

Guidance for Organizations and Individuals regarding Canadian Residency Requirements under the *Human Pathogens and Toxins Act*

Introduction

This guidance document has been developed by the Public Health Agency of Canada’s Centre for Biosecurity to assist applicants and regulated parties in understanding the residency requirements when applying for, or holding, a Pathogen and Toxin Licence issued under section 18 of the *Human Pathogens and Toxins Act*.

Please note that the following requirements **do not apply** to applicants for, or holders of, a Pathogen and Toxin Licence that is issued **only** under section 160 of the [Health of Animals Regulations](#) by the Public Health Agency of Canada.

This document is not a substitute for the Act that is currently in effect. In the event of an inconsistency between this document and the Act, what is stated in the Act will prevail. You are advised to consult the applicable sections of the [Human Pathogens and Toxins Act](#).

Intent of the Canadian residency requirements under the *Human Pathogens and Toxins Act*

These requirements address a need to enhance oversight of controlled activities with human pathogens and toxins in Canada, and to facilitate compliance and enforcement activities. They ensure that key personnel associated with a Pathogens and Toxins Licence issued under the Human Pathogens and Toxins Act are ordinarily resident in Canada, and that the organizations are incorporated, formed or otherwise organized in Canada. Similar residency requirements exist in current Canadian federal legislation and align with established practices in other domains of health oversight (for example, [Cannabis Act](#), [Food and Drug Regulations](#)).

What You Need to Know

The [Pathogen and Toxin Licence application process](#) stays otherwise the same and Pathogen and Toxin Licences may still be held or applied for by individuals or organizations.

You need to know that the residency requirements impact applicants for a Pathogen and Toxin Licence as well as existing Licence Holders, Licence Holder Representatives and Biological Safety Officers.



For Organizations

It means that **organizations** applying for, or holding, a Pathogen and Toxin Licence must be incorporated, formed or otherwise organized in Canada. These organizations must also designate a Licence Holder Representative [*Human Pathogens and Toxins Act* 36.1] (in addition to the existing requirement to designate a Biological Safety Officer [*Human Pathogens and Toxins Act* 36]), and both their designated Licence Holder Representative and Biological Safety Officer must be ordinarily resident in Canada [*Human Pathogens and Toxins Act* 18(1.1)(b)].

To obtain documentation which confirms that your organization is incorporated, formed or otherwise organized in Canada, you can consult your organization's financial, accounting, legal, corporate services or human resources department.

For Individuals

If the applicant is an **individual**, they must still designate a Biological Safety Officer [*Human Pathogens and Toxins Act* 36], and both the applicant and the Biological Safety Officer must be ordinarily resident in Canada [*Human Pathogens and Toxins Act* 18(1.1)(a)].

For the purposes of the *Human Pathogens and Toxins Act*, an individual is considered ordinarily resident in Canada if they can establish they are regularly and customarily resident (apart from temporary or occasional absences) in a Canadian jurisdiction to which they have strong personal, economic and social ties. Such ties are to be maintained throughout the entire period that they exercise their duties and functions associated with a Pathogen and Toxin Licence issued by the Public Health Agency of Canada. The individual does not have to be a Canadian citizen or a permanent resident to meet this requirement.

Guidance for Possible Situations and Scenarios

To provide further targeted guidance, the following are some possible situations that applicants or existing regulated parties may find themselves in as of the day the amended *Human Pathogens and Toxins Act* comes into force.



Scenario 1: Planning to Apply for a Licence for the First Time

You plan to apply for a Pathogen and Toxin Licence for the first time but haven't submitted an application. Consult the [Pathogen and Toxin Licence application process](#) to learn more about how to apply for a Pathogen and Toxin Licence.

Once the Pathogen and Toxin Licence application has been submitted, the Licensing group will contact the applicant or the Licence Holder Representative by email — in a timely manner — to obtain applicable additional information and attestations.

If the applicant is an organization

- It must be incorporated, formed or otherwise organized in Canada;
- The application must include the designation of a Licence Holder Representative and a Biological Safety Officer that are both ordinarily resident in Canada and;
- They must provide proof **only** upon request by the Centre for Biosecurity;
- A Provincial, Territorial or Federal Business Number to confirm that the organization is incorporated, formed or otherwise organized in Canada, and a formal attestation from the designated Licence Holder Representative and Biological Safety Officer confirming that they are ordinarily resident in Canada will be requested. Please, consult your organization's financial, accounting, legal, corporate services or human resources department to obtain this information;
- You can also consult your provincial, territorial or federal authority to learn more about business number or for additional information visit:
 - [Incorporating in a specific province or territory](#)
 - [Incorporating federally](#)
- If your organization doesn't hold a Provincial, Territorial or Federal Business Number, please contact the Licensing group to discuss your options and if alternative proof or documentation can be considered.

If the applicant is an individual

- They can identify themselves as the Licence Holder and add their name in the Organization Name field of the Organization Information section when registering on the [Biosecurity Portal](#);
- The application must include the designation of a Biological Safety Officer and both the applicant and the Biological Safety Officer must be ordinarily resident in Canada and;
- They must provide proof **only** upon request by the Centre for Biosecurity;
- An attestation will be requested from both the applicant and designated Biological Safety Officer confirming they are ordinarily resident in Canada.

Validation

Be aware that once a Pathogen and Toxin Licence has been granted, at any time during the validity period of a Pathogen and Toxin Licence (for example during a virtual or on-site inspection, or upon request) residency compliance of the Licence Holder (individual), the Licence Holder Representative and the Biological Safety Officer can be verified. This means that, upon request, you will need to provide proof or documentation of being ordinarily resident in Canada.

If proof is requested by the Centre for Biosecurity

- Instructions for secure submission of documents will be provided;
- Accepted types of proof of being **ordinarily resident in Canada** include, but are not limited to:
 - driver's licence,
 - [certificate of residency issued by the Canada Revenue Agency](#),
 - [voter information card](#), or
 - any other types of valid identification document issued by a federal, provincial or territorial Canadian authority, with your current personal Canadian address.
- The examples of accepted types of proof listed above are not exhaustive, and alternatives can be considered. If you have questions about whether your documentation is satisfactory proof, please contact the Licensing group.

Note:

- If the individual Licence Holder, designated Licence Holder Representative and/or Biological Safety Officer do not meet the ordinarily resident in Canada requirement, alternate individuals that meet the residency requirement must be designated and the Centre for Biosecurity must be notified of that change without delay.
- Failure to comply with the requirements will result in a refusal to issue the Pathogen and *Toxin Licence* [*Human Pathogens and Toxins Act* 18(1.1)].



Scenario 2: Pending Licence Requests at Coming-into-Force

You have submitted one of the following, and it is in progress at the time the amended Act comes into force and are waiting for a response regarding:

- A new Pathogen and Toxin Licence application;
- A request to modify (vary) your current Pathogen and Toxin Licence; or
- A renewal for a Pathogen and Toxin Licence that does not expire within 30 days after the day the amended *Human Pathogens and Toxins Act* comes into force.

Any of these situations **will be subject to the new residency requirements** and reviewed to ensure compliance. The Licensing group will contact you by email — in a timely manner — to obtain applicable additional information and attestations.

If the applicant is an organization

- A Provincial, Territorial or Federal Business Number to confirm that the organization is incorporated, formed or otherwise organized in Canada, and a formal attestation from the designated Licence Holder Representative and Biological Safety Officer confirming that they are ordinarily resident in Canada will be requested.
- Please, consult your organizations financial, accounting, legal, corporate services or human resources department to obtain this information. You can also consult your provincial, territorial or federal authority to learn more about business number or for additional information visit:
 - [Incorporating in a specific province or territory](#)
 - [Incorporating federally](#)
- If your organization doesn't hold a Provincial, Territorial or Federal Business Number, please contact the Licensing group to discuss your options and if alternative proof or documentation can be considered.

If the applicant is an individual

An attestation will be requested from both the applicant and designated Biological Safety Officer confirming they are ordinarily resident in Canada.

Validation

Be aware that once a Pathogen and Toxin Licence has been granted, at any time during the validity period of a Pathogen and Toxin Licence (such as during a virtual or on-site inspection, or upon request) residency compliance of the Licence Holder (individual), the Licence Holder Representative and the Biological Safety Officer can be verified. This means that, upon request, you will need to provide proof or documentation of being ordinarily resident in Canada.

If proof is requested by the Centre for Biosecurity

- Instructions for secure submission of documents will be provided;
- Accepted types of proof of being **ordinarily resident in Canada** include, but are not limited to:
 - driver's licence,
 - [certificate of residency issued by the Canada Revenue Agency](#),
 - [voter information card](#), or
 - any other types of valid identification document issued by a federal, provincial or territorial Canadian authority, with your current personal Canadian address.
- The examples of accepted types of proof listed above are not exhaustive, and alternatives can be considered. If you have questions about whether your documentation is satisfactory proof, please contact the Licensing group.

Note:

- If the individual Licence Holder, designated Licence Holder Representative and/or Biological Safety Officer do not meet the ordinarily resident in Canada requirement, alternate individuals that meet the residency requirement must be designated and the Centre for Biosecurity must be notified of that change without delay.
- Failure to comply with the 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)].
- Under the amended *Human Pathogens and Toxins Act*, the Minister may only vary a licence if it poses no risk to the health, safety and security of the public and residency requirements are met. However, under section 19(1.1) and 19(1.2) of the *Human Pathogens and Toxins Act*, if you are not already in compliance with the residency requirements and if the Minister is of the opinion that exigent circumstances exist, the validity period of your Pathogen and Toxin Licence may be varied to allow for an extension of up to 90 days after the day on which the Pathogen and Toxin Licence was varied. This is a discretionary authority that can allow an existing Licence Holder to come into compliance with the residency requirements.
- If you believe that you or your organization may not be able to demonstrate that the requirements are met, please contact the Licensing group as soon as possible to discuss your options.

Scenario 3: Valid Licences Not Meeting Residency Requirements at Coming-into-Force

You have a valid Pathogen and Toxin Licence that does not expire within 30 days after the day the amended *Human Pathogens and Toxins Act* comes into force, but:

- The Licence Holder, the Licence Holder Representative and/or Biological Safety Officer do not meet the residency requirements; and
- A request for renewal or modification (variation) of the licence has not been made.

The Licence Holder, the Licence Holder Representative and Biological Safety Officer associated with a Pathogen and Toxin Licence that is not expiring within 30 days after the day the amended *Human Pathogens and Toxins Act* comes into force are not required to demonstrate the residency requirements until an application for a new licence, licence renewal or variation is submitted, or a request is made from the Centre for Biosecurity.

However, it is important to ensure that the Licence Holder, the designated Licence Holder Representative and Biological Safety Officer meet the residency requirements at all times. Otherwise, failure to comply with the requirements may result in the suspension or revocation of an active Pathogen and Toxins 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)].

Validation

Be aware that once a Pathogen and Toxin Licence has been granted, at any time during the validity period of a Pathogen and Toxin Licence (for example, during a virtual or on-site inspection, or upon request) residency compliance of the Licence Holder (individual), the Licence Holder Representative and the Biological Safety Officer can be verified. This means that, upon request, you will need to provide proof or documentation of being ordinarily resident in Canada.



If proof is requested by the Centre for Biosecurity

- Instructions for secure submission of documents will be provided;
- Accepted types of proof of being **ordinarily resident in Canada** include, but are not limited to:
 - licence,
 - [certificate of residency issued by the Canada Revenue Agency](#),
 - [voter information card](#), or
 - any other types of valid identification document issued by a federal, provincial or territorial Canadian authority, with your current personal Canadian address.
- Accepted types of proof of being **incorporated, formed or otherwise organized in Canada** include, but are not limited to a:
 - Provincial,
 - Territorial, or
 - Federal Business Number
- Please, consult your organizations financial, accounting, legal, corporate services or human resources department to obtain this information. You can also consult your provincial, territorial or federal authority to learn more about business number or for additional information visit:
 - [Incorporating in a specific province or territory](#)
 - [Incorporating federally](#)
- The examples of accepted types of proof listed above are not exhaustive, and alternatives can be considered. If you have questions about whether your documentation is satisfactory proof, please contact the Licensing group.

Note:

- Under the amended *Human Pathogens and Toxins Act*, the Minister may only vary a licence if it poses no risk to the health, safety and security of the public and residency requirements are met. However, under section 19(1.1) and 19(1.2) of the *Human Pathogens and Toxins Act*, if you are not already in compliance with the residency requirements and if the Minister is of the opinion that exigent circumstances exist, the validity period of your Pathogen and Toxin Licence may be varied to allow for an extension of up to 90 days after the day on which the Pathogen and Toxin Licence was varied. This is a discretionary authority that can allow an existing Licence Holder to come into compliance with the residency requirements.
- If you believe that you or your organization **do not meet** requirements, please contact the Licensing group as soon as possible.

Scenario 4: Licence expiring within 30 days of Coming-into-Force

Your Pathogen and Toxin Licence will expire within 30 days after the day the amended *Human Pathogens and Toxins Act* comes into force and does not meet the residency requirements.

If your Pathogen and Toxin Licence is set to expire within 30 days after the day the amended *Human Pathogens and Toxins Act* comes into force and you believe that you or your organization does not meet the requirements, **please contact the Licensing group as soon as possible**.

In such a circumstance, the validity period of your Pathogen and Toxin Licence may be extended for up to 60 days starting from the date the amended *Human Pathogens and Toxins Act* comes into force. The transitional provision 56 of the amended *Human Pathogens and Toxins Act* is intended to provide that specific group of Licence Holders additional time to meet the residency requirements introduced by the amended *Human Pathogens and Toxins Act*. Afterward, it will be mandatory to comply with the residency requirements at all times. Otherwise, failure to comply with the 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)].

Note:

This temporary measure will no longer apply starting on the 31st day after the amended *Human Pathogens and Toxins Act* comes into force.