

A Canadian Approach: Oversight of Human and Animal Pathogens and Toxins

Marianne Heisz and Corrine Harris
 Email: HPTA.LAPHT.consultations@phac-aspc.gc.ca
 Website: www.publichealth.gc.ca/pathogens

Introduction:

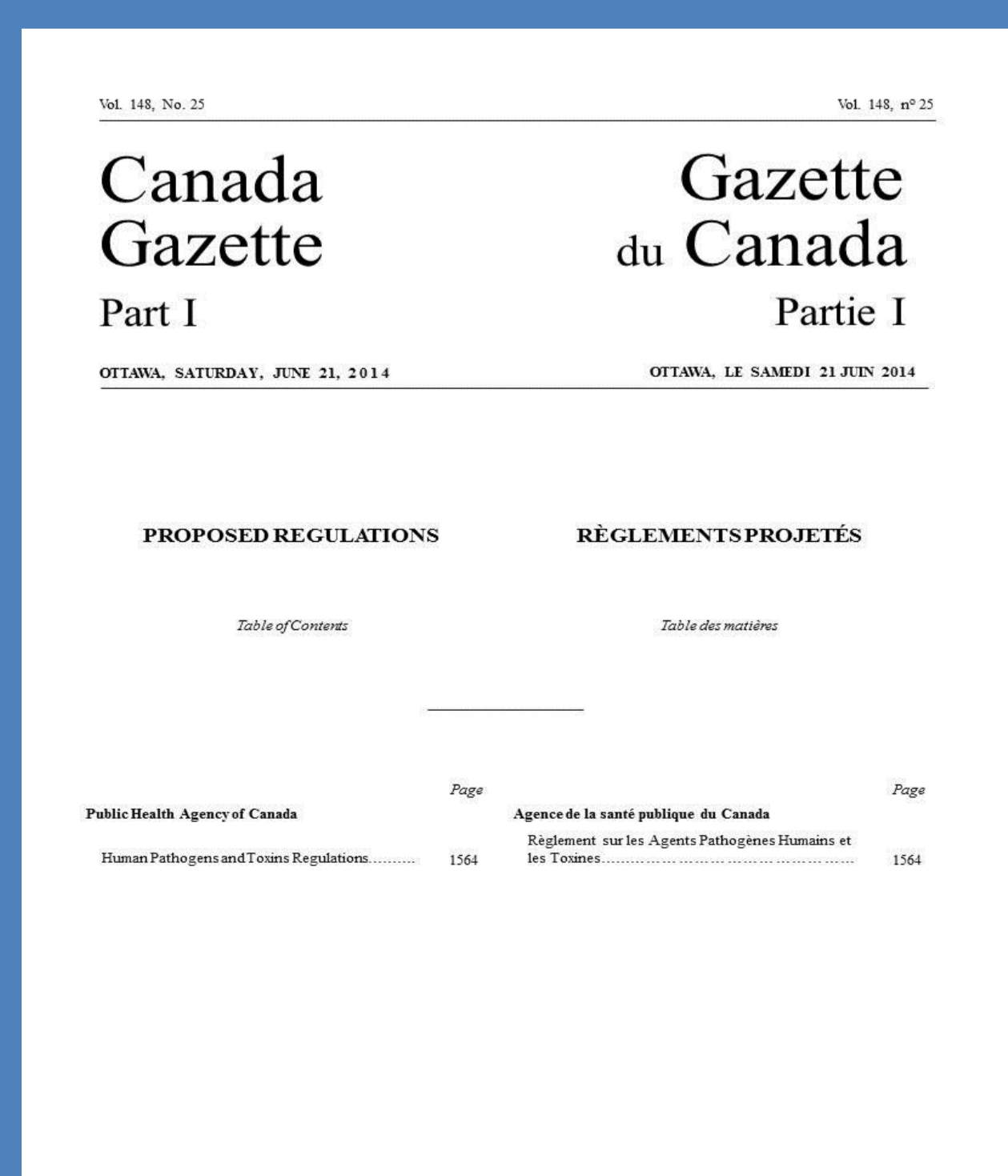
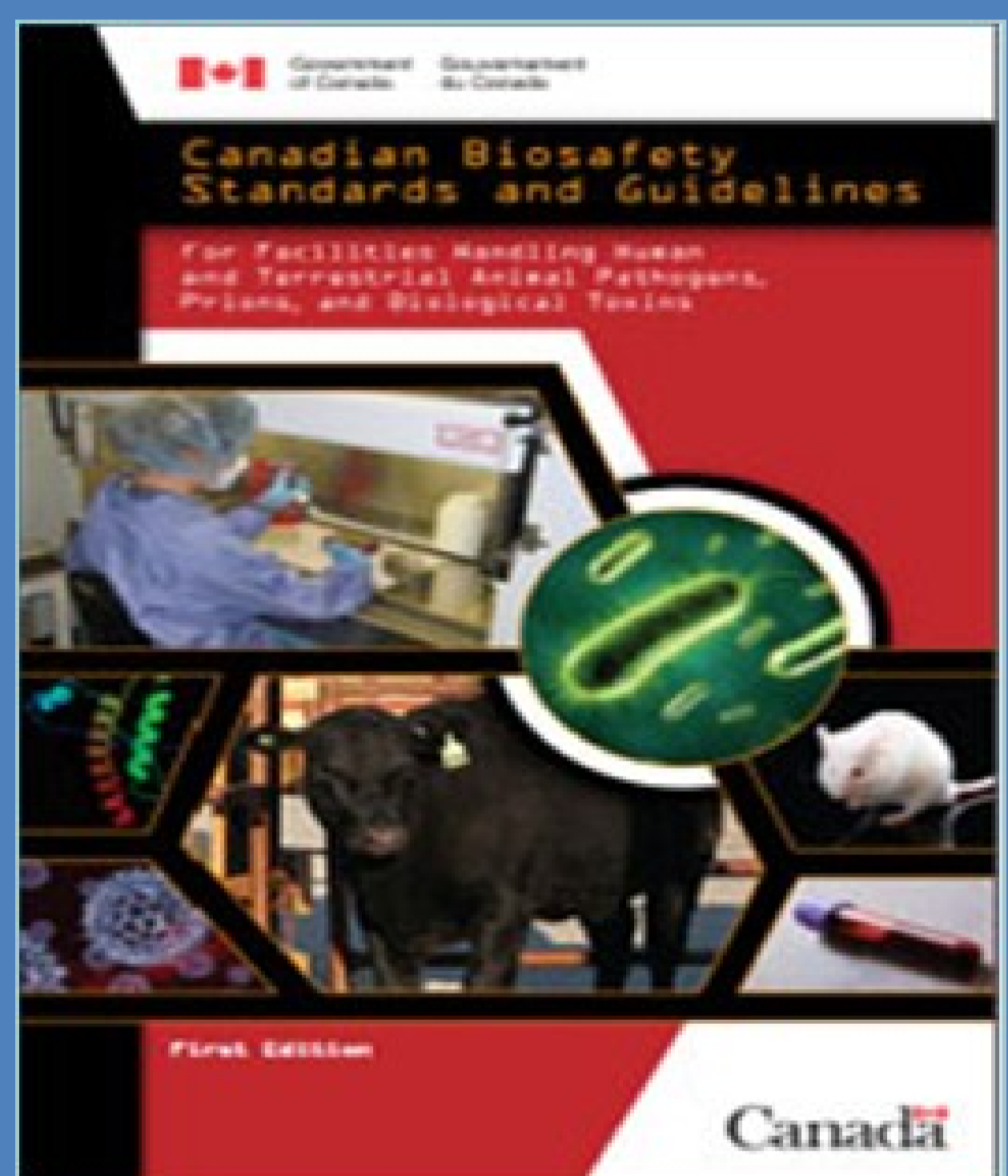
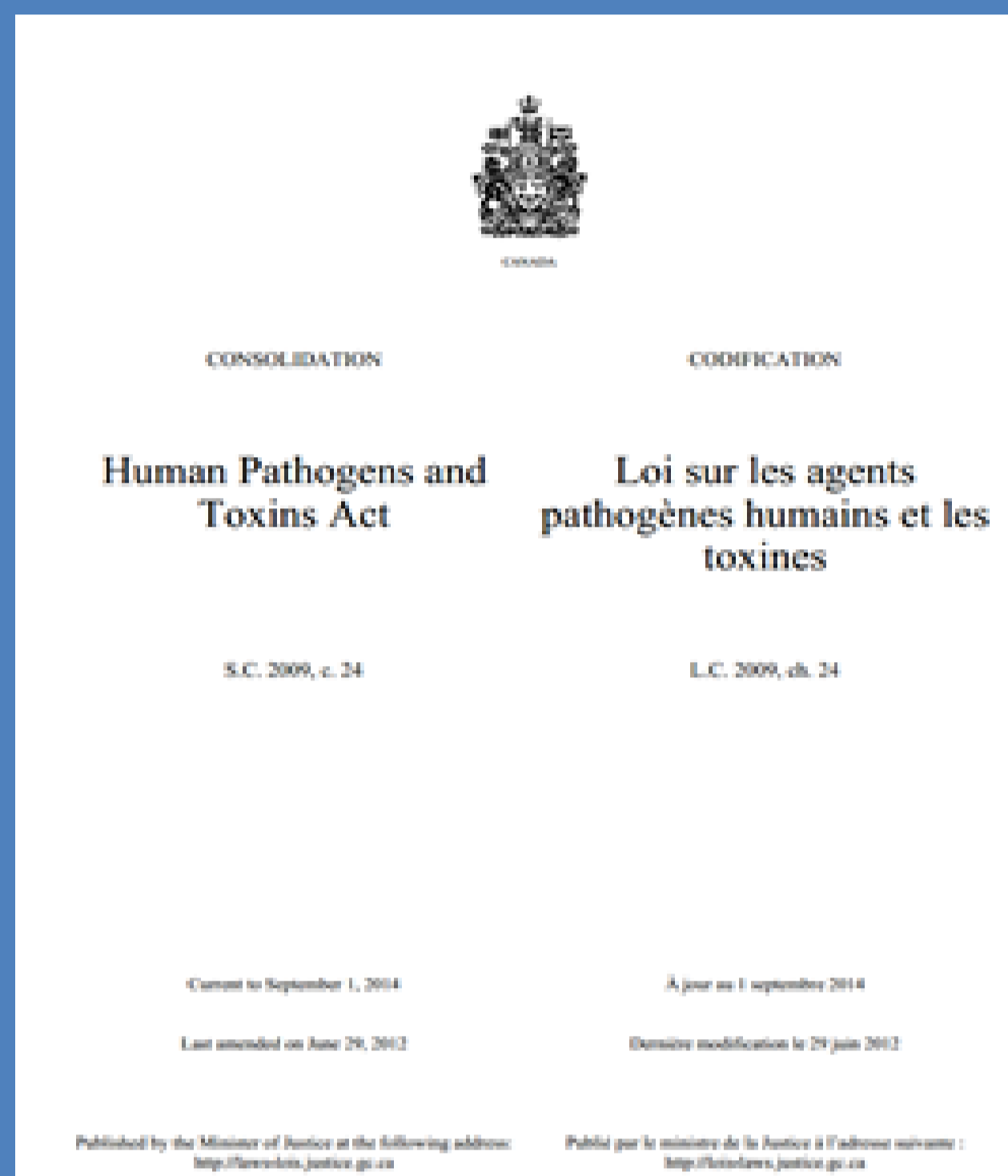
The HPTA received Royal Assent on June 23, 2009. The purpose of the HPTA is to establish a safety and security regime to protect the health and safety of the public against the risks posed by human pathogens and toxins. The HPTA applies to everyone conducting specified activities with human pathogens and toxins.

Methods:

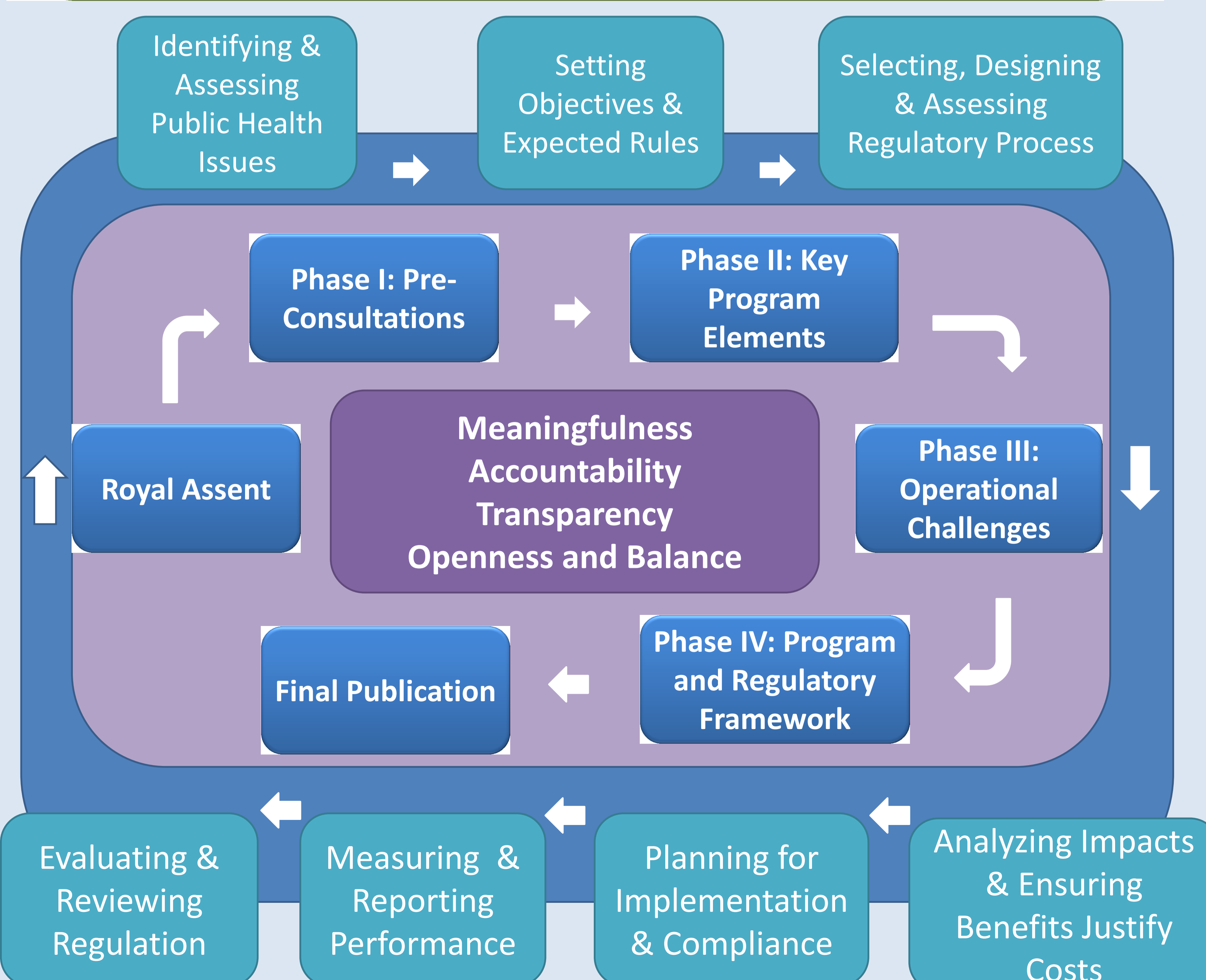
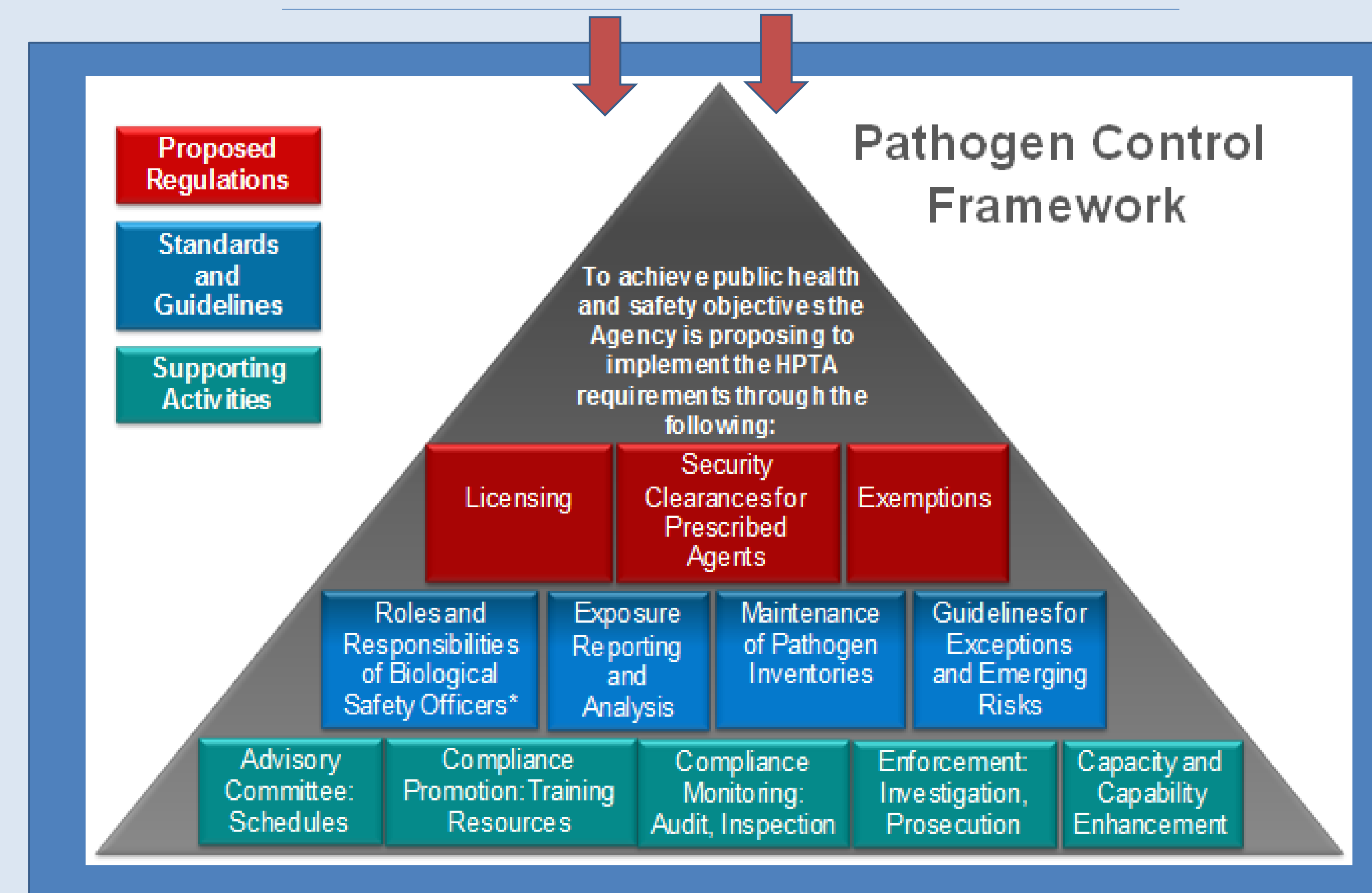
Regulated and interested parties were consulted over 4 years in an iterative process to develop the proposed *Human Pathogens and Toxins Regulations (HPTR)* and the *Canadian Biosafety Standard (CBS)* to support the full implementation of the HPTA scheduled for December 2015. The Agency developed a comprehensive consultation strategy to solicit and incorporate input and feedback from stakeholders and other interested parties on the development of the program and regulatory framework required to fully implement the HPTA.

Results:

The Agency has now developed a risk-based program and regulatory framework based on requirements set out in the HPTA, stakeholder input from consultations and other engagement activities, policy decisions and other considerations such as domestic and international best practices.



stakeholder consultation driven



Conclusion:

The HPTA Framework is designed to be flexible in its implementation with risk and performance-based expectations for biosafety oversight. It contains a wide range of new and updated requirements to help institutions manage its biological risks such as the Administrative Oversight Plan for Pathogens and Toxins in a Research Setting. This is the risk mitigation approach that has been developed to balance public health and safety concerns with the importance of promoting vibrant and innovative Canadian research with human pathogens and toxins.