Office of the Chief Risk Officer
bio.safety@uottawa.ca

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 An RG 2 LICENCE AND An RG3 LICENCE (HIV). These regulates acquisition, use, transfer and disposal of the material. The biosafety risk specialist must approve all acquisition and transfer of material.

PHAC defines a **pathogen** as a **microorganism**, nucleic acid, protein or other infectious agent that is transmissible and capable of causing **disease** or infection in humans or 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. **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 and therefore, poses a risk to human or animal health 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, authorized at the University of Ottawa if below the trigger quantity)

Note: For more details refer to the Human Pathogens and Toxins Act (Schedule 1 to 4).

To ensure compliance the Biosafety Program requires all research involved in 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 provides relevant documents from time to time. Their Biosafety Directives, Notices and Advisories is designed to clarify issues and provide direction.