl/index-eng.php>
  - > [standards.normes@phac-aspc.gc.ca](mailto:standards.normes@phac-aspc.gc.ca)
  - > 613-957-1779



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