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1.0 PURPOSE

The Public Health Agency of Canada (PHAC) regulates human pathogens and toxins under the Human Pathogens and Toxins Act (HPTA) and associated Regulations (HPTR). Controlled activities (e.g., using, storing, importing) with human pathogens that are classified as Risk Group 2-4, or with toxins listed in Schedule 1 of the HPTA, require a license, issued by PHAC.

PROCEDURE

Risk groups (RG) are assigned to organisms/pathogens based on multiple factors-

- Pathogenicity
- Infectious dose
- Mode of transmission
- Host range
- Availability of effective preventative methods
- Availability of effective treatment

Risk Group 1 - Low individual and community risk:

RG-1 includes microorganisms (including nucleic acids or proteins) that are either

a) not capable of causing human or animal disease; or

b) capable of causing human or animal disease but unlikely to do so.

RG-1 pathogens of the latter type pose a low risk to the health of individuals or animals and a low risk to the public health or animal population. RG1 pathogens can be opportunistic and may pose a threat to immunocompromised individuals.

The PHAC or CFIA regulates neither RG1 subsets due to the low risk to public health and the animal population. Nonetheless, exercise caution and adhere to safe work practices (e.g., good microbiological practices) when handling RG-1 pathogens.

Risk Group 2 - Moderate individual risk, low community risk:

RG-2 includes pathogens that pose a moderate risk to the health of individuals and/or animals but a low risk to public health and animal population. These pathogens are capable of causing serious disease in humans or animals but are unlikely to do so. Additionally, effective treatment and preventative measures are available and the risk of community spread of diseases caused by these pathogens is low. **Keenan Research Centre in Biomedical Science (KRCBS) is licensed for work with RG-1 and RG-2 pathogens.**

WORK WITH RG-3 AND RG-4 PATHOGENS IS NOT PERMITTED AT KRCBS.

Risk Group 3 - High individual risk, low community risk:

RG-3 includes pathogens that pose a high risk to the health of individuals and/or animals and a low risk to public health. These pathogens are likely to cause serious disease in humans or animals. Effective treatment and preventive measures are usually available and the risk of spread of disease caused by these pathogens is low for the public. The risk of spread to livestock or poultry, however, can range from low to high depending on the pathogen.

Risk Group 4 - High individual risk, High community risk:

RG-4 includes pathogens that pose a high risk to the health of individuals and/or animals and a high risk to public health. These pathogens are likely to cause serious disease in a humans or animals which can often lead to death. Effective treatment and preventive measures are not usually available and the risk of spread of disease caused by these pathogens is high for the public.

Overview of the risk groups:

Risk Group	Individual Risk	Community Risk	Example
RG-1	None or Low	Low	Commensal Bacteria
RG-2	Moderate	Low	Pathogenic Escherichia coli
RG-3	High	Low	Bacillus anthracis
RG-4	High	High	Ebola virus

2.0 DEFINITIONS

Term/Acronym	Definition
PHAC	Public health agency of Canada
RG	Risk Group

3.0 REFERENCES

https://health.canada.ca/en/epathogen

Canadian Biosafety Guideline Pathogen Risk Assessment- https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/guidance/pathogen-risk-assessment/document.html#a1.1

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