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Quick Reference - Biohazard Import, Export, Transfer or Receipt

As per regulatory requirements, the Biosafety Officer (BSO) must be **notified** before arrangements are made to do import, export, transfer or purchase a biohazardous material as described in this document.

To notify the BSO, choose the pertinent section in this document and follow the instructions provided. Forms are available [online](#) and are to be completed electronically by the Principal Investigator and submitted to the [BSO via email](#). Paper copies are not required.

Note: To process import/export approvals, CFIA import permits, purchases, and/or transfer approvals, applicants i.e. Principal Investigators (PIs) must hold a valid University of Guelph Biohazard Permit including approval for the pathogen of interest. For adding biohazards, review how to add/delete biohazards from existing biosafety permit. Additionally, all biological transfer, imports and export require a Material Transfer Agreement (MTA).

❖ Import/Export

Import and/or export refers to an international shipment or transfer across the Canadian border. Records for imported pathogens must be retained for a minimum of 2 years and/or in accordance with CFIA conditions of importation.

1. Risk Group 2 Pathogens

- a. For import and/or export of the following, complete [Biohazard Import/Export Approval](#)

[Form](#) only and email it to the [BSO](#):

- **Risk Group 2** human and/or terrestrial animal pathogen including microorganisms (e.g., bacteria, viruses, fungi, parasites)
- Risk Group 2 cell lines with the potential to contain intact pathogens.
- Genetically modified microorganisms, recombinant DNA & synthetic biology products
- Microbial toxins
- Viral vectors

Response: the BSO will add University's Human Pathogens and Toxins licence number, sign and email the approval back to the applicant. The approval must accompany the shipment.

b. If importing any of the above listed items with an **animal by-product** (e.g., horse serum, skimmed milk) the PI must also complete the appropriate CFIA Import application as shown below.

- Form 5858: Application for Permit to [Import Animal Pathogens](#)
- Form 5859: Application for Permit to [Import Animal Products and By-Products](#)
- Form 5860: Application for Permit to [Import Live Animals, Hatching Eggs and Animal Germplasm](#)

Response: The BSO will sign the permit application and email it back to the applicant. The applicant must submit the signed permit application through their departmental representative to the [myCFIA](#) portal. Email/ fax application is no longer accepted by CFIA.

2. Risk Group 1

a. For import and/or export of the following, complete [Statement for HPTA licence # Non-disclosure Exemption form](#) only.

- **Risk Group 1** biological agents including microorganisms (e.g., bacteria, viruses, fungi, parasites) and /nucleic acids/proteins, cell lines and viral vectors (designated as risk group 1 or requiring containment level 1)
- **DNA, RNA or plasmids of risk group 2 human pathogens or human tissues** (except animal pathogens or animal tissues which are regulated by CFIA),

Response: The BSO will sign and email the completed Non-Disclosure Exemption form to the applicant.

3. Animal Pathogens regulated by CFIA.

a. For import and/or export of the following, complete [Biohazard Import/Export Approval Form](#) only and email it to the [BSO](#). For import of the following, a Form 5858:

Application for Permit to [Import Animal Pathogens](#) must also be completed.

- Bee pathogens
- Non-indigenous terrestrial animal pathogen
- Terrestrial animal pathogen imported in a live animal, animal product or by product e.g. blood, horse serum, skimmed milk, semen, tissue, cell lines such as macrophage alveolar MH-S (ATCC CRL 2019) may contain SV 40 virus
- Terrestrial animal pathogen or part of one that retains its pathogenicity (e.g., full genome or toxin etc. such as *Mammalian 1 borna virus* regulated by CFIA)
- Aquatic pathogen (e.g., *Vibrio parahaemolyticus*, *Hafnia* spp.)

CFIA will also require a CL2 compliance letter obtained with completion of [CFIA CL2 checklist](#) for the verification of compliance with the [CL 2 terrestrial animal](#) or [aquatic laboratories requirements](#).

Note that if deficiencies are identified, an action plan must be submitted to accompany the CFIA CL-2 checklist.

Response: The BSO will add University's Human Pathogens and Toxins licence number, sign and email the approval back to the applicant. The requisition must accompany the shipment.

The BSO will sign the import permit application based on PI's valid permit and approved inventory. Completion of CFIA CL2 checklist requires physical in-person inspection by BSO.

The applicant should then submit the signed application &/or checklist through their departmental representative to the [myCFIA](#) portal.

Export: If only **exporting** the above listed materials, submit the importer's import permit to BSO along with the completed [Biohazard Import/Export Approval Form](#).

4. Animal Products

- a. For import of animal products (e.g. frozen clam tissues) and related nucleic acids e.g. DNA of animal products, by-products or primary animal derived cell lines (not yet established), first search CFIA's Automated Import Reference System [AIRS](#) site to determine the documentation required by CFIA. Complete the documentation requested by CFIA and email it to the BSO.

Note: If animal by products or primary animal derived cell lines are from ruminants or if there is likelihood of an outbreak of disease from a pathogen contained in the animal product then a Zoo sanitary Export Certificate of Origin from the exporter may be required by CFIA.

5. Plant Pests

- a. For import of the regulated plant pest, a CFIA permit application is required.
 - Complete [Permit to Import Plant pathogen](#).
 - If importing a plant pest, which requires Plant Pest Containment (PPC) level 1, contact your local CFIA inspection office Guelph: 226-217-1200 or the Invasive Alien Species & Domestic Program section (cfia.ias-eee.acia@canada.ca) to obtain a copy of a self-assessment checklist.
 - If only exporting the plant pathogens, complete [Biohazard Import/Export Approval Form](#). Your collaborating importer needs to confirm their country's import requirements.

Response: the BSO will sign the permit. If PPC-1 is required, CFIA Plant Pest inspectors will visit the site to perform inspections for completion of checklist prior to issuing the import permit.

❖ **Domestic Transfers**

Domestic transfers refer to non-commercial transfers within Canada.

1. **Domestic Transfer External to the University**

a. **Human/animal pathogen**

- i. For transfers of human/animal pathogens from University of Guelph to another Canadian facility, complete the [Biohazard Transfer Notification Form](#).
- ii. Ensure that the receiver institution has signed prior to submission to the BSO.

Response: BSO will add the Human Pathogens and HPTA licence # and signature. BSO will sign only after the receiver institute signature.

- ii. For transfer of human/animal pathogens from another Canadian facility to University of Guelph, submit the [Biohazard Transfer Notification Form](#)

Response: BSO will sign and email the form. After the signoff from supplier facility, applicant must provide a copy to the BSO for maintenance of records.

b. **Regulated plant pest, exotic plant pest or earlier imported but native pest**

- i. For transfers from the University of Guelph to another Canadian facility or vice versa, complete a written authorization request to CFIA. This request must be in writing, signed and dated by the person seeking to receive the pest and conduct restricted activities.

For further details, refer to section 3.4 in the directive linked below

[D-12-03 – Domestic Requirements for Potentially Injurious Organisms \(Other than Plants\) to Prevent the Spread of Plant Pests Within Canada](#).

2. Transfers within the University (Internal)

a. Human/animal pathogen

- i. For internal transfers complete the [Internal Biohazard transfer and Material Transfer Agreement \(IBMTA\)](#), which serves as both MTA, and transfer notification.

❖ **Purchase**

For this procedure, purchase refers to commercial purchase from a Canadian vendor and source only.

- For domestic purchase (within Canada), complete the [Biohazard Purchase Approval Form](#).

Response: the BSO will sign on the approval and email the approval back to the applicant. Approved purchase approvals can be used to purchase directly from the vendor or through the PI's departmental purchase clerk in accordance with your department purchase policy.

Note: If purchasing RG2 outside of Canada, complete [Biohazard Import/Export Approval Form](#). If purchasing RG1 outside of Canada, complete [Statement for HPTA exempt](#) to serve as BSO notification.

❖ **Exemptions**

No notification to the BSO is required for the following biological agents or materials:

- Transfer, import, export, or purchase of human clinical specimens (body fluids and tissues)
- Transfer, export, or purchase of animal clinical specimens (body fluids and tissues). Refer to section 3 above for import of terrestrial animal pathogen in animal products or byproducts.
- Transfer, import, export, or purchase of polymerase Chain reaction (PCR) primers (synthetic oligonucleotide).
- Transfer, export or purchase of fetal bovine serum or animal sourced monoclonal antibodies.
- Transfer, import, export, or purchase of agricultural and food testing samples.

Note: CFIA Import permit and/or Zoo sanitary export certificate with notification to BSO is required for import of proficiency testing samples (for microbiological analysis and/or containing pathogens as regulated by CFIA).