Application for a Risk Group 3 Pathogen and Toxin Licence

All persons that perform controlled activities (i.e. possess, use, transfer, import, etc.) with human pathogens or toxins that are not specifically exempted from the licence requirement will need to apply for a Pathogen and Toxin Licence.

A person requiring a permit under the *Health of Animals Regulations (HAR)* to import animal pathogens regulated by the Public Health Agency of Canada (PHAC) will need to apply for a Pathogen and Toxin Licence.

To apply for a Pathogen and Toxin Licence, please complete one or more of the following applications forms.

- **Risk Group 2** (Risk Group 2 pathogens, toxins[i] and prions)
- **Security Sensitive Biological Agent** (SSBA) **toxins**
- **Risk Group 3** (with or without SSBA agents)
- **Risk Group 4** (with or without SSBA agents)

When completed, please submit your application by email, fax, or mail to:

Centre for Biosecurity
Public Health Agency of Canada
100 Colonnade Road, Loc.: 6201D
Ottawa, ON, K1A 0K9
Tel: (613) 957-1779
Fax: (613) 941-0596

Email: PHAC.pathogens-pathogenes.ASPC@canada.ca. Upon receipt of your application, you should receive an emailed correspondence from us within two business days. After a satisfactory assessment, a Pathogen and Toxin Licence will be issued to you. If you have any questions regarding this matter, please do not hesitate to contact our office.

*Required fields are marked with an **

Organization Information

1. *Organization Name

2. *Legal Status (Select One)

Sole Proprietorship/Individual	☐	Partnership	☐
Public Institution	☐	Incorporated Foreign Company	☐
Incorporated Canadian Company	☐		

3. Human Pathogens & Toxins Act Registration Number (if applicable)

4. Website
   ZXZXZZZZZXX

5. **Sector Information**

Sector (choose one)/Lead	Division or Affiliation (choose one)	Size (choose one)	Principal area(s) of focus (choose all that apply)
Academic ☐	University ☐ Veterinary College ☐ College ☐ CEGEP ☐ High School ☐ Other: specify below ☐		Diagnostics ☐ Education ☐ Manufacturing ☐ Quality Control ☐
Hospital ☐	Academic-Affiliated ☐ Non-Academic Affiliated ☐		
Private Industry/Business ☐	Animal Health ☐ Human Health ☐ Biotechnology ☐ Pharmaceutical ☐ Food Industry ☐ Pathogen or Toxin	Small ☐ Medium ☐ Large ☐	Research/Scientific (f selected further specify whether Applied, Basic, or Experimental) ☐ a) Applied Research ☐ b) Basic Research ☐

	Distributor¥ ☐ Other: specify below ☐		c) Experimental Development ☐
Public Health – Government ☐	Federal ☐ Provincial/Territorial ☐ Municipal ☐		Vaccine Development ☐ Waste Management ☐
Environmental – Government ☐	Federal ☐ Provincial/Territorial ☐ Municipal ☐		Other: specify below ☐
Veterinary/Animal Health – Government ☐	Federal ☐ Provincial/Territorial ☐ Municipal ☐		¥ Note that Pathogen or Toxin Distributors will not select from the Principal areas of focus section.
Other Government ☐	Federal ☐ Provincial/Territorial ☐ Municipal ☐		

6. If **other** Sector was selected specify here:

7. If **other** Division or Affiliation was selected specify here:

8. If **other** Principal area of focus was selected specify here:

Contact Information

9. * Will you be the Licence Holder for the Organization?

Yes ☐ No ☐

10. * Are you authorized to complete and submit this application on behalf of the licence applicant?

Yes ☐ No ☐

11. *****Language Preference

English ☐ French ☐

12. Salutation

Dr. ☐ Mrs. ☐ Mr. ☐ Miss ☐ Ms. ☐

13. *Given Name

14. *Surname

15. *Job Title

16. *Email

17. *Address Line 1

18. *City

19. *Province / Territory (Select One)

Alberta	☐	Nunavut	☐
British Colombia	☐	Ontario	☐
Manitoba	☐	Prince Edward Island	☐
New Brunswick	☐	Quebec	☐
Newfoundland and Labrador	☐	Saskatchewan	☐
Northwest Territories	☐	Yukon	☐
Nova Scotia	☐		

20. *Country Canada

21. *Postal Code

22. *Business Phone

23. Alternate Business Phone

24. *Fax

Licence Application Facility Information

Does your facility conduct or plan to conduct any of the following?

25. * Import or transfer imported Canadian Food Inspection Agency's reportable animal diseases [ii]

Yes ☐ No ☐

26. * Import or transfer imported Canadian Food Inspection Agency's immediately or annually notifiable diseases [iii]

Yes ☐ No ☐

27. * Import or transfer imported other diseases monitored by the Canadian Food Inspection Agency [iv]

Yes ☐ No ☐

28. * Import or transfer imported aquatic animal pathogens regulated by the Canadian Food Inspection Agency [v]

Yes ☐ No ☐

29. * Import or transfer imported bee animal pathogens regulated by the Canadian Food Inspection Agency [vi]

Yes ☐ No ☐

30. * Import or transfer imported animal, animal product and by-product containing animal pathogens [vii]

Yes ☐ No ☐

31. * Activities with Influenza A viruses

Yes ☐ No ☐

32. * Activities with wild poliovirus – including infectious materials and potentially infectious materials [viii]

Yes ☐ No ☐

33. * Activities with poliovirus Sabin and Oral Polio Vaccine-like polioviruses – including infectious materials and potentially infectious materials [ix]

Yes ☐ No ☐

34. * Activities with fragments of variola virus (Smallpox) DNA

Yes ☐ No ☐

* If you answered **Yes** to question 34, then please answer question 35. If you answered **No** to question 34, then skip to question 36.

35. Are these fragments of Variola Virus (Smallpox) DNA, exceeding 500 base pairs in length?

Yes ☐ No ☐

36. * I am aware that as per section 8 of the *Human Pathogens and Toxins Act*, possession of Variola virus (Smallpox) is prohibited, and I have taken all reasonable precautions to ensure that this agent is not present in this facility [x]

Yes ☐

37. * Are you only applying for a Permit under the Health of Animals Regulations? [xi]

Yes ☐ No ☐

38. *Are you conducting Scientific Research? [xii]

Yes ☐ No ☐

* If you answered **Yes** to question 38, then you must attach your **Plan for Administrative Oversight** [xiii] with this document when you submit it to the Centre for Biosecurity. For security reasons, do not attach any documents that may contain security sensitive information such as facility floor plans and access control information. [xiv]

Biological Safety Officer and Alternate Biosafety Contacts:

Biological Safety Officer[xv]

Only one person can be designated as the Biological Safety Officer for this licence application. A Licence Holder can designate oneself as the Biological Safety Officer, if desired.

39. **Table 1. Biological Safety Officer*

Given Name(s)	Surname	Email

Alternate Biosafety Contacts

Any additional biosafety contacts you wish you include in this licence application can be entered below and will be considered Alternate Biosafety Contacts. You may add additional rows as needed to the table if you have more Alternate Biosafety Contacts than there are rows provided.

40. *Table 2. Alternate Biosafety Contact*

Given Name(s)	Surname	Email

Location(s)

Areas within an organization that conduct the same type of work will be grouped into one entry (i.e., same type of biological agents, work area, activities and containment level) regardless of geographic location. Add as many locations as required by adding rows to the table below. Once a licence is issued, each location will have specific conditions.

41. **** Table 3. Location(s)*** **Add Location Table**

Location #	Indicate the subtype of biological agents specific to this location Risk group 3 Pathogens[xvi] or Risk group 3 Pathogens, including Security Sensitive Biological Agents[xvii]	Identify the containment level where the activities will take place for this specific location. [xviii] Containment Level 1, 2, 3 or 4	Identify the type of work area(s) specific for this containment level [xix] Laboratory Work Area Small Animal Zone Large Animal Zone (specify if it includes a Post Mortem Room) and/or Large Scale Production	If Small Animal Zone or Large Animal Zone was selected, list the animals species with which controlled activities will take place for this specific location[xx]	Indicate whether you will conduct Direct or Indirect Manipulation the controlled activities within this location [xxi]	List the Biological Agents with which controlled activities will be conducted in this specific location
Ex. 1	Risk group 3 pathogens, including SSBA	Containment level 3	Laboratory Work area, Small Animal Zone	Amphibians, Dogs, Ferrets & Weasels, Invertebrates	Direct	Biological Agent name; Biological Agent name; etc.

39. * Do you intend to conduct the following controlled activities at this location? (Select One) [xxii]

Release? Abandon?

Containment Zones

Each location must have at least one Containment Zone. Identify the Location the Containment Zone is associated with by using the appropriate Location # from Table 3 above. A location may have as many containment zones as needed. If you have additional containment zones, please indicate on a separate page including the information under the same headings.

40. **Table 4. Containment Zones*

Location #	Building Name	Room(s)	Address	City	Province	Postal Code

Privacy Notice

The personal information you provide to the Public Health Agency of Canada (PHAC) is handled in accordance with the Privacy Act. PHAC collects the information that relates directly to the administration of the Human Pathogens and Toxins Act and the Health of Animals Act. PHAC will be disclosing the relevant information CFIA requires to administer the Health of Animals Act.

The information collected will be used to identify and licence and/or permit people conducting activities with risk group 2, 3, and 4 human and animal pathogens and toxins; and it is the basis for the evaluation of your eligibility for a licence and/or import permit as per the requirements set out in the legislation. In limited and specific situations, your personal information may be disclosed without your consent in accordance with 8(2) of the Privacy Act.

A refusal to provide the information requested on this form will result in the denial of your application for a licence and/or import permit.

This personal information collection is described in Info Source, available online at www.infosource.gc.ca under PHAC PPU 306 or CFIA PPU 011.

In addition to protecting your personal information, the Privacy Act gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact either PHAC's Privacy Coordinator at 613-954-9165 or privacy-vie.privee@hc-sc.gc.ca or CFIA's Privacy Coordinator at 613-773-5990 or ATIP-CFIA-AIPRP@inspection.gc.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

Attestation

The Biological Safety Officer and the Licence Holder must provide their attestation by signing below before the licence application can be sent to the Centre for Biosecurity.

Biological Safety Officer

☐ *To the best of my knowledge, the information contained in this application is correct and complete, and I understand that it is an offence under the *Human Pathogens and Toxins Act* to knowingly provide false or misleading information.

☐ *I have read and I understand the Privacy Notice

Signature:_____

Date:_____

Licence Holder

☐ *I declare and certify that I am the duly-authorized representative of the licence applicant. To the best of my knowledge, the information contained in this application is correct and complete, and I understand that it is an offence under the *Human Pathogens and Toxins Act* to knowingly provide false or misleading information.

☐ *I have read and I understand the Privacy Notice

Signature:_____

Date:_____

References

[i] Including those present on the Security Sensitive Biological Agent (SSBA) List when under the trigger quantity.

[ii] The Schedule to the Reportable Diseases Regulations and Schedules VII and VIII of the Health of Animals Regulations (HAR) list the reportable and notifiable diseases that affect terrestrial animals. Consult the Canadian Food Inspection Agency website for complete schedule.

[iii] The Schedule to the Reportable Diseases Regulations and Schedules VII and VIII of the Health of Animals Regulations (HAR) list the reportable and notifiable diseases that affect terrestrial animals. Consult the Canadian Food Inspection Agency website for complete schedule.

[iv] The Schedule to the Reportable Diseases Regulations and Schedules VII and VIII of the Health of Animals Regulations (HAR) list the reportable and notifiable diseases that affect terrestrial animals. Consult the Canadian Food Inspection Agency website for complete schedule.

[v] The Schedule to the Reportable Diseases Regulations and Schedules VII and VIII of the Health of Animals Regulations (HAR) list the reportable and notifiable diseases that affect terrestrial animals. Consult the Canadian Food Inspection Agency website for complete schedule.

[vi] The Schedule to the Reportable Diseases Regulations and Schedules VII and VIII of the Health of Animals Regulations (HAR) list the reportable and notifiable diseases that affect terrestrial animals. Consult the Canadian Food Inspection Agency website for complete schedule.

[vii] The Schedule to the Reportable Diseases Regulations and Schedules VII and VIII of the Health of Animals Regulations (HAR) list the reportable and notifiable diseases that affect terrestrial animals. Consult the Canadian Food Inspection Agency website for complete schedule.

[viii] **Poliovirus:** A picornavirus consisting of three serotypes: 1, 2, and 3. Poliovirus serotypes are further sub-divided into wild (circulating in nature) and Sabin strains (attenuated strains used for oral polio vaccines (OPV)). Polioviruses use CD155 as the primary cellular receptor.

Poliovirus, wild:

- Wild polioviruses are naturally occurring isolates known or believed to have circulated persistently in the community.
- Vaccine-derived polioviruses (VDPV) are classified with wild polioviruses and demonstrate usually 1–15% sequence difference from the parental OPV strain; they may have circulated in the community (cVDPV) or have replicated for prolonged periods in immunodeficient subjects (iVDPV) or be ambiguous environmental of unknown origin (aVDPV).
- Attenuated strains not licensed for use as live vaccines (Cox/Lederle and Koprowski/Wistar series) are classified with wild polioviruses as their clinical properties

are unproven. Wild poliovirus materials may be (a) infectious or (b) potentially infectious (b).

a. **Poliovirus infectious materials, wild:** These include:
    - Clinical materials from confirmed wild poliovirus (including VDPV) infections
    - Environmental sewage or water samples that have tested positive for the presence of wild polioviruses
    - Cell culture isolates, and reference strains of wild poliovirus
    - Seed stocks and infectious materials from IPV production
    - Infected animals or samples from such animals, including human poliovirus receptor (PVR) transgenic mice
    - Derivatives produced in the laboratory that have capsid sequences from wild polioviruses, unless demonstrably proven to be safer than Sabin strains. Safety of new derivatives containing WPV capsid sequences will be assessed by an expert panel on the basis of comparison to reference Sabin strains of a) degree and stability of attenuation; b) potential for person to person transmission; and c) neurovirulence in animal models.
    - Full-length RNA or cDNA that include capsid sequences derived from wild poliovirus, unless viruses derived from them are demonstrably proven to be safer than Sabin strains. Safety of full-length RNA or cDNA containing WPV capsid sequences will be assessed by an expert panel convened by WHO, on the basis of comparison to reference Sabin strains of a) degree and stability of attenuation; b) potential for person to person transmission; and c) neurovirulence in animal models.
    - Cells persistently infected with poliovirus strains whose capsid sequences are derived from wild poliovirus
b. **Poliovirus potentially infectious materials, wild:** These include:
    - Faecal or respiratory secretion samples collected for any purpose in a time and geographic area of wild poliovirus (including VDPV) circulation
    - Products of such materials in poliovirus permissive cells or animals
    - Uncharacterized enterovirus-like cell culture isolates from countries known or suspected to have circulating wild poliovirus or VDPV at the time of collection
    - Respiratory and enteric virus stocks handled under conditions where poliovirus contamination or replication is possible

[ix] **Poliovirus:** A picornavirus consisting of three serotypes: 1, 2, and 3. Poliovirus serotypes are further sub-divided into wild (circulating in nature) and Sabin strains (attenuated strains used for oral polio vaccines (OPV)). Polioviruses use CD155 as the primary cellular receptor.

Poliovirus Sabin: OPV/Sabin strains are attenuated poliovirus strains (approved for use in oral polio vaccines by national regulatory authorities, principally Sabin strains). OPV-like polioviruses: For the laboratory network not involved in manufacture, OPV like polioviruses are defined as isolates consistent with a limited period of virus excretion or person-to-person transmission, demonstrating less than 1% difference from parent OPV strains for poliovirus

types 1 and 3 and less than 0.6% difference from the type 2 parent OPV strain by full VP1 sequence homology. The phenotype of clinical and environmental OPV-like isolates need not be determined as the great majority are assumed to be of low virulence. Sabin materials may be (a) infectious or (b) potentially infectious. The attenuated phenotype of viruses resulting from manufacture based on the Sabin OPV seeds must be assured and cannot rely on lack of sequence drift alone.

a. **Poliovirus infectious materials, OPV/Sabin:** These include:
    - Cell culture isolates and reference OPV/Sabin strains
    - Seed stocks and live virus materials from OPV production
    - Environmental sewage or water samples that have tested positive for the presence of OPV/Sabin strains
    - Faecal or respiratory secretion samples from recent OPV recipients
    - Infected animals or samples from such animals, including PVR transgenic mice
    - Derivatives produced in the laboratory that have capsid sequences from OPV/Sabin strains
    - Full-length RNA or cDNA that include capsid sequences derived from OPV/Sabin strains
    - Cells persistently infected with poliovirus strains whose capsid sequences are derived from OPV/Sabin strains
b. **Poliovirus potentially infectious materials, OPV/Sabin:** These include:
    - Faecal or respiratory secretion samples collected for any purpose in a time and geographic area of OPV use
    - Products of such materials from poliovirus permissive cells or animals
    - Respiratory and enteric virus stocks handled under conditions where OPV/Sabin strain contamination or replication is possible

[x] As a mandatory field, this box must be selected in order for you to proceed with this application. Please contact the Public Health Agency of Canada if you require further instruction.

[xi] Select yes if your facility conducts activities with strict terrestrial animal pathogens and does not require a licence under the *Human Pathogens and Toxins Act*.

[xii] Scientific research means the following types of systematic investigation or research that are carried out in a field of science or technology by means of controlled activities:

a. basic research, when the controlled activities are conducted for the advancement of scientific knowledge without a specific practical application;
b. applied research, when the controlled activities are conducted for the advancement of scientific knowledge with a specific practical application;

c. experimental development, when the controlled activities are conducted to achieve scientific or technological advancement for the purpose of creating new or improving existing materials, products, processes, or devices.

[xiii] Plan that sets out administrative measures for managing and controlling biosafety and biosecurity risks during the period in which the licence is in effect. Additional information on the Plan for Administrative Oversight can be found on the Public Health Agency of Canada's website.

[xiv] Additional information on security sensitive information can be found within the Canadian Biosecurity Guidelines.

[xv] A Biological Safety Officer must be designated for each licence and this person shall be responsible for carrying out the Biological Safety Officer functions identified within the *Human Pathogens and Toxins Regulations*. Only one person can be designated as the Biological Safety Officer for this licence application. A Licence Holder can designate his or herself as the Biological Safety Officer, if desired. Any additional biosafety contacts you provide will be considered Alternate Biosafety Contacts.

[xvi] Select if you are applying for a licence to work with Risk Group 3 pathogens that does not include any Security Sensitive Biological Agents.

[xvii] Select if you are applying for a licence to work with Risk Group 3 pathogens that does include Security Sensitive Biological Agents.

[xviii] Select the containment level where the activities will take place for this specific location. If controlled activities will be conducted in different containment levels, a new location must be created for each one. Refer to the Canadian Biosafety Standard for definitions of containment levels.

[xix] Select the Type of Work Area(s) where controlled activities will occur at this Containment Level with this subtype of pathogens and toxins. Select all that apply. Refer to the Canadian Biosafety Standard for definitions of the Type of Work Areas

[xx] Amphibians
Aquatic Animals [xx]
Bats
Birds [xx]
Cats (felines)
Camels (camelids)
Cattle, Bison and Buffalo
Deer (cervids)
Horse (equids)
Invertebrates [xx]
Non-human Primates
Pigs (swine)
Rabbits and Hares
Raccoons
Rodents
Seals and Walruses

Dogs
Ferrets and Weasels
Goats (caprids)
Sheep (ovines)
Skunks

[xxi] Select whether the pathogens or toxins will be released or abandoned at this location. The Public Health Agency of Canada may contact you to request additional information for these activities.

Direct Manipulation involves the following controlled activities:
Possessing, Handling, Storing, Permitting Access to, Transferring, Importing, Exporting, Disposing and **Using and Producing.**

Indirect Manipulation involves the following controlled activities:
Possessing, Handling, Storing, Permitting Access to, Transferring, Importing, Exporting, Disposing.

[xxii] Select whether the pathogens or toxins will be released or abandoned at this location. The Public Health Agency of Canada may contact you to request additional information for these activities.