Procurement and Transfer of Organisms and Biological Materials

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University of Saskatchewan

Contents

1 Definitions

Animal Pathogen: A microbe or microorganism that can cause disease in animals. Zoonotic agents are animal pathogens that can cause disease in animals and humans.

Authorized Worker: A University of Saskatchewan employee, student, visitor or contractor who has acquired the appropriate biosafety training and is approved to work with biological materials and/or biohazardous materials specified under an active biosafety permit.

Biological Material: Any material that originates from living organisms, which may be infectious or non-infectious.

Biohazardous Material: Materials of biological origin that have the capacity to produce deleterious effects on humans and/or animals. Examples, but not limited to, include:

- Recombinant DNA molecules that are transferred into human research participants (human gene transfer);
- Recombinant DNA that is introduced into animals (transgenic animals);
- Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or pharmacologically active agent);
- Microorganisms where there is a deliberate transfer of a drug resistant trait or of recombinant DNA containing genes for the biosynthesis of products potentially toxic for vertebrates;
- Microorganisms classified as Risk Group 2 (RG-2) or Risk Group 3 (RG3) agents (Risk Group 4 agents are not allowed on the University of Saskatchewan campuses) whether infectious or defective;
- Microorganisms where more than two-thirds of the DNA from RG-2 or RG-3 agents is cloned into other nonpathogenic agents;
- Biological products derived from RG-2 or RG-3 microorganisms;
- Clinical/medical waste (e.g., diagnostic specimens), that are used in research and known, or reasonably expected to contain pathogens classified as RG-2, RG-3, or toxins;
- Prions;
- Human bodily fluids, blood, tissues, and cell lines; and/or
- Large scale cultures of a biological material.

Biological Material: Pathogenic and non-pathogenic microorganisms, proteins, and nucleic acids, as well as any biological matter that may contain microorganisms, proteins, nucleic acids, or parts thereof. Examples include, but are not limited to, bacteria, viruses, fungi, prions, toxins, genetically modified organisms, nuclei acids, tissue samples, diagnostic specimens, live vaccines, material derived synthetically, and isolates of a pathogen (e.g. pure culture, suspension, purified spores).

Biosafety: Containment principles, technologies, and practices that are implemented to prevent unintentional exposure to infectious material and toxins, or their accidental release.

Biosafety Cabinet (BSC): A primary containment device that provides protection for personnel, the environment, and the product (depending on the BSC class), when working with biological material.

Biosafety Group: Includes the Biosafety and Environmental Officer and the Biosafety Officer (BSO), which act to administer and support the University's biosafety program, processes, and services. The group serves as the expert resource on biosafety to the campus community.

Biosafety Permit: A biosafety permit is a formal authorization granted by the Biosafety Group or the Biosafety Protocol Approval Committee (BPAC) to individuals requesting approval for the acquisition, use, storage, transportation and disposal of select Risk Group 2 and 3 biological materials. A biosafety permit is only granted to individuals meeting the requirements as stipulated in the *Biosafety Code of Practice*.

Biosafety Plan: A written document that acts as an individualized biosafety manual for the permit holder. The plan describes the hazard assessment and the health, safety, and biosecurity measures supporting the responsible use and management of biological materials. A biosafety plan is required under a biosafety permit at the University of Saskatchewan.

Biosecurity: Security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of pathogens, toxins, and other related assets (e.g. personnel, equipment, non-infectious material, and animals).

Biotechnology: The application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.

Containment Level 1: Containment Level 1 laboratories/facilities require no special design features beyond those suitable for a well-designed and functional laboratory. Biological Safety Cabinets (BSCs) are not required. Work may be done on an open bench top, and containment is achieved through the use of practices normally employed in a basic microbiology laboratory.

Containment Level 2: The primary exposure hazards associated with organisms requiring containment level 2 are through the ingestion, inoculation and mucous membrane route. Agents requiring containment level 2 facilities are not generally transmitted by airborne routes, but care must be taken to avoid the generation of aerosols (aerosols can settle on bench tops and become an ingestion hazard through contamination of the hands) or splashes. Primary containment devices such as BSCs and centrifuges with sealed rotors or safety cups are to be used as well as appropriate personal protective equipment. As well, environmental contamination must be minimized by the use of hand washing sinks and decontamination facilities (autoclaves).

Containment Level 3: Agents requiring containment level 3 may be transmitted by the airborne route, often have a low infectious dose to produce effects and can cause serious or life-threatening disease. Containment level 3 emphasizes additional primary and secondary barriers to minimize the release of infectious organisms into the immediate laboratory and the environment. Additional features to prevent transmission of organisms requiring containment

level 3 are appropriate respiratory protection, HEPA filtration of exhausted laboratory air and strictly controlled laboratory access.

Dual-use potential: Qualities of a pathogen or toxin that allow it to be either used for legitimate scientific applications (e.g., commercial, medical, or research purposes), or intentionally misused as a biological weapon to cause disease (e.g., bioterrorism).

Emergency Response Plan (ERP): A document outlining the actions to be taken and the parties responsible in emergency situations such as a spill, exposure, release of infectious material or toxins, animal escape, personnel injury or illness, power failure, fire, explosion, or other emergency situations (e.g., flood, earthquake, hurricane).

Good Microbiological Laboratory Practices: A basic laboratory code of practice applicable to all types of activities with biological material. These practices serve to protect workers and prevent contamination of the environment and the samples in use.

Genetically Modified Organism (GMO): An organism whose genetic material has been altered using genetic engineering techniques.

Genetically Modified Microorganisms (GMMO): Any organism or consortium of organisms of microscopic size, including bacteria, protozoa, fungi, algae, and viruses, whose genetic material has been altered using genetic engineering techniques.

Human Pathogen: A microbe or microorganism that can cause disease in humans.

Incident: Any undesirable or unplanned event or sequence of events that has had an unintended effect on the health and safety of University of Saskatchewan employees, students or contractors, or the safety and security of facilities, operations, and property, or on legal or regulatory compliance.

Infectious Materials: 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.

***In-vitro*:** In an artificial environment outside of a living organism.

***In-vivo*:** Occurring in a living organism.

Large Scale: Activities generally involving volumes of toxins or the in vitro culture of infectious material on a scale of 10 litres or greater. This could be a single vessel with a volume of 10 litres or greater, or based on the processes and pathogen used, could be multiple vessels with a total volume of 10 litres or greater. It is determined in consultation with the Public Health Agency of Canada and/or the Canadian Food Inspection Agency on a case-by-case basis, whether or not particular activities conducted in a containment zone are required to follow the increased or unique requirements for large scale production areas.

Microorganisms: A cellular or non-cellular microbiological entity, capable of replication or transferring genetic material and that cannot be reasonably detected by the naked eye. Microorganisms include bacteria, fungi, viruses, and parasites, and may be pathogenic or non-pathogenic in nature.

Notifiable Biological Substances: Are substances listed in the *Saskatchewan Occupational Health and Safety Regulations* requiring written notice and permission from the Director of Saskatchewan Ministry of Labour Relations and Workplace Safety to acquire, use, store and dispose. Notifiable biological substances also include those GMMO's or 'Biotechnology Substances' requiring permits from the PHAC, CFIA or the Canadian Environment Protection Agency (CEPA) under the *New Substance Notification Regulations*.

Organism: Any living entity (e.g. animals, plants, cell (tissue) cultures, microorganisms).

Pathogen: A microorganism, nucleic acid, or protein capable of causing disease or infection in humans or animals. Examples of human pathogens are listed in Schedules 2 to 4 and in Part 2 of Schedule 5 of the Human Pathogens and Toxins Act, but these are not exhaustive lists. Examples of animal pathogens can be found through the Automated Import Reference System on the Canadian Food Inspection Agency website.

Principal Investigator: The person who takes direct responsibility for completion of a research project under a biosafety permit.

Permit Holder: An individual authorized to work with organisms, biological materials, or biohazardous materials under the *Biosafety Policy* and *Biosafety Code of Practice*.

Prion: Small proteinaceous infectious particle generally considered to be responsible for causing a group of neurodegenerative diseases in humans and animals known as transmissible spongiform encephalopathies.

Risk Group (RG): The classification of biological material based on its inherent characteristics, including pathogenicity, virulence, risk of spread, and availability of effective prophylactic or therapeutic treatments, that describes the risk to the health of individuals and the public as well as the health of animals and the animal population.

Risk Group 1 (RG1): 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 Public Health Agency of Canada (PHAC) or the CFIA due to the low risk to public health and the animal population.

Risk Group 2 (RG2): 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.

Risk Group 3 (RG3): A pathogen that poses a high risk to the health of individuals or animals, and a low risk to public health. These pathogens are likely to cause serious disease in a human or animal. 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 the animal population, however, can range from low to high depending on the pathogen. Examples of RG3 human pathogens are included in Schedule 3 of the HPTA.

Security Sensitive Biological Agents (SSBAs): The subset of human pathogens and toxins that have been determined to pose an increased biosecurity risk due to their potential for use as a biological weapon. SSBAs are identified as prescribed human pathogens and toxins by Section 10 of the Human Pathogens and Toxins Regulations.

Supervisor: A person who is authorized by the university to oversee or direct the work of employees and students. The authority to supervise employees and students is inherent in their job function. Although the university recognizes the ultimate responsibility of performing work in a safe manner lies with the individual employee, supervisors have additional responsibilities, which arise from their role as persons responsible for providing competent supervision and managing the workplace under their authority.

Terrestrial Animal Pathogen: A pathogen that causes diseases in terrestrial animals, including avian and amphibian animals, but excluding aquatic animals and invertebrates.

Toxin: A poisonous substance that is produced or derived from a microorganism and can lead to adverse health effects in humans or animals. Human toxins are listed in Schedule 1 and Part 1 of Schedule 5 in the Human Pathogens and Toxins Act.

Transgenic Plants and Animals: The results of the transmission of genes within the same species or into other animal or plant species

Worker: A person who is engaged in an occupation in the service of an employer.

2 Purpose

This procedure outlines the processes to be followed by individuals who wish to procure and/or transfer organisms and biological material intended for research, teaching, or other activities at the University of Saskatchewan.

The *Procurement and Transfer of Organisms and Biological Material Procedure* is applicable to all university faculty, staff, students and visitors who intend to procure and/or transfer organisms or biological materials, including biohazardous materials.

3 Scope

In accordance with the University of Saskatchewan *Biosafety Policy* and *Biosafety Code of Practice*, individuals intending to acquire, possess, use, store, transport, or dispose of organisms, biological materials or biohazardous materials must notify the Biosafety Group prior to the procurement and/or transfer of the biological materials.

The Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) regulate the importation of organisms and biological materials that pose a health risk to humans and to animals.

University faculty, staff, students, or visitors wishing to acquire organisms, biological materials, and known biohazardous materials (human, animal, plant), or other prescribed organisms must notify the Biosafety Group prior to the procurement and/or transfer of the biological materials.

The procurement and/or transfer of risk group level 4 biohazardous materials from domestic or foreign sources is not permitted at the University of Saskatchewan.

4 Procurement and/or Transfer Procedures

Under the *Human Pathogens and Toxins Act and Regulations* (HPTA/R), the PHAC requires that all persons wishing to access, transfer, import, export, release, abandon, and/or dispose of a human pathogen, and/or toxin must apply for a license. As outlined in the *Biosafety Code of Practice*, the University of Saskatchewan has obtained a blanket license which allows controlled activities being conducted with the following:

- All RG 2 human pathogens, prions, and all toxins that are not identified as Security Sensitive Biological Agents (SSBA);
- Specific list of prescribed toxins that are identified as SSBA; and/or
- Specific list of RG 3 human pathogens in a defined laboratory space (list may or may not include SSBA).

The blanket licence acts as the import permit for the procurement and/or transfer of human pathogens and toxins within and outside of Canada.

Under the *Health of Animals Act* and its regulations, the Canadian Food Inspection Agency (CFIA) controls the use of imported animal pathogens and pathogens associated with reportable animal diseases.

As of April 1, 2013, CFIA transferred the administrative component of import permits to the PHAC as a single window for stakeholders who require an import permit for both human and terrestrial animal pathogens. The PHAC blanket licence issued to the university acts as the import permit for the procurement of pure cultures of terrestrial animal pathogens.

The CFIA continues to issue permits for animal pathogens that are not indigenous to Canada (pathogens causing foreign animal and emerging animal diseases), aquatic and plant pathogens as well as for animals, animal products and by-products, tissue, sera and blood that are infected with animal pathogens, and plant materials and soils.

Refer to the procedure section below entitled, **Canadian Food Inspection Agency Import Permit (Section 4.3)**.

4.1 Procurement and/Transfer of a RG 1 Biological Materials

Principal investigators (PIs) who intend to acquire, use, store, transport, or dispose of RG 1 organisms or biological materials do not require a biosafety permit with the exception of some select organisms and biological materials. Examples of RG 1 organisms or biological materials include:

- Blood or tissue samples taken from healthy animal donors;
- Select strains of *E. coli*;
- Purified complete DNA samples;
- Cytological slides for microscopy;
- Fixed animal tissues (non-neurological); and
- Animal cell lines free of viral infection.

Instead, the PI must complete a *Biological Materials Declaration Form*, which is available on the Safety Resources Website and is reviewed by the Biosafety Group before being recorded and kept track of internally. The procurement of some RG 1 biological materials may require an import permit or other certification from CFIA. Contact the Biosafety Group to ascertain if an import permit or other certification is required.

4.2 Procurement and/Transfer of *RG 2 or 3 Human Pathogen, Toxin, or Terrestrial Animal Pathogen*

The University of Saskatchewan requires that all individuals who intend to acquire, use, store, transport, abandon, transfer, export, release, and/or dispose of biological materials of RG 2 and 3 organisms or biological materials must obtain or be operating under a biosafety permit. A biosafety permit is obtained by submitting an application and supporting documentation to the Biosafety Group. Biosafety permit applications for the use of RG 2 or 3 biological materials shall be reviewed and approved by the BPAC and a biosafety permit shall be granted only when all university, legislative, and granting agency requirements have been met. Permit holders must list all RG 1, RG2, and RG 3 biological materials on their biosafety permit.

Permit holders are only authorized to acquire only those organisms, biological materials, or biohazardous materials listed under their biosafety permit. If the permit holder wishes to add a new RG 1, 2 or 3 biological agent to their permit, it is subject to approval by the Biosafety Group and/or BPAC.

The **procedure** for the procurement and/or transfer of a RG 2 or 3 human pathogen, toxin, and/or terrestrial animal pathogen (pure cultures only) is as follows:

1. Determine if the biological agent is currently listed on an active biosafety permit. If not, a biosafety permit application or permit amendment will be required. Complete a *Biosafety Permit Amendment Form* (to amend an existing permit) or a *Biosafety Permit Application Form* (if a permit needs to be obtained) and include the required supporting documents, such as the *Biosafety Plan*. Both forms are available on the Safety Resources Website.

2. Submit the completed application or amendment and supporting documents (e.g. *Biosafety Plan*) to the Biosafety Group for review.

3. Once reviewed by the Biosafety group and no further changes required, the application or amendment package is distributed to the BPAC for review and approval.

4. Once approval is provide and biosafety permit is updated or issued, the permit holder must complete the *Biohazardous Agent Transfer Notification Form* (*BAT Form)* (http://safetyresources.usask.ca/) and submit the completed form to the Biosafety Group for review and authorization.

5. Once approved, the *BAT Form* will act as the permit to procure (import) or transfer the RG 2 or 3 human pathogen, toxin, and/or terrestrial animal pathogen (pure cultures only). Ensure a copy of the *BAT Form* accompanies the biological material by providing a copy to the supplier or when sending the material to a recipient.

4.3 Canadian Food Inspection Agency Import Permit

The CFIA issues permits for the importation from outside Canada of animal pathogens that are not indigenous to Canada (pathogens causing foreign animal and emerging animal diseases), aquatic and plant pathogens, animals, animal products and by-products, such as tissue, semen, embryos, sera and/or blood, that are infected with animal pathogens, veterinary biologics, and live animals, animal products and by-products.

4.3.1 Animal Based By-products and Pathogens

Under the *Health of Animals Act* and its regulations, the CFIA regulates the import of products such as:

- Non-indigenous animal pathogens;
- Aquatic animal pathogens of which includes aquatic animals (e.g. zebrafish);
- Animal products and by-products, includes but limited to tissues, semen, embryos, sera, and/or blood;
- Animal products containing infectious materials; and
- Live animals, semen and embryos.

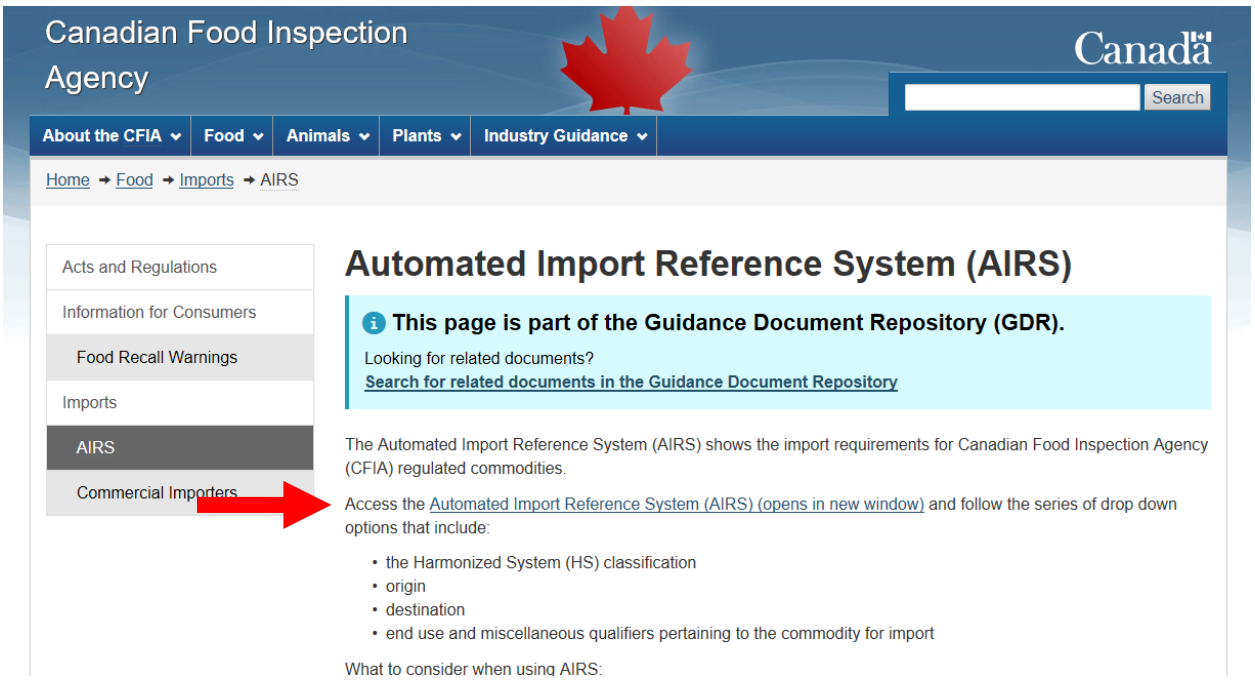
PIs and/or permit holders wanting to import the above materials, the following must be done:

1. The PI or permit holder must consult with the biosafety group to determine if the biological material is on a current biosafety permit or a *Biological Material Declaration Form* needs to be completed. If not, refer to **section 4.1 or 4.2** above.
2. In consultation with the Biosafety Group, it must be determined if an import permit is required by using the CFIA Automated Import Reference System (AIRS) (http://www.inspection.gc.ca/food/imports/airs/eng/1300127512994/1326599324773#).

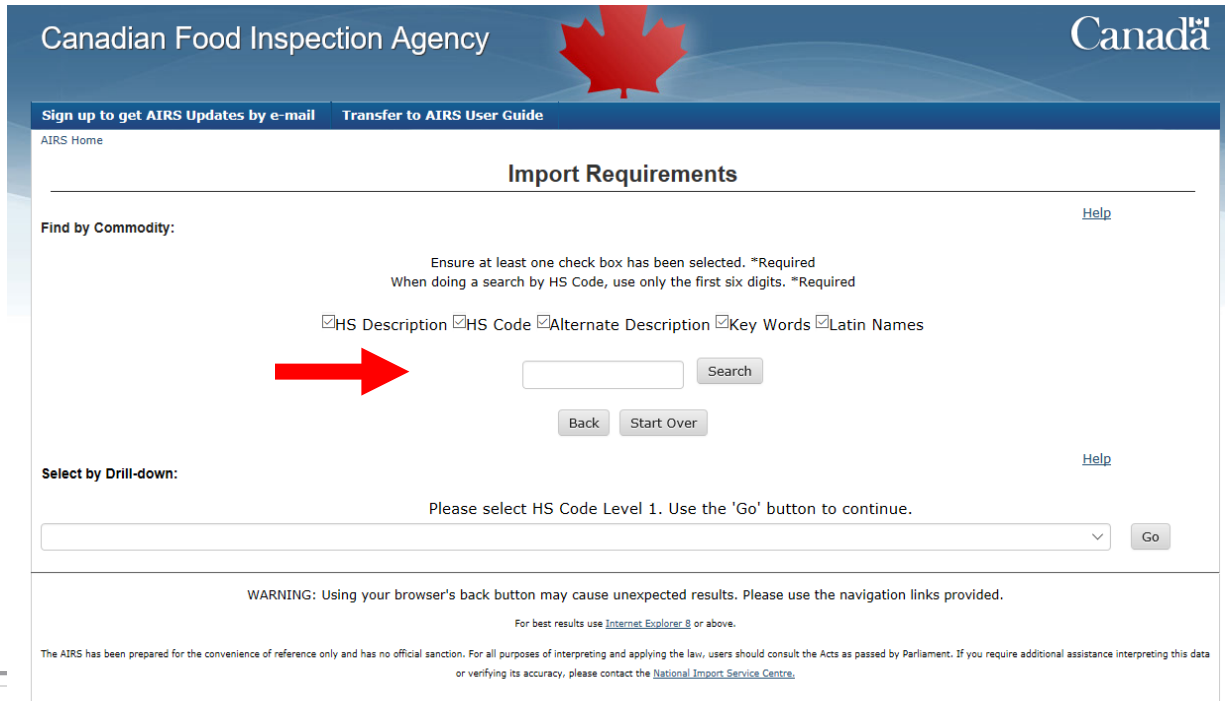
   The CFIA AIRS is a searchable database of CFIA import requirements. Through a series of questions and answers, the system will lead the user through the applicable regulations and policies to information on all CFIA import requirements for specific commodities.

Refer to images **a.** and **b.** below:

a)



b)



3. The CFIA AIRS system will determine if an import permit is required for the biological material and which application forms need to be completed. If an import permit is required, contact the Biosafety Group.
4. For the current CFIA import permit application form and the facility certification checklist, contact the Biosafety Group as import permits contain specific requirements based on the disease risks associated with the animal, the origin, and other relevant health information.
5. Once an import permit and facility certification is issued by CFIA, the PI or permit holder must provide a copy of the import permit to the Biosafety Group.

For the importation of aquatic animals, the CFIA may require a health certification from the country of origin, to ensure that the animals imported into Canada meet Canada's aquatic animal health requirements. General import conditions for aquatic animals are provided on the CFIA website. Contact the Biosafety Group and the University Animal Care Committee (UACC) Animal Order Desk for all inquiries regarding the importation of aquatic animals.

For the importation of live animals, an Animal Use Protocol must be obtained prior to importation of the animal. Contact the Ethics Office.

For the importation of organisms or biohazardous materials that may cause disease in animals and humans (zoonotic), a *BAT Form* will be required. Refer to **section 4.2** above.

Facilities where animals, animal pathogens, animal products and byproducts will be used or stored must meet the requirements of the *Canadian Biosafety Standard (2nd Ed., 2015),* the *Canadian Biosafety Handbook (2nd Ed., 2016)*, and/or the CFIA *Standards for Facilities Handling Aquatic Animal Pathogens.* Refer to the following link for a copy of the listed Biosafety standards and guidelines: https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines.html .

4.3.2 Vet Biologics

Under the *Health of Animals Act* and its regulations, the CFIA regulates the import of vet biologics, which includes:

- Vaccines;
- Autogenous vaccines;
- Antibody production; or
- Diagnostic kits.

PIs and/or permit holders wanting to import veterinary biologics, the following must be conducted:

1. The PI or permit holder must consult with the Biosafety Group to determine if the biological material is on a current biosafety permit or a *Biological Material Declaration Form* needs to be completed. If not, refer to **section 4.1 or 4.2** above.
2. In consultation with the Biosafety Group, it must be determined if an import permit is required by using the CFIA AIRS.
3. If an import permit is required, complete the application form, *Application for Permit into Import Veterinary Biologics into Canada*.

Refer to the image below:

4. Submit the completed application to the Biosafety Group for review and authorization.
5. The import permit application is submitted to CFIA.
6. Upon receipt of the application and its satisfactory assessment by CFIA, an import permit will be issued by the CFIA. The CFIA may specify conditions on the permit depending on the biohazardous material and its use.
7. Once an import permit is issued by CFIA, the PI or permit holder must provide a copy of the import permit to the Biosafety Group.

4.3.3 Plant Pests and Pathogens

The CFIA regulates the import of products such as:

- Plant pathogens;
- Plant pests (e.g. insects);
- Plant materials (e.g. seeds, dried leaves);
- Live plants and fungi (e.g. mushrooms); and/or
- Soil and related matter (including clay, silt, sand, soil minerals, humus, compost, earthworm castings, muck, plant litter and debris)

The CFIA issues import permits in accordance with national policy guidelines under provision of the *Plant Protection Act and Regulations*. The CFIA is also responsible for plant protection import control and enforcement issues, and provides interpretation and advice respecting the *Plant Protection Act and Regulations*.

Frequently asked questions about importing plants and plant products can be found on the website.

Facilities using and storing plant pathogens and pests must meet the requirements of the CFIA *Standards for Facilities Handling Plant Pests*.

PIs and/or permit holders wanting to import plant pathogens, pests, plant materials, and/or soil materials, must abide by the following procedure:

1. The PI or permit holder must consult with the biosafety group to determine if the biological material is on a current biosafety permit or a *Biological Material Declaration Form* needs to be completed. If not, refer to **section 4.1 or 4.2** above.
2. In consultation with the Biosafety group, it must be determined if an import permit is required by using the CFIA Automated Import Reference System (AIRS) (http://www.inspection.gc.ca/food/imports/airs/eng/1300127512994/1326599324773#)
3. If an import permit is required, complete the application form, *Application for Permit to Import Plants and Other Things*, http://www.inspection.gc.ca/english/agen/fore.shtml.

Refer to the image below:

4. Submit the completed application to the Biosafety Group for review and authorization.
5. Once authorized, the import permit application is sent to CFIA. CFIA may require an onsite inspection prior to issuing an import permit. If an on-site inspection is conducted by CFIA, notify the Biosafety group who will attend the scheduled inspection.
6. Upon receipt of the application and its satisfactory assessment by CFIA, an import permit will be issued by the CFIA. The CFIA may specify conditions on the permit depending on the biohazardous material and its use.
7. Once an import permit is issued, provide a copy of the import permit to the Biosafety Group.

5 Material Transfer Agreements

In addition to the requirement of an import permit or completion of a *BAT Form* for the procurement and/or transfer of biological materials within and outside of Canada, the PI or permit holder may be required to obtain a *Material Transfer Agreement* with the recipient facility in an effort to address liabilities and the protection of intellectual property. The PI or permit holder should consult with the University of Saskatchewan's Innovation Enterprise office: 306-966-1465 or iecontact@usask.ca.

6 Records

Applicants, PIs, and permit holders shall maintain copies of all information related to the *Biological Declaration Form*, biosafety permit, and/or import permits as required under the *Biosafety Code of Practice*.

Safety Resources shall maintain records of all permit applications, associated documents, related correspondence, and biosafety permits. All information provided by the applicant shall be treated as confidential.

7 Contact Information

Following, is the contact information for the Biosafety Group.

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References

- *Biosafety Code of Practice (2017)*, University of Saskatchewan.
- *Human Pathogens and Toxins Act and Regulations*, Public Health Agency of Canada.
- *Health of Animals Act*, Canadian Food Inspection Agency.
- *Health of Animals Regulations*, Canadian Food Inspection Agency.
- *Plant Protection Act* and *Regulations*, Canadian Food Inspection Agency.
- *Canadian Biosafety Standard (2nd Ed., 2015)*
- *Canadian Biosafety Handbook (2nd Ed., 2016)*
- *Containment Standards for Facilities Handling Plant Pests*, Canadian Food Inspection Agency.
  Containment Standards for Facilities Handling Aquatic Animal Pathogens, Canadian Food Inspection Agency.