

Roles and responsibilities of individuals associated with a Pathogen and Toxin Licence

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

- Licence Holder and 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 is not a substitute for the Acts nor the Regulations that are currently in effect. In the event of an inconsistency between this guide and the Acts or the Regulations, what is stated in the Acts or the Regulations will prevail. You are advised to consult the applicable sections of the:

- [Human Pathogens and Toxins Act](#)
- [Human Pathogens and Toxins Regulations](#)
- [Health of Animals Act](#)
- [Health of Animals Regulations](#)
- [Canadian Biosafety Standard](#)

New

The *Human Pathogens and Toxins Act* was amended to include the following new requirements that must be met in order to apply for, or hold a Pathogen and Toxin Licence issued under section 18:

- a Licence Holder Representative must be designated if the Licence Holder is an organization [*Human Pathogens and Toxins Act* 36.1];
- the Licence Holder (if an individual), the Licence Holder Representative and the Biological Safety Officer must be ordinarily resident in Canada;
- the Licence Holder (if an organization) must be incorporated, formed or otherwise organized in Canada.

Non-compliance with the residency requirements may result in the suspension or revocation of an active Pathogen and Toxin Licence [*Human Pathogens and Toxins Act* 20(1)] or the refusal to issue or renew a Pathogen and Toxin Licence [*Human Pathogens and Toxins Act* 18(1.1)].

To learn more about how to comply with these specific requirements, please consult [Guidance for Organizations and Individuals regarding Canadian Residency Requirements under the Human Pathogens and Toxins Act](#).

Note: Pathogen and Toxin Licences issued only under section 160 of the *Health of Animals Regulations* by the Public Health Agency of Canada **do not require** the Licence Holder (if an individual), the Licence Holder Representative and the Biological Safety Officer to be ordinarily resident in Canada nor for the Licence Holder (if an organization) to be incorporated, formed or otherwise organized in Canada.



Licence Holder and Licence Holder Representative

LH/LHR

Role

The Licence Holder, whether an individual or an organization, assumes legal responsibility for complying with the *Human Pathogens and Toxins Act*, *Human Pathogens and Toxins Regulations*, licence conditions, and the applicable sections of the *Health of Animals Act* and *Health of Animals Regulations*. Generally, the organization is identified as the Licence holder.



A Licence Holder Representative must be designated when the Licence Holder is an organization [*Human Pathogens and Toxins Act* 36.1] [*Health of Animals Regulations* 160(1)]. The Licence Holder Representative is the administrative point of contact generally responsible for acting on behalf of the Licence Holder with respect to matters prescribed under *Human Pathogens and Toxins Act*, *Human Pathogen and Toxins Regulations*, licence conditions, and the applicable sections of the *Health of Animals Act* and *Health of Animals Regulations*. The Licence Holder Representative 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.

Responsibilities and Requirements

Responsibilities and requirements may 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 Pathogen and Toxin Licence via the Biosecurity Portal in collaboration with the Biological Safety Officer.
- **Specific for the *Human Pathogens and Toxins Act*:** demonstrate that the organization is incorporated, formed or otherwise organized in Canada, if the Licence Holder is an organization. If the Licence Holder is an individual, they must ordinarily reside in Canada throughout the entire period that they exercise their duties and functions associated with the Pathogen and Toxin Licence. If the designated Licence Holder Representative leaves their position or no longer complies with the residency requirement, the Licence Holder must, without delay, designate a new Licence Holder Representative and notify the Centre for Biosecurity of that change [*Human Pathogens and Toxins Act* 36.1(4)]. Failure to comply with the residency requirement may result in the suspension or revocation of an active Pathogen and Toxin Licence [*Human Pathogens and Toxins Act* 20(1)] or the refusal to issue or renew a Pathogen and Toxin Licence [*Human Pathogens and Toxins Act* 18(1.1)].
- Notify the Centre for Biosecurity in writing and within 30 calendar days of a change to the Licence Holder's name (meaning the name of the organization) [*Human Pathogen and Toxins Regulations* 6(2)] [*Health of Animals Regulations* 160(2)(a)].
- Designate a Biological Safety Officer to oversee biosafety and biosecurity practices related to a Pathogen and Toxin Licence [*Human Pathogens and Toxins Act* 36(1)] [*Health of Animals Regulations* 160(1)].



- Designate a new Biological Safety Officer and notify the Centre for Biosecurity without delay, if the Biological Safety Officer leaves their position or no longer complies with the residency requirement [Human Pathogens and Toxins Act 36(6)] [Health of Animals Regulations 160.1]. Failure to comply with the residency requirement may result in the suspension or revocation of an active Pathogen and Toxin Licence [Human Pathogens and Toxins Act 20(1)] or the refusal to issue or renew a Pathogen and Toxin Licence [Human Pathogens and Toxins Act 18(1.1)].
- Take reasonable measures to ensure continuous and uninterrupted communication with the Centre for Biosecurity, even during short or long-term absences of the designated Biological Safety Officer or Licence Holder/Licence Holder Representative (for example, vacation, parental or sick leave, etc.). This could, for example, be achieved by temporarily assigning another person holding the appropriate qualifications and requirements to perform the duties of those positions.
- Support and collaborate with the Biological Safety Officer to ensure ongoing compliance with the Human Pathogens and Toxins Act, Human Pathogens and Toxins Regulations, licence conditions and, Health of Animals Act and Health of Animals Regulations when applicable.
- Comply with conditions listed on the Pathogen and Toxin Licence [Human Pathogens and Toxins Act 18(7)] [Health of Animals Regulations 160.1].
- Communicate licence conditions to all persons conducting activities under that licence [Human Pathogens and Toxins Act 18(6)].
- Appoint an Alternate Biosafety Contact, if necessary.
- Provide to the Centre for Biosecurity, and maintain up-to-date, professional contact details of all individuals associated with the Pathogen and Toxin Licence; this includes Alternate Biosafety Contacts, Biological Safety Officers and Licence Holders/Licence Holder Representative. It is important to note that Centre for Biosecurity will not share any information related to the Pathogen and Toxin Licence with an individual that is not associated with the Pathogen and Toxin Licence.
- Never obstruct the Biological Safety Officer when they are exercising their powers or when they are carrying out their functions [Human Pathogens and Toxins Regulations 4(1)(a)].
- Keep a list of all persons authorized to access (remotely or in person) a facility listed on that Pathogen and Toxin Licence, including persons holding Human Pathogens and Toxins Act security clearances for that facility and visitors [Human Pathogens and Toxins Act 31].
- Possess a valid [Human Pathogens and Toxins Act security clearance](#), if applicable.
- Notify the Centre for Biosecurity without delay, when:
 - there are reasonable grounds to suspect that a human pathogen or toxin has been released inadvertently from a facility (for example, package leaked outside of the containment zone) [*Human Pathogens and Toxins Act 12(1)*];
 - there are reasonable grounds to suspect an incident involving a human pathogen or toxin has, or may have, caused disease in an individual [*Human Pathogens and Toxins Act 13*]:
 - the notification must include a description of the incident and the name of the human pathogen or toxin that was involved [*Human Pathogens and Toxins Act 13(a) and (b)*]; and



- 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 prescribed pathogen or toxin (meaning a Security Sensitive Biological Agent) [*Canadian Biosafety Standard, Third Edition* 4.8.12].
- there are reasonable grounds to suspect that a human pathogen or toxin that was in their possession has been stolen or is otherwise missing [*Human Pathogens and Toxins Act* 14];
 - in this situation, reasonable measures must be taken to locate the missing human pathogen or toxin [*Human Pathogens and Toxins Act* 14]; and
 - the 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 [*Human Pathogens and Toxins Act* 14].
- there are reasonable grounds to suspect that any of these three types of human pathogen or toxin have been involved in an incident that is not referred in subsections 12(1), 12(2), 13 or 14 of the *Human Pathogens and Toxins Act* and is specified in the *Human Pathogens and Toxins Regulations* [*Human Pathogens and Toxins Act* 14.1]:
 - a prescribed (meaning a Security Sensitive Biological Agent) risk group 3 human pathogen;
 - a risk group 4 human pathogen; or
 - a prescribed toxin (meaning a Security Sensitive Biological Agent).
- a decision is made to prohibit the holder of an *Human Pathogens and Toxins Act* security clearance from accessing a facility listed on the Pathogen and Toxin Licence, including the reasons for that decision [*Human Pathogens and Toxins Act* 32 and *Human Pathogens and Toxins Regulations* 7].
- a human pathogen for which controlled activities are authorized by a Pathogen and Toxin Licence is modified to the extent that it poses a lower risk to the health of individuals or to public health [*Human Pathogens and Toxins Regulations* 6(3)].
- Notify the Centre for Biosecurity before making any of the following changes that could affect the biocontainment where controlled activities with risk group 3 or 4 human pathogens or prescribed pathogens or toxins (meaning Security Sensitive Biological Agents) are conducted [*Human Pathogens and Toxins Regulations* 6(1)]:
 - changes to the physical structure of the facility;
 - changes to any equipment; or
 - changes to Standard Operating Procedures.

Biological Safety Officer

BSO

Role

- A Biological Safety Officer must be designated [Human Pathogens and Toxins Act 36(1)] [Health of Animals Regulations 160(1)] to oversee biosafety and biosecurity practices related to a Pathogen and Toxin Licence. As the established biosafety and the biosecurity primary contact, the Biological Safety Officer communicates with the Centre for Biosecurity on behalf of Licence Holder [Human Pathogens and Toxins Regulations 9(1)(b)].
- The Biological Safety Officer has the power to require any person conducting controlled activities authorized by the a Pathogen and Toxin Licence to provide them with any records that are necessary to assist them in carrying out their functions [*Human Pathogens and Toxins Regulations* 9(2)].
- **Specific to the *Human Pathogens and Toxins Act*:** the Biological Safety Officer 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 [*Human Pathogens and Toxins Regulations* 8(a)];
 - knowledge of the *Human Pathogens and Toxins Act*, the *Human Pathogens and Toxins Regulations*, and any applicable federal or provincial legislation [*Human Pathogens and Toxins Regulations* 8(b)], including applicable sections of the *Health of Animals Act* and the *Health of Animals Regulations*; and
 - knowledge of applicable biosafety and biosecurity policies, standards, and practices, appropriate to the risks associated with the controlled activities being conducted [*Human Pathogens and Toxins Regulations* 8(c)].
- Promote and monitor compliance with the regulations, which includes, but is not limited to:
 - arranging for and documenting training related to biosafety and biosecurity policies, standards, and practices [*Human Pathogens and Toxins Regulations* 9(1)(c)(i)];
 - conducting periodic internal inspections and biosafety audits and reporting findings to the Licence Holder/Licence Holder Representative [*Human Pathogens and Toxins Regulations* 9(1)(c)(iv)];
 - informing the Licence Holder/Licence Holder Representative in writing of any non-compliance by a person conducting activities under the a Pathogen and Toxin Licence that is not corrected after that individual has been made aware of it [*Human Pathogens and Toxins Regulations* 9(1)(c)(v)];
 - assisting in the development and maintenance of the biosafety manual and standard operating procedures related to biosafety and biosecurity [*Human Pathogens and Toxins Regulations* 9(1)(d)]; and
 - assisting with internal investigations of incidents [*Human Pathogens and Toxins Regulations* 9(1)(e)].

Responsibilities and Requirements

Responsibilities and requirements may 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.
- **Specific for the *Human Pathogens and Toxins Act*:** comply with the residency requirement throughout the entire period that they exercise their duties and functions associated with the a Pathogen and Toxin Licence [*Human Pathogens and Toxins Act* [*Human Pathogens and Toxins Act* 20(1)].
- Maintain and update, as required, the Pathogen and Toxin Licence via the Biosecurity Portal in collaboration with the Licence Holder/Licence Holder Representative.
- Comply with conditions listed on the a Pathogen and Toxin Licence [*Human Pathogens and Toxins Act* 18(7)] [*Health of Animals Regulations* 160.1].
- Appoint an Alternate Biosafety Contact, if necessary.
- Possess a valid [Human Pathogens and Toxins Act security clearance](#), if applicable.
- 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 Pathogen and Toxin Licence [*Human Pathogens and Toxins Regulations* 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 [*Human Pathogens and Toxins Regulations* 4(1)(d)].
- Notify the Centre for Biosecurity without delay of:
 - any occurrences of inadvertent possession of human pathogens and toxins [*Human Pathogens and Toxins Regulations* 9(1)(c)(ii)]; or
 - any prescribed pathogens or toxins (meaning Security Sensitive Biological Agents) not received within 24 hours of the date and time expected [*Human Pathogens and Toxins Regulations* 9(1)(c)(iii)].



Alternate Biosafety Contact

ABC

Role

There is no legal requirement to designate an Alternate Biosafety Contact, but if needed, an Alternate Biosafety Contact may be appointed to support the Biological Safety Officer or the Licence Holder/Licence Holder Representative in fulfilling some of their responsibilities.

If the Alternate Biosafety Contact meets the appropriate requirements and holds the appropriate qualifications of a Biological Safety Officer, the Alternate Biosafety Contact can act as a substitute for the designated Biological Safety Officer during short or long-term absences.

Responsibilities and Requirements

Responsibilities and requirements may 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.
- Comply with conditions listed on the Pathogen and Toxin Licence [*Human Pathogens and Toxins Act* 18(7)] [*Health of Animals Regulations* 160.1].
- Possess a valid [Human Pathogens and Toxins Act security clearance](#), if applicable.



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



Role

Conduct controlled activities under the authority of a Pathogen and Toxin Licence, under the direction of the Licence Holder.

Responsibilities and Requirements

Responsibilities and requirements may include, but are not limited to:

- Comply with conditions listed on the a Pathogen and Toxin Licence [*Human Pathogens and Toxins Act* 18(7)] [*Health of Animals Regulations* 160.1].
- Never obstruct the Biological Safety Officer when they are exercising their powers or when they are carrying out their functions [*Human Pathogens and Toxins Regulations* 4(1)(a)].
- Inform the Licence Holder/Licence Holder Representative without delay:
 - of any inadvertent release or production of a human pathogen or toxin [*Human Pathogens and Toxins Act* 15];
 - of any incident involving a human pathogen or toxin that has, or may have, caused disease in an individual [*Human Pathogens and Toxins Act* 15]; or
 - if a pathogen or toxin has been stolen or is otherwise missing [*Human Pathogens and Toxins Act* 15].
 - if any of these three types of human pathogen or toxin have been involved in an incident that is not referred in subsections 12(1), 12(2), 13, 14 or 14.1 of the *Human Pathogens and Toxins Act*, but that are specified in the *Human Pathogens and Toxins Regulations* [*Human Pathogens and Toxins Act* 15]:
 - a prescribed (meaning a Security Sensitive Biological Agent) risk group 3 human pathogen;
 - a risk group 4 human pathogen; or
 - a prescribed toxin (meaning a Security Sensitive Biological Agent).
- Inform the Licence Holder/Licence Holder Representative and the Biological Safety Officer 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 [*Human Pathogens and Toxins Regulations* 5].
- Notify the Biological Safety Officer before arrangements are made to do the following:
 - import or export a human pathogen or toxin [*Human Pathogens and Toxins Regulations* 4(1)(b)(i)];
 - receive a human pathogen or toxin from another facility [*Human Pathogens and Toxins Regulations* 4(1)(b)(ii)]; or



- transfer a human pathogen or toxin to another facility [*Human Pathogens and Toxins Regulations* 4(1)(b)(iii)].
- Notify the Biological Safety Officer, without delay, if:
 - human pathogens and toxins were not received within a reasonable time after it was expected to be received [*Human Pathogens and Toxins Regulations* 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 [*Human Pathogens and Toxins Regulations* 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 Pathogen and Toxin Licence [*Human Pathogens and Toxins Regulations* 4(1)(c)]; or
 - in a foreign country, the recipient will follow applicable biosafety and biosecurity standards and policies in the foreign jurisdiction [*Human Pathogens and Toxins Regulations* 4(1)(d)].
- When knowingly conducting controlled activities under the Human Pathogens and Toxins Act, all reasonable precautions must be taken to protect public health, safety and security against any risks posed by such activity or activities [*Human Pathogens and Toxins Act* 6].



Individuals conducting controlled activities with Security Sensitive Biological Agents

SSBA

Role

A Human Pathogens and Toxins Act security clearance is mandatory to enter (remotely or in person) the part of a facility in which controlled activities with prescribed pathogens or toxins (meaning Security Sensitive Biological Agents) are authorized.

A *Human Pathogens and Toxins Act* Security Clearance holder can only enter (remotely or in person) the parts of a facility for which they are authorized [*Human Pathogens and Toxins Act* 33.1(3)].

Responsibilities and Requirements

Responsibilities and requirements may 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 [Human Pathogens and Toxins Act security clearance](#) is valid and has not been withdrawn by the Licence Holder [*Human Pathogens and Toxins Act* 33].
- Notify the Centre for Biosecurity without delay, if ever convicted of a criminal offence [*Human Pathogens and Toxins Regulations* 19].
- Comply with conditions listed on the Pathogen and Toxin Licence [*Human Pathogens and Toxins Act* 18(7)] [*Health of Animals Regulations* 160.1].
- Comply with biosecurity plans, biosecurity policies, and procedures implemented for the part of a facility in which controlled activities with prescribed pathogens or toxins (meaning Security Sensitive Biological Agents) are authorized.
- Maintain confidentiality of documentation pertaining to controlled activities, as guided by information management and security policies of their facility [*Canadian Biosafety Standard, Third Edition* 4.9.3].
- Notify the Biological Safety Officer before preparing a shipment, or the transport of a prescribed pathogen or toxin (meaning a Security Sensitive Biological Agent) [*Human Pathogens and Toxins Regulations* 4(1)(b)].
- Notify the Biological Safety Officer, without delay, if the intended recipient of prescribed pathogens or toxins (meaning Security Sensitive Biological Agents) does not receive it within 24 hours after the expected date and time [*Human Pathogens and Toxins Regulations* 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 [*Canadian Biosafety Standard, Third Edition* 4.8.9].
- When knowingly conducting a controlled activity or activities under the Act, all reasonable precautions must be taken to protect public health, safety and security against any risks posed by such activity or activities [*Human Pathogens and Toxins Act* 6].