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1. Purpose:

The following information is provided by the Queen's University Biohazard Committee to clarify how biohazardous agents are to be classified for the purposes of a Queen's Biohazard Permit. Those wishing to use any biological material that is included in the risk groups below must obtain a permit from the Queen's Biohazard Committee prior to importing or commencing work with the material.

2. Applicable Legislation, Standards, Guidelines:

Public Health Agency of Canada (PHAC) Human Pathogens and Toxins Act and Regulations
PHAC Canadian Biosafety Standards 2nd Edition, 2015
Canadian Food Inspection Agency (CFIA) Health of Animals Act and Regulations, the Plant Protection Act, and other Acts and Regulations that may apply as noted on the CFIA website

3. Definition:

Culturing – *in vitro*, propagative activity with the intention to grow/isolate cells or grow/isolate microorganisms. Does not include sealed-container diagnostic culture where the culture vessel is not opened prior to disposal.

4. Requirements:

Plant pathogens, soil, plants, or other material that might contain plant or animal pathogens exotic to Canada and/or Ontario: In addition to the biological material listed below, material source from outside Canada that might contain plant or animal pathogens exotic to Canada will be subject to regulation by the Canadian Food Inspection Agency (CFIA). Any CFIA-imposed containment requirements will be monitored by the Queen's Biohazard Committee and will require a Queen's Biohazard Permit Application and laboratory inspection. CFIA often requires containment similar to BSL2 and strict decontamination and inventory requirements for imported soil and associated plant or animal pathogens.

Movement of **soil from *certain* areas within Canada** to other areas in Canada is also prohibited because of plant pathogens that are present, unless a special permit is issued. Check with CFIA prior to moving soil from one area to another to determine whether a permit is required and provisions need to be made for appropriate containment and destruction of biohazards in the soil. If so, then a Queen's Biohazard Permit is also required.

Note that culturing of any agents/microorganisms, even if obtained within Canada, will require a biohazard permit for work with a containment level of at least level 1 (see below).

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4.1.Risk Group 1

The PHAC Canadian Biosafety Standards (2nd edition, 2015) define Risk Group 1 (*RG1, low individual and low community risk*) as, "A microorganism, nucleic acid, or protein that is either a) not capable of causing human or animal disease; or b) capable of causing human or animal disease, but unlikely to do so. RG1 organisms capable of causing disease are considered pathogens that pose a low risk to the health of individuals or animals, and a low risk to public health and the animal population. RG1 pathogens can be opportunistic and may pose a threat to immunocompromised individuals. Neither of the RG1 subsets is regulated by the PHAC or the CFIA due to the low risk to public health and the animal population."

RG1 organisms usually require Containment Level 1 (CL1; also called Biosafety Level 1, BSL1), containment facilities and practices. These are equivalent to good general microbiological practices.

It should be noted that some agents in this category (termed opportunistic) may cause disease in compromised individuals (e.g. in the aged or in infants or in immunosuppressed individuals, such as those taking immunosuppressive drugs or undergoing cancer chemotherapy). Vaccine strains that have undergone multiple *in vivo* passages should not be considered non-virulent simply because they are vaccine strains.

It should also be noted that in some countries the classification of agents as Risk Group 1 or Biosafety Level 1 (RG1/BSL1) is solely based on the fact that they do not cause disease in healthy human adults, but these agents might be classified differently and be regulated by Canadian agencies (PHAC and/or the CFIA). To determine whether the containment level in Canada should be level 1 or higher, the agent's pathogenicity for both humans and animals should be considered and indicated on the Queen's Biohazard Permit application. For example *Pseudomonas aeruginosa* has commonly been designated as RG1 in the United States, but in Canada it is regulated as an RG2 agent because it is a significant opportunistic pathogen.

Risk Group 1 Biohazardous Material Includes:

1. Agents (bacteria, fungi, viruses and cell lines) classified as Risk Group 1 or classified as requiring Containment Level 1 or Biosafety Level 1 (CL1/BSL1) containment by the Public Health

Agency of Canada (PHAC), the Canadian Food Inspection Agency (CFIA), the ATCC, or other recognized organizations, will be regulated through the Biohazard Committee.

a. Also agents derived from Risk Group 1 agents using methods or vectors that do not increase the risk group will be considered Risk Group 1.

2. Unidentified bacteria, fungi or viruses sourced from material in Canada (e.g. soil, healthy wild animals in Canada) that is unlikely to contain human or animal pathogens, provided that they are not cultured in a way likely to select for pathogens, will be regulated through the Biohazard Committee as Risk Group 1.

a. Such agents sourced from outside Canada require evaluation by the Canadian Food Inspection Agency prior to importation into Canada

3. The relevant target tissues from animals intentionally infected with Risk Group 1 agents will be regulated through the Biohazard Committee.
4. The tissues of animals that are purpose bred for research and tested to be Specific Pathogen Free (SPF), may contain significant numbers of non-pathogenic viruses and bacteria. However the non-propagative use of these tissues will not be regulated by the Biohazard Committee because the oversight and standard practices at Queen's provided by the University Animal Care Committee and the Animal Care Facilities are sufficient to mitigate the associated risk.

Note the following:

a. Cell, organ, or embryo culture in which the intension is for growth to occur will be regulated through the Biohazard Committee.
b. Short term, non-propagative "culture" of animal tissues from SPF animals will <u>not</u> be regulated by the Biohazard Committee (e.g. organ "culture" for physiological studies, neuron "culture" for electrophysiology)

3.2 Risk Group 2

The PHAC Canadian Biosafety Standards (2nd edition, 2015) define Risk Group 2 (*RG2, moderate individual risk, low community risk*) as, **"**A pathogen or toxin that poses a moderate risk to the health of individuals or animals, and a low risk to public health and the animal population. These pathogens are able to cause serious disease in a human or animal but are unlikely to do so. Effective treatment and preventive measures are available and the risk of spread of diseases caused by these pathogens is low. Examples of RG2 human pathogens are included in Schedule 2 of the HPTA.**"**

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For Risk Group 2 organisms the primary exposure hazards are through the ingestion, inoculation and mucous membrane routes.

Risk Group 2 organisms usually require Containment Level 2 (CL2; also called Biosafety Level 2, BSL2) containment facilities and practices as described in the PHAC Canadian Biosafety Standards and Guidelines.

- Particular care is taken to use equipment and practices to contain aerosols.
- Biosafety Level 2 conditions avoid splashes, environmental contamination and the generation of aerosols (aerosols can settle on bench tops and become an ingestion hazard through contamination of the hands).
- A risk assessment of the agent or biological material (including for example such information as diseases of risk in the population from which the biological material was obtained) and the experimental procedures to be performed will help to indicate what mitigating measures should be put in place, in particular which procedures require the use of a biological safety cabinet to contain aerosols.

Risk Group 2 Biohazardous Material Includes:

Agents (microorganisms) classified as requiring Biosafety Level 2 containment on MSDS forms found on the PHAC web site at http://www.phac-aspc.gc.ca/msds-ftss/ . ATCC classifies the containment requirements for agents that they supply http://www.atcc.org/ and risk groups assigned by other countries can be found on the American Biological Safety Association website risk group database https://my.absa.org/tiki-index.php?page=RiskgroupsIf there is disagreement about the risk group from these sources then the decision of Canadian agencies, PHAC and CFIA will be accepted. If a risk group is not identified by these sources then a risk assessment will have to be performed to determine the risk group of the agent/material. The Queen's Biosafety Officer, in consultation with PHAC or CFIA can assist with a risk assessment.

Human bodily fluids or tissues including mucous membranes (but not intact skin on live healthy human subjects) should be handled as if they contain a human pathogen unless they have been treated in some way that would destroy pathogens (eg. fixation). Operational practices known as "Standard Precautions" or "Universal Precautions" are commonly used in health care settings. They are compatible with BSL2 containment practices, and may be useful guidance when determining appropriate precautions for projects at Queen's that involve obtaining biological material directly from human subjects.

Live animals or animal tissues or bodily fluids that have the potential to contain zoonotic pathogens (microorganisms carried by animals that can cause disease when they infect humans) will be treated as biohazards requiring the containment level appropriate for the particular animal

and microorganism. Whether or not these require a biohazard permit from the University Biohazards Committee in addition to the University Animal Care Committee will be decided on a case by case basis through consultation between the Principal Investigator, the University Veterinarian/Director of Animal Care and the University Biosafety Officer. The Principal Investigator should initiate this consultation through a written or verbal request.

The risk of some zoonotic pathogen exposures in animals are effectively mitigated by the standard good animal care practices and facilities in place at Queen's University. For example the risk of exposure to salmonella bacteria from amphibians is mitigated by the normal measures in place including properly designed and clean facilities, the wearing of lab coats and gloves, with thorough hand washing upon removal of gloves. Other animals are higher risk because of the severity of the potential zoonotic infection and/or the route of transmition (airborne or aerosol transmission being more problematic to control compared to the more common fecal/oral route). These higher risk situations will likely require additional precautions and will likely to require a Biohazard Permit. For example Macaque monkeys can carry *Maccacine herpesvirus 1* (B-virus) which causes lesions like cold sores in the monkey, but can cause a fatal infection in humans if not properly treated. Despite the frequent contact of humans with monkeys these infections are rare, for reasons that are not known. Macaque monkeys are therefore treated as level 2 biohazards, level 2 operational practices are used in handling them or tissues derived from them and specific appropriate first aid and medial response requirements are taught to all who work with these animals. A biohazard permit is required for work with Macaque monkeys.

3.3 Risk Group 2+

Containment Level 2+ (Biosafety Level 2+) is the term commonly applied to the situation in which Containment Level 2 facilities are used with Containment Level 3 operational practices as specified in the PHAC Canadian Biosafety Standards, except for those level 3 practices that are not possible in a level 2 facility. Containment Level 2+ (BSL2+) may be required in some circumstances. This level of containment may be specified by the PHAC or the CFIA as a condition on an import permit, or may be determined by the Queen's Biohazard Committee. For example work with certain viral vectors or viral vectors expressing oncogenes or biological toxins may require CL2+/BSL2+ containment.

3.4 Risk Group 3 and 4

There are currently no facilities to permit work with Risk Group 3 or 4 organisms on Queen's University Campus. **4.0 Information and Enquires:**

For further information regarding Biohazard Permits, contact the University Biosafety Officer (613-533-6000 ext. 77077).

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Revision History:

1.0: Initial Release - March 11, 2008

2.0: Revision to describe the process for permitting work with animals potentially carrying zoonotic pathogens – November 15, 2012

3.0 Revision to describe when a permit is required for work involving material from Specific Pathogen Free animals. Also to update legislation and biosafety standards.