

# Roles and Responsibilities of Individuals Associated to a Pathogen and Toxin Licence

This document has been developed by the Public Health Agency of Canada's Centre for Biosecurity as a guide to clarify the roles and responsibilities of individuals associated to a Pathogen and Toxin Licence issued under section 18 of the *Human Pathogens and Toxins Act* or under section 160 of the *Health of Animals Regulations*; these individuals include:

- Licence Holder or Licence Holder Representative
- Biological Safety Officer
- Alternate Biosafety Contact
- Individuals conducting controlled activities under the authority of a Pathogen and Toxin Licence
- Individuals conducting controlled activities with Security Sensitive Biological Agents

This guide does not replace the act nor the regulations that are currently in effect. In the event of an inconsistency between this guide and the act or the regulations, what is stated in the act, or the regulations will prevail. This guide must be used in conjunction with the applicable sections of the:

- [Human Pathogens and Toxins Act](#) (HPTA)
- [Human Pathogens and Toxins Regulations](#) (HPTR)
- [Health of Animals Act](#) (HAA)
- [Health of Animals Regulations](#) (HAR)
- [Canadian Biosafety Standard](#) (CBS)
- Statement of Administrative Intent for [Licence Holder and Licence Holder Representative: Defining terms in the context of the Human Pathogens and Toxins Act](#)



# Licence Holder and Licence Holder Representative

# LH/LHR

## Role

**The Licence Holder (LH)**, whether it is an individual or an organization, assumes legal responsibility for complying with the HPTA, HPTR, licence conditions, and the applicable sections of the HAA and HAR. Generally, the organization is considered the LH.

**The Licence Holder Representative (LHR)** is the administrative point of contact responsible for acting on behalf of the LH, when it is an organization, with respect to matters prescribed under the HPTA, HPTR, HAA, HAR and licence conditions. The Licence Holder Representative is designated by the LH and serves as an important contact for communicating with the Centre for Biosecurity for all matters related to the administration of the Pathogen and Toxin Licence (PTL).

## Responsibilities

Responsibilities include, but are not limited to:

- Possess a valid [Biosecurity Portal account](#) and never transfer or share the access code or the account with another individual or employee.
- Apply for, maintain, and update, as required, the PTL via the Biosecurity Portal in collaboration with the Biological Safety Officer (BSO).
- Comply with conditions listed on the PTL [HPTA 18(7)].
- Communicate licence conditions to all persons conducting activities under that licence [HPTA 18(6)].
- Notify the Centre for Biosecurity in writing and within 30 calendar days of a change to the LH's name (i.e., the name of the organization) [HPTR 6(2)].
- Designate a BSO that possesses the minimum qualifications listed in section 8 of the HPTR to oversee biosafety and biosecurity practices [HPTA 36(1)(3)].
- Immediately designate a new BSO and notify the Centre for Biosecurity within 30 calendar days, if the BSO leaves their position, [HPTA 36(6)].
- Take reasonable measures to ensure continuous and uninterrupted communication with the Centre for Biosecurity, even during short or long-term absences of the designated BSO or the LHR (e.g., vacation, parental or sick leave, etc.); this could for example, be achieved by temporarily assigning another person to perform the duties of those positions. The person selected as replacement for the BSO must meet the qualifications listed in section 8 of the HPTR.
- Support and collaborate with the BSO to ensure ongoing compliance with the HPTA, HPTR, licence conditions, and the HAA and HAR when applicable.
- Designate an Alternate Biosafety Contact (ABC), if necessary.





- Provide to the Centre for Biosecurity, and maintain up-to-date, contact details of all individuals associated to the licence; this includes ABCs, BSOs and LHRs. It is important to note that PHAC will not share any information related to the PTL to an individual that is not associated to the PTL.
- Never obstruct the BSO when they are exercising their powers or when they are carrying out their function [HPTR 4(1)(a)].
- Keep a list of all persons authorized to access a facility listed on that PTL, including persons holding HPTA security clearances for that facility and visitors [HPTA 31];
  - must keep a record of the full name of every individual who enters, under accompaniment and supervision, a facility listed on the licence where Security Sensitive Biological Agents (i.e., prescribed pathogens or toxins) are present, including the date and the full name of the individual who accompanied and supervised them [HPTR 25].
- Notify the Centre for Biosecurity without delay (i.e., immediately), when:
  - there is reason to believe that a human pathogen or toxin has been released inadvertently from a facility (e.g., package leaked outside of the containment zone) [HPTA 12(1)];
  - an incident involving a human pathogen or toxin has, or may have, caused disease in an individual [HPTA 13];
    - ✓ a follow-up report with investigation details must be provided to the Centre for Biosecurity within 30 calendar days, or within 15 calendar days when it concerns a Security Sensitive Biological Agent (i.e., prescribed pathogen or toxin) [CBS3 4.8.12].
  - there is reason to believe that a human pathogen or toxin that was in their possession has been stolen or is otherwise missing [HPTA 14];
    - ✓ in this situation, reasonable measures must be taken to locate the missing human pathogen or toxin [HPTA 14]; and
    - ✓ notification to the Centre for Biosecurity must also include any information relating to the incident that is under their control and that the Centre for Biosecurity may require [HPTA 14].
  - a decision is made to prohibit the holder of an HPTA security clearance from accessing a facility listed on the PTL, including the reasons for that decision [HPTA 32 and HPTR 7].
- Notify the Centre for Biosecurity before making any of the following changes that could affect the biocontainment where controlled activities with Risk Group (RG) 3 or 4 human pathogens or Security Sensitive Biological Agents (i.e., prescribed pathogens or toxins) are conducted [HPTR 6(1)]:
  - changes to the physical structure of the facility;
  - changes to any equipment; or
  - changes to Standard Operating Procedures (SOP).
- Possess a valid HPTA security clearance, when applicable;
  - an **HPTA security clearance** is mandatory if the LHR is expected to enter (or accompany a person without an HPTA security clearance) in the part of a facility in which controlled activities with Security Sensitive Biological Agents (i.e., prescribed pathogens or toxins) are authorized.

# Biological Safety Officer

# BSO

## Role

The **Biological Safety Officer (BSO)** oversees biosafety and biosecurity practices related to a PTL. As the established biosafety and the biosecurity primary contact, the BSO communicates with the Centre for Biosecurity on behalf of the LH [HPTR 9(1)(b)]. The BSO has the power to require any person conducting controlled activities authorized by the licence to provide them with any records that are necessary to assist them in carrying out their functions [HPTR 9(2)].



### The BSO must possess the following qualifications:

- knowledge of microbiology, appropriate to the risks associated with the controlled activities being conducted, attained through a combination of education, training, and experience [HPTR 8(a)];
- knowledge of the HPTA, the HPTR, and any applicable federal or provincial legislation [HPTR 8(b)], including certain sections of the HAA and the HAR; and
- knowledge of applicable biosafety and biosecurity policies, standards, and practices, appropriate to the risks associated with the controlled activities being conducted [HPTR 8(c)].

### The BSO's functions are to promote and monitor compliance, which includes but is not limited to:

- arranging for and documenting training related to biosafety and biosecurity policies, standards, and practices [HPTR 9(1)(c)(i)];
- conducting periodic internal inspections and biosafety audits and reporting findings to the LHR [HPTR 9(1)(c)(iv)];
- informing the LHR in writing of any non-compliance by a person conducting activities under the licence that is not corrected after that individual has been made aware of it [HPTR 9(1)(c)(v)];
- assisting in the development and maintenance of the biosafety manual and standard operating procedures (SOPs) related to biosafety and biosecurity [HPTR 9(1)(d)]; and
- assisting with internal investigations of incidents [HPTR 9(1)(e)].

## Responsibilities

### Responsibilities include, but are not limited to:

- Possess a valid [Biosecurity Portal account](#) and never transfer or share the access code or the account with another individual or employee.
- Maintain and update, as required, the PTL via the Biosecurity Portal in collaboration with the LHR.
- Designate an ABC, if necessary.



- Notify the Centre for Biosecurity without delay of:
  - any occurrences of inadvertent possession of human pathogens and toxins [HPTR 9(1)(c)(ii)]; or
  - any Security Sensitive Biological Agents (i.e., prescribed pathogens or toxins) not received within 24 hours of the date and time expected [HPTR 9(1)(c)(iii)].
- Take reasonable care, before transferring regulated materials, to satisfy themselves:
  - that if the intended recipient is in Canada, the recipient is licensed to work with the regulated material, or is otherwise exempted from the requirement to hold a PTL [HPTR 4(1)(c)]; or
  - that if the intended recipient is in a foreign country, the recipient will follow applicable biosafety and biosecurity standards and policies in the foreign jurisdiction [HPTR 4(1)(d)].
- Possess a valid HPTA security clearance, if applicable;
  - an [HPTA security clearance](#) is mandatory if the BSO is expected to enter (or accompany a person without an HPTA security clearance) in the part of a facility in which controlled activities with Security Sensitive Biological Agents (i.e., prescribed pathogens or toxins) are authorized.

# Alternate Biosafety Contact

# ABC

## Role

The **Alternate Biosafety Contact (ABC)** may support the BSO or the LHR in fulfilling some of their responsibilities.

If holding the qualifications of a BSO as per section 8 of the HPTR, the ABC can be identified to act as a substitute for the designated BSO, during short or long-term absence, by fulfilling the BSO's responsibilities detailed in this guide.

## Responsibilities

Responsibilities include, but are not limited to:

- Possess a valid [Biosecurity Portal account](#) and never transfer or share the access code or the account with another individual or employee.
- Possess a valid HPTA security clearance, if applicable:
  - an [HPTA security clearance](#) is mandatory if the ABC is expected to enter (or accompany a person without an HPTA security clearance) in the part of a facility in which controlled activities with Security Sensitive Biological Agents (i.e., prescribed pathogens or toxins) are authorized.





# Individuals conducting controlled activities under the authority of a Pathogen and Toxin Licence

## Role

Conduct controlled activities under the authority of a PTL, under the direction of the LH.

## Responsibilities

Responsibilities include, but are not limited to:

- Comply with conditions listed on the PTL [HPTA 18(7)].
- Never obstruct the BSO when they are exercising their powers or when they are carrying out their functions [HPTR 4(1)(a)].
- Inform the LHR without delay:
  - of any inadvertent release or production of a human pathogen or toxin [HPTA 15];
  - of any incident involving a human pathogen or toxin that has, or may have, caused disease in an individual [HPTA 15]; or
  - if a pathogen or toxin has been stolen or is otherwise missing [HPTA 15].
- Inform the LHR and the BSO in writing, if they intend to increase the virulence, pathogenicity, or communicability of a human pathogen, the resistance of a human pathogen to preventive or therapeutic treatments, or the toxicity of a toxin [HPTR 5].
- Notify the BSO before arrangements are made to do the following:
  - import or export a human pathogen or toxin [HPTR 4(1)(b)(i)];
  - receive a human pathogen or toxin from another facility [HPTR 4(1)(b)(ii)]; or
  - transfer a human pathogen or toxin to another facility [HPTR 4(1)(b)(iii)].
- Notify the BSO, without delay, if:
  - human pathogens and toxins were not received within a reasonable time after it was expected to be received [HPTR 4(1)(e)]; or
  - a person discovers that they are inadvertently in possession of a human pathogen or toxin that they are not authorized to possess [HPTR 4(1)(f)(i)].
- Take reasonable care, before transferring or exporting regulated materials, to satisfy themselves that, if the recipient is:
  - in Canada, the recipient is licensed to work with the regulated material, or is otherwise exempted from the requirement to hold a PTL [HPTR 4(1)(c)]; or
  - in a foreign country, the recipient will follow applicable biosafety and biosecurity standards and policies in the foreign jurisdiction [HPTR 4(1)(d)].
- Never conduct controlled activities that may pose a risk to public health safety and security [HPTA 6].



# Individuals conducting controlled activities with Security Sensitive Biological Agents

# SSBA

## Role

An **HPTA Security Clearance (HPTA SC)** is necessary to enter the part of a facility in which controlled activities with Security Sensitive Biological Agents (i.e., prescribed pathogens or toxins) are authorized.

**HPTA SC holders** can enter or accompany a person without an HPTA SC in the part of a facility in which controlled activities with Security Sensitive Biological Agents (i.e., prescribed pathogens or toxins) are authorized.



## Responsibilities

Responsibilities include, but are not limited to:

- Possess a valid [Biosecurity Portal account](#) and never transfer or share the access code or the account with another individual or employee.
- Ensure at all times that their [HPTA Security Clearance](#) is valid and has not been withdrawn by the LH [HPTA 33].
- Notify the Centre for Biosecurity immediately, if ever convicted of a criminal offence [HPTR 19].
- Comply with conditions listed on the PTL [HPTA 18(7)].
- Comply with biosecurity plans, biosecurity policies, and procedures implemented for the part of a facility in which controlled activities with Security Sensitive Biological Agents (i.e., prescribed pathogens or toxins) are authorized.
- Directly supervise, when accompanying persons without an HPTA Security Clearance, in the part of a facility in which controlled activities with Security Sensitive Biological Agents (i.e., prescribed pathogens or toxins) are authorized [HPTA 33(b)].
- Maintain confidentiality of documentation pertaining to controlled activities, as guided by information management and security policies of their facility [CBS3 4.9.3].
- Notify the BSO before preparing a shipment, or the transport of a Security Sensitive Biological Agents (i.e., prescribed pathogens or toxins) [HPTR 4(1)(b)].
- Inform the BSO if the intended recipient of Security Sensitive Biological Agents (i.e., prescribed pathogens or toxins) does not receive it within 24 hours after the expected date and time [HPTR 4(2)].
- Notify the appropriate internal authority if theft, misuse, diversion, intentional release, has occurred, is suspected to have occurred, or may occur in the near future [CBS3 4.8.9].
- Never conduct controlled activities that may pose a risk to public health safety and security [HPTA 6].