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Development of the *Canadian Biosafety Standards and Guidelines*

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Outline

- *Overview of the regulation of pathogens in Canada*
- *CBSG Project Overview*
- *CBSG Development Process*
- *Status of Development Phases*
- *Draft CBSG Layout*
- *Contact Information*
- *Questions*



Regulatory Roles

- *Human Pathogen Importation Regulations, 1994, and the Human Pathogens and Toxins Act, 2009*
 - > give the Public Health Agency of Canada (PHAC) the authority to govern activities with **human** pathogens and toxins.
- *Health of Animals Act, 1990, & Regulations*
 - > give the Canadian Food Inspection Agency (CFIA) the authority to govern the importation of **animal** pathogens.



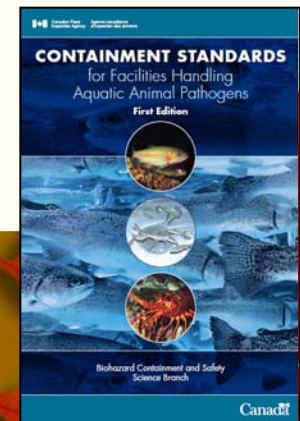
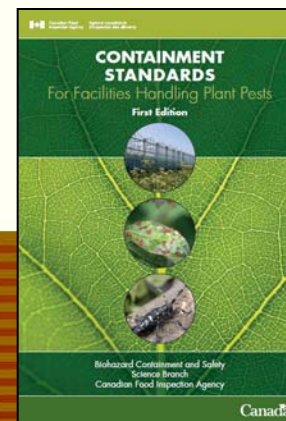
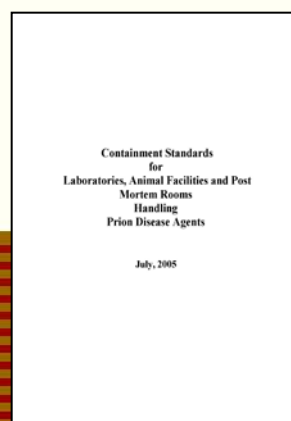
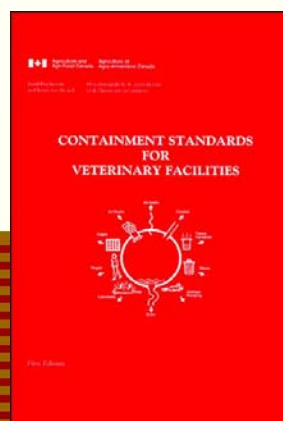
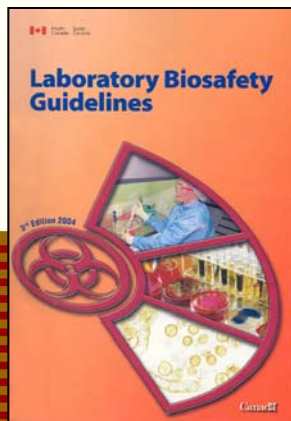
Current Biosafety Guidelines and Standards

Public Health Agency of Canada

- > *Laboratory Biosafety Guidelines*, 3rd edition, 2004.

Canadian Food Inspection Agency

- > *Containment Standards for Veterinary Facilities*, 1996.
- > *Containment Standards for Laboratories, Animal Facilities and Post Mortem Rooms Handling Prion Disease Agents*, 2005.
- > *Containment Standards for Facilities Handling Plant Pathogens*, 2007.
- > *Containment Standards for Facilities Handling Aquatic Animal Pathogens*, 2010.





Canadian Biosafety Standards and Guidelines

- CFIA and PHAC are in the process of developing a harmonized *Canadian Biosafety Standards and Guidelines* (CBSG).
 - > ***Harmonized initiative*** that combines 3 existing biosafety guidelines and standards for working with human and terrestrial animal pathogens and toxins.
 - > ***Clear update*** of the existing standards and guidelines, but the harmonization of the CFIA's and PHAC's biocontainment requirements is a ***NEW*** approach.



Benefits to Regulated Parties

- Nationally streamline biosafety requirements and practices;
- Single reference document for facilities handling animal **and** human pathogens;
- Ease burden for regulatory compliance; and,
- Continued collaboration between PHAC and CFIA to harmonize regulatory processes.



CBSG Development Process

- > **PHASE I - Seed Document Development** (Sept. 2010 - Oct. 2011)
- > **PHASE II - Expert Working Group** (Nov. 2011 - July 2012)
- > **PHASE III - Consultation** (fall 2012)
- > **PHASE IV - Design and formatting** (spring 2013)
- > **PHASE V - Distribution and Implementation** (by fall 2013)

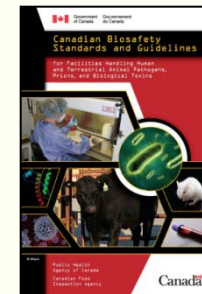
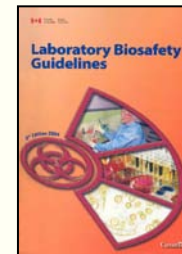
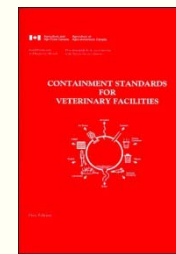


PHASE I - Seed Document Development



- **Seed Document Development Phase**

- > Initial draft seed document was completed in the fall of 2011.
- > Several rounds of internal reviews by PHAC and CFIA occurred before and during PHASE II.





PHASE II – Expert Working Group

- EWG established to provide recommendations, technical advice and input into the CBSG.
- Member representation from industry, academic institutions, federal and provincial/territorial government agencies.
- EWG members provided comments on the Draft Seed CBSG electronically and at a face-to-face meeting.
- Expert input into key areas:
 - Prions
 - Large scale
 - Toxins
 - Planning/design/biosafety equipment
 - Animal work
 - Biosafety program management
 - Science and research



PHASE III - Consultations

- Consultations on the draft CBSG are currently underway with stakeholders and other interested parties.
- Key opportunity for stakeholders to review the draft CBSG and become involved in the development process.
- Consultation phase will include:
 - > CBSG Draft Review Process (*online soon!*)
 - > Face-to-face Consultation Sessions (*coming soon!*)



PHASES IV and V - Printing, Distribution and Implementation

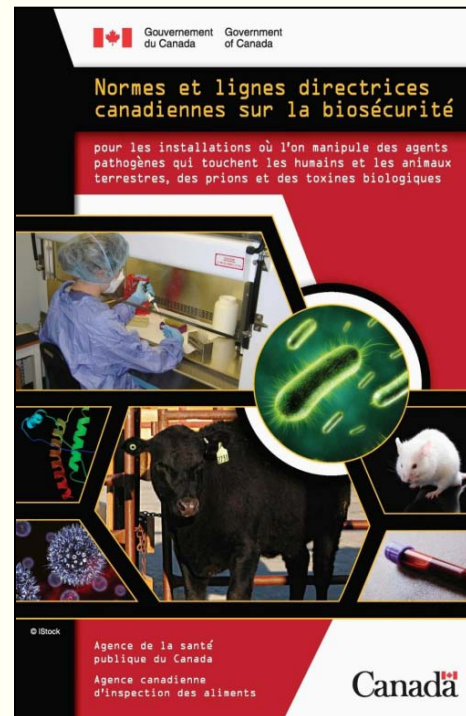
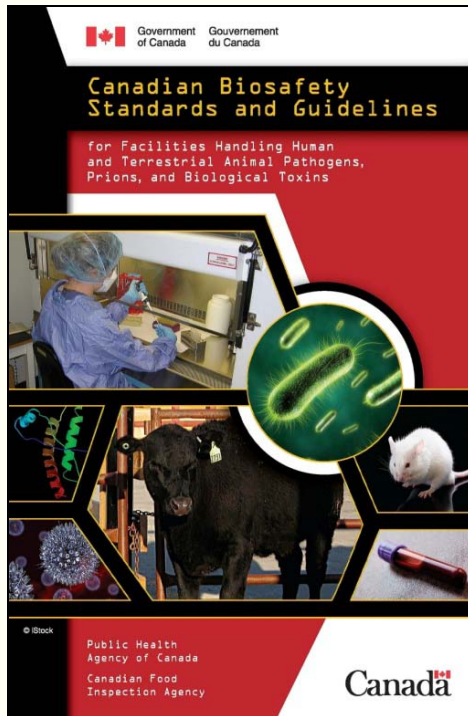
- Printing and distribution of CBSG to be completed by fall 2013.
- The CBSG will be distributed electronically and in printed form.
- Implementation of CBSG will be phased in to allow regulated parties time to become familiar with and adjust to its requirements.



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Draft CBSG Layout



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Draft CBSG: Part I - Standards

- Contains biosafety requirements for engineering controls and facility design (Chapter 3 – Physical Containment Requirements).
- Contains biosafety requirements for administrative controls and procedures (Chapter 4 – Operational Practice Requirements).
- Clear and concise wording in matrix format for consistency and ease of use.



Draft CBSG: Part I – Matrix Layout

matrix #	requirement #	matrix title	containment level (CL)					
3.2		Containment Barrier	CL1* (FBE)	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.2.1		Windows that can be opened and are positioned on the containment barrier to provide effective pest control and security. [Only applies to CL2 laboratory work areas.]	Φ	■				
3.2.2		Windows on the containment barrier to be non-opening and sealed.	□ P	■	■	■	■	■

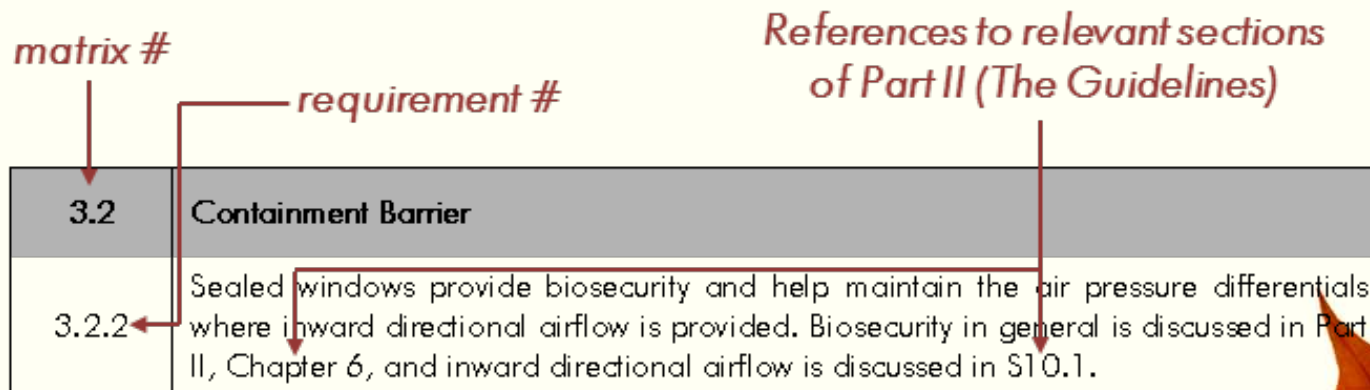
Exempt areas are listed in square brackets below the requirement

- Φ Foundational Biosafety Element
 - Required Physical Containment Element
 - Required Physical Containment Element, excluding CL2 laboratory work areas
 - P Increased Physical Containment Requirement beyond CL2 or CL2-Ag
- The absence of a symbol in the tables indicates that the item is not required.



Draft CBSG: Transition Index

- Transition Index located between Parts I and II and provides:
 - > **why** a requirement from Part I is needed.
 - > supplementary information.
 - > **where** to find further guidance on the subject in Part II.





Draft Document: Part II - Guidelines

- Contains guidance information on ***how to achieve*** compliance with the Standards outlined in Part I.
- Existing information from previous standards/guidelines was updated and further information added based on requests and feedback over the years.
- Integrates the principles of biological risk management strategies.



Draft Document: Part II - Guidelines

- Contains 22 chapters and 2 appendices that flow from the basics of biosafety through the management of a complex biosafety program.
- Topics discussed in Part II include:
 - > Fundamentals of biosafety and biosecurity
 - > Risk assessments
 - > Core biosafety program elements such as training and infectious material and toxin accountability
 - > Guidance on certain technical components such as air handling, decontamination, and waste management
 - > And more!



Draft Document: Figures, Diagrams and Tables

- Diagrams:
 - > Updated BSC diagrams to better show air flow in 3D.
 - > Laboratory diagrams to help visualize different containment zones.
 - > Diagrams of containment caging and other caging systems to help understand the difference between SA and LA zones.
- Figures:
 - > Biohazard warning sign that users can adapt to their own facilities.
- Tables:
 - > Summary of record retention times.
 - > Comprehensive disinfectant tables.



Website

- <http://canadianbiosafetystandards.collaboration.gc.ca>
- <http://normescanadiennesbiosecurite.collaboration.gc.ca>

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Canadian Biosafety Standards and Guidelines

The Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) are developing joint Canadian Biosafety Standards and Guidelines (CBSG) pertaining to human and terrestrial animal pathogens. These standards and guidelines are used by laboratory researchers and workers in facilities possessing, handling, storing or using such pathogens. [More...](#)

The project is planned to be completed by autumn 2012. The Agencies will be seeking input through consultations in early 2012.

For more information on existing standards and guidelines, please see:

PHAC: <http://www.phac-aspc.gc.ca/ols-bsl/pub-eng.php>

CFIA: <http://www.inspection.gc.ca/english/sci/bio/bioe.shtml>

If you have questions, contact us.

Date Modified: 2011-02-07

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Important Notices



Contact Information

- Pathogen Regulation Directorate (PHAC)
 - > <http://www.phac-aspc.gc.ca/ols-bsl/index-eng.php>
 - > standards.normes@phac-aspc.gc.ca
 - > 613-957-1779
- Office of Biohazard Containment & Safety (CFIA)
 - > <http://www.inspection.gc.ca/english/sci/bio/bioe.shtml>
 - > standardsnormes@inspection.gc.ca
 - > 613-773-5276



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Questions?



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