



HUMAN PATHOGENS AND TOXINS ACT LICENCE

The Public Health Agency of Canada (PHAC) regulates biological material and toxin outlined in the Human Pathogen and Toxin Act (HPTA), and are listed as a Risk Group 2, 3 or 4 or above trigger quantities of a toxin.

The UNIVERSITY OF OTTAWA POSSESSES BOTH A RG 2 LICENCE AND A RG3 LICENCE (HIV ONLY). These regulates acquisition, use, transfer and disposal of the material. The biosafety officer must approve all acquisition and transfer of material.

PHAC defines a **pathogen** is a **microorganism**, nucleic acid, or protein capable of causing **disease** in humans or terrestrial animals. This can include bacteria, viruses, fungi, parasites, **prions**, recombinant DNA, genetically modified microorganisms, viral vectors, and synthetic biology products. Human pathogens are capable of causing disease in humans; **animal pathogens** cause disease in animals. For the purposes of the Canadian Biosafety Standard (CBS), the term "animal pathogens" from this point forward refers only to pathogens that cause disease in terrestrial animals, including avian and amphibian animals. **Zoonotic pathogens** are pathogens that cause diseases in humans and terrestrial animals and that can be transmitted from animals to humans or vice versa (i.e., **zoonoses**), and are, therefore, considered as both human and animal pathogens. In the context of the CBS, any isolate of a pathogen or any **biological material** that contains human or animal pathogens is referred to as "infectious material".

Risk Groups are classified as

- Risk Group 1 (RG1; low individual and community risk)
- Risk Group 2 (RG2; moderate individual risk, low community risk)
- Risk Group 3 (RG3; high individual risk, low community risk)
- Risk Group 4 (RG4; high individual risk, high community risk)

A list of regulated material is found as:

- [Toxins](#)
- [Risk Group 2 Human Pathogens](#)
- [Risk Group 3 Human Pathogens](#) (at present only HIV is authorized at the University of Ottawa)
- [Risk Group 4 Human Pathogens](#) (not authorized at the University of Ottawa)
- [Security Sensitive Biological Agents](#) (SSBA)

To ensure compliance the Biosafety Program requires all research to involved using these agents to seek institutional approval and to obtain a **Biohazardous Material Use Certificate (BMUC)**. *RG1 use is also regulated internally but to a significant lesser degree; with the focus to ensure that RG2 agents are not used inadvertently (E-coli strains can be RG1 or 2) or work does not result in a higher risk group.*

In addition, the PHAC has issues from time to time. Their [Biosafety Directives, Notices and Advisories](#) is designed to clarify issues and provide direction.



The following documents specifically address issues of concern at the University of Ottawa:

- [Determining if Cells and Cell Lines are under the authority of the Human Pathogens and Toxins Act](#)
- [Biosafety Directive for Human immunodeficiency virus \(HIV\), Human T-lymphotropic virus \(HTLV\), and Related Simian Retroviruses](#)