PUBLIC HEALTH AGENCY OF CANADA

Program: Human and Terrestrial Animal Pathogens & Biological Toxins

LIVINGSTON
Simplify Trade

PGA: Public Health Agency of Canada

Program: Human and Terrestrial Animal Pathogens & Biological Toxins

The Public Health Agency of Canada (PHAC) is responsible for biosafety regulation (anticipating and averting public health threats), biosafety information (reducing risks and promoting professional practices), and biosafety expertise (providing technical advice and tools to biosafety stakeholders).

The Public Health Agency of Canada (PHAC) regulates human pathogens and toxins under the authority of the Human Pathogens and Toxins Act (HPTA) and associated Regulations (HPTR). Controlled activities (e.g., using, storing, importing) with human pathogens that are classified as Risk Group 2-4, or with toxins listed in Schedule 1 of the HPTA, require a licence, issued by PHAC. PHAC is also responsible for issuing permits for the importation or transfer of pure cultures of terrestrial animal pathogens and toxins under the authority of the Health of Animals Regulations (HAR).

PHAC is also responsible for the administration of certain provisions of the Health of Animals Act and Health of Animals Regulations (HAA/HAR). It issues import permits and transfer authorizations for most terrestrial animal pathogens (excluding aquatic animals, bees, invertebrates and pathogens that cause emerging or foreign animal diseases).

Regulated goods: Pathogens & Biological Toxins

Documents required

- License
- Acknowledgment letter

Commercial importations

Importers or the person in possession, or care and control of the goods are responsible for ensuring that their goods comply with the requirements of all government departments and agencies prior to importation into Canada.

Implementation of the CBSA Single Window Initiative (SWI)

Under the Single Window Initiative, release requests will be submitted utilizing a new Integrated Import Declaration (IID) that allows custom brokers to submit and obtain electronic release for goods also regulated by participating department and agencies.

Release requests for regulated goods under all the programs may be provided to the CBSA electronically by submitting an IID and Document Image Functionality (DIF), License, Permit, Certificate and other documents (LPCO) and UNDG code. The IID must include the following information:

a. Pathogens & Toxins Licence
b. Letter Acknowledging Receipt of a Licence Application
c. Exception/Intended End-Use
d. United Nations Dangerous Goods (UNDG) code
e. Canadian Product Category (risk group)

Note: Under SWI, information requirements will remain the same. There are no additional data requirements for the import process.

Harmonized System (HS) Codes

Listing of HS codes, which may be applicable to the PHAC programs:
https://www.cbsa-asfc.gc.ca/prog/sw-gu/regcom-marreg/phac-aspc-eng.html

Data Element Rationales

The following data element rationales provide additional information of the specific data element requirements required under the Single Window Initiative Public Health Agency of Canada (PHAC) for regulated Pathogens & Biological Toxins.

Importer Contact Name	Required to be able to contact the importer in the event additional information is needed to make admissibility or release decision.
Importer Contact Telephone Number	Required to be able to contact the importer in the event additional information is needed to make admissibility or release decision.
Importer Contact Email Address	Required to be able to contact the importer in the event additional information is needed to make admissibility or release decision.
LPCO Type / Authorization Type	Facilities importing pathogens and toxins into Canada must have a valid Pathogens and Toxins Licence or Letter Acknowledging the Receipt of a Licence Application issued by PHAC as per the Human Pathogens and Toxins Act and Health of Animals Act and Regulations. As such, importers must provide their authorization type and number so that it can be verified against the PHAC issued Licences.
File	This field is optional and provides the importer the ability to attach files related to the imported material and this may assist PHAC in making a release decision.
Effective Date	Pathogen and Toxins Licences and Letters Acknowledging the Receipt of a Licence Application have effective and expiry dates. Requesting this information from the importer and verifying it against the PHAC licence data provides an additional level of assurance that the importer possesses a valid licence to import the goods.
Expiry Date	Pathogen and Toxins Licences and Letters Acknowledging the Receipt of a Licence Application have effective and expiry dates. Requesting this information from the importer and verifying it against the PHAC licence data provides an additional level of assurance that the importer possesses a valid licence to import the goods.
Exception Process	Certain facilities may be conducting activities that are exempt from the Human Pathogens and Toxins Act or excluded from the licencing requirement under the regulations. This data element allows importers to identify that they are exempt or excluded and therefore do not need a licence to import.
Intended Use	The intended use of a Pathogen or Toxin combined with the product category will impact whether PHAC authorizes the import of a good or not. For instance, PHAC will not authorize the import of a pathogen that falls within the product categories of RG3 or RG4 if the intended use is for education and resale purposes.
UNDG	The UNDG code is optional but useful in understanding the nature of the imported pathogen or toxin. This may help PHAC when making a release decision.
Commodity Type	The type of Pathogen and Toxin Licence issued by PHAC is based on the risk group (i.e. product category) the facility is authorized to conduct controlled activities with, including import. The Canadian product category is an essential piece of information that will allow the determination as to whether the importer has the appropriate licence type to import the goods.

Intended use and Program conditions for Consumer Products

Commodities regulated by Public Health Agency of Canada's Human & Terrestrial Animal Pathogens & Biological Toxins Program are subject to HS classification control and specific intended use provisions, the following are the applicable intend use conditions:

Intended use	Description
PH01	PHAC - Generic - Educational Purposes
PH02	PHAC - Generic - Diagnostic Purposes
PH03	PHAC - Generic - Emergency Use
PH04	PHAC - Generic - Quality Control Purposes
PH05	PHAC - Generic - Research or Scientific Use
PH06	PHAC - Generic - Resale

Electronic Commerce Client Requirements Document (ECCRD)

The following table provides the specific rules and conditions associated to each of the data elements (for PHAC). The data elements are: Mandatory (M), Conditional (C) or Optional (O).

Data element name	PGA element definition	Data element status	Data element rules and conditions
Contact Identification	Importer Contact Name	M	For The Public Health Agency of Canada, an importer contact name must be provided for this declaration.
Contact Method	Importer Contact Telephone Number	C	For The Public Health Agency of Canada, either an importer contact telephone number or a contact email address must be provided.
Contact Method	Importer Contact Email Address	C	For The Public Health Agency of Canada, either an importer contact email address or a contact telephone number must be provided.
Document Type (Licence, Permit, Certificate, Other)	LPCO/ Authorization Type	C	The coded identifier of applicable document types being provided at the declaration level must be provided in this field. Document types provided here must be applicable to all commodities on this declaration. If not applicable to all commodities, please provide the document types at the commodity line level (SG121). Acceptable documents types depend on the Intended Use (SG117 APP) and Canadian Product Category (SG117 PGI) provided. Refer to Appendix A for Intended Use Codes, Canadian Product Categories, and Document Types.

Document Reference Number	LPCO Number	C	For each document provided at the declaration level, an associated reference number related to that document must be provided. Refer to Appendix B for Reference Type and Reference Number.
Document Source Description	File	O	For each document provided at the declaration level, it is strongly recommended to provide an image of the document that can be accessed by qualified CBSA and PHAC employees. Providing an image will improve communication in case of a referral and generally expedite processing of this declaration.
LCPO Effective Date	Effective Date	C	For each Licence Number provided at the declaration level, the date on which the Pathogen and Toxin Licence became effective must be provided.
LCPO Expiry Date	Expiry Date	C	For each Licence Number provided at the declaration level, the date on which the Pathogen and Toxin Licence expires must be provided.
PGA Exception Processes	Exception Processes	C	Specific activities related to the importations of pathogens and biological toxins may be exempted under the Human Pathogens and Toxins Regulations. Use the following code: PHAC – Exempt Pathogen/Toxin. Exempted activities are not required to provide LPCO information (SG9 and/or SG121).
Intended Use Code	Intended Use	M	The intended end-use of the commodity must be provided. Depending on the intended end-use code, additional details are required. Refer to Appendix C for Intended Use Codes, Canadian Product Categories, and Document Types.
Commodity Identifier	UNDG	O	Imported pathogens and biological toxins can be identified through the UNDG (United Nations Dangerous Goods) Code. Although not required, this information would allow a clearer identification of the product and may expedite processing in case of a referral. The qualifier for United Nations Dangerous Goods (UNDG) Code must be provided in the 7402, 2 field.
Canadian Product Category	Commodity Type	M	A Canadian Product Category must be provided: • Risk Group 1 (RG1) Pathogen • Risk Group 2 (RG2) Pathogen • Risk Group 3 (RG3) Pathogen • Risk Group 4 (RG4) Pathogen • Biological Toxin • Inactivated Biological Toxin The qualifier for field 5389 must be the code for PHAC.

Document Type (Licence, Permit, Certificate, Other)	LPCO / Authorization Type	C	The coded identifier of any applicable document must be provided in this field if applicable to a specific commodity line entry. If applicable to all commodities, please provide the documents at the declaration level (SG9). Acceptable documents types depend on the Intended Use (SG117 APP) and Canadian Product Category (SG117 PGI) provided. Refer to Appendix D for Intended Use Codes, Canadian Product Categories, and Document Types.
Document Reference Number	LPCO Number	C	For each document provided at the commodity line level, an associated reference number related to that document must be provided. Refer to Appendix B for Reference Type and Reference Number.
LCPO Effective Date	Effective Date	C	For each PHAC Licence Number provided at the commodity line level, the date on which the Pathogen and Toxin Licence
LCPO Expiry Date	Expiry Date	C	For each PHAC Licence Number provided at the commodity line level, the date on which the Pathogen and Toxin Licence expires must be provided.
Document Source Description	File	O	For each document provided at the commodity line level, it is strongly recommended to provide an image of the document that can be accessed by qualified CBSA and PHAC employees. Providing an image will improve communication in case of a referral and generally expedite processing of this declaration.

Additional resources

Regulated Commodities
Reference Code Tables

Legislation:
Human Pathogens and Toxins Act (HPTA): **http://lois-laws.justice.gc.ca/eng/acts/H-5.67/FullText.html**

Lists of Acts and Regulations:
Human Pathogens and Toxins Regulations:
http://laws.justice.gc.ca/eng/regulations/SOR-2015-44/index.html

Canadian Biosafety Standards and Guidelines:
https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines.html

Appendix A: Intended Use Codes, Canadian Product Categories, and Document Types

Intended Use Code	Canadian Product Category (SG117 PGI)	Document Type(s) (SG9 or SG121)
Diagnostic Purposes	Biological Toxin OR Risk Group 2 (RG2), 3 (RG3) OR 4 (RG4) Pathogen	Pathogen and Toxin Licence
	Inactivated Biological Toxin OR RG1 Pathogen	None required
Educational Purposes	Biological Toxin OR RG2 Pathogen	Pathogen and Toxin Licence
	Inactivated Biological Toxin OR RG1 Pathogen	None required
Emergency Use	Biological Toxin OR RG2, RG3 OR RG4 Pathogen	Pathogen and Toxin Licence
	Inactivated Biological Toxin OR RG1 Pathogen	None required
Quality Control Purposes	Biological Toxin OR RG2, RG3 OR RG4 Pathogen	Pathogen and Toxin Licence
	Inactivated Biological Toxin OR RG1 Pathogen	None required
Research or Scientific Use	Biological Toxin OR RG2, RG3 OR RG4 Pathogen	Pathogen and Toxin Licence
	Inactivated Biological Toxin OR RG1 Pathogen	None required
Resale	Risk Group 2 (RG2) OR Biological Toxin	Pathogen and Toxin Licence
	Risk Group 1 (RG1) OR Inactivated Biological Toxin	None required

Appendix B: Reference Type and Reference Number

Document Type	Reference Number
Pathogen and Toxin Licence	Licence Number

Appendix C: Intended Use Codes, Canadian Product Categories, and Document Types		
Intended Use Code	**Canadian Product Category (SG117 PGI)**	**Document Type(s) (SG9 or SG121)**
Educational Purposes	Biological Toxin OR RG2 Pathogen	Pathogen and Toxin Licence
	Inactivated Biological Toxin OR RG1 Pathogen	None required
Diagnostic Purposes	Biological Toxin OR Risk Group 2 (RG2), OR 3 (RG3) OR 4 (RG4) Pathogen	Pathogen and Toxin Licence
	Inactivated Biological Toxin OR RG1 Pathogen	None required
Emergency Use	Biological Toxin OR RG2, OR RG3 OR RG4 Pathogen	Pathogen and Toxin Licence
	Inactivated Biological Toxin OR RG1 Pathogen	None required
Quality Control Purposes	Biological Toxin OR RG2, OR RG3 OR RG4 Pathogen	Pathogen and Toxin Licence
	Inactivated Biological Toxin OR RG1 Pathogen	None required
Research or Scientific Use	Biological Toxin OR RG2, OR RG3 OR RG4 Pathogen	Pathogen and Toxin Licence
	Inactivated Biological Toxin OR RG1 Pathogen	None required
Resale	Risk Group 2 (RG2) OR Biological Toxin	Pathogen and Toxin Licence
	Risk Group 1 (RG1) OR Inactivated Biological Toxin	None required

Appendix D: Intended Use Codes, Canadian Product Categories, and Document Types		
Intended Use Code	**Canadian Product Category (SG117 PGI)**	**Document Type(s) (SG9 or SG121)**
Diagnostic Purposes	Biological Toxin OR Risk Group 2 (RG2), 3 (RG3) OR 4 (RG4) Pathogen	Pathogen and Toxin Licence
	Inactivated Biological Toxin OR RG1 Pathogen	None required
Educational Purposes	Biological Toxin OR RG2 Pathogen	Pathogen and Toxin Licence
	Inactivated Biological Toxin OR RG1 Pathogen	None required
Emergency Use	Biological Toxin OR RG2, RG3 OR RG4 Pathogen	Pathogen and Toxin Licence
	Inactivated Biological Toxin OR RG1 Pathogen	None required

Quality Control Purposes	Biological Toxin OR RG2, RG3 OR RG4 Pathogen	Pathogen and Toxin Licence
	Inactivated Biological Toxin OR RG1 Pathogen	None required
Research or Scientific Use	Biological Toxin OR RG2, RG3 OR RG4 Pathogen	Pathogen and Toxin Licence
	Biological Toxin OR RG2, RG3 OR RG4 Pathogen Inactivated Biological Toxin OR RG1 Pathogen	None required
Resale	Risk Group 2 (RG2) OR Biological Toxin	Pathogen and Toxin Licence
	Risk Group 1 (RG1) OR Inactivated Biological Toxin	None required

Contact Livingston

Have questions or need help with your SWI imports?
Contact your Livingston client services representative.
Write to us at: **clientserviceCanada@livingstonintl.com** or give us a call at **1-855-225-5544**.