HEALTH CANADA

Program: Cells, Tissues and Organs

LIVINGSTON
Simplify Trade

PGA: Health Canada

Program: Cells, Tissues and Organs

Implementation of the CBSA Single Window Initiative (SWI)

The Canada Border Services Agency (CBSA) assists Health Canada in administering Food and Drugs Act and regulations.

These activities apply to all drugs and devices as defined by the Food and Drug Act, including cells, tissues and organs for transplantation.

Human Cells Tissues and Organs (CTO) are regulated by Health Canada under the authority of the Food and Drugs Act and the Safety of Human Cells, Tissues and Organs for Transplantation Regulations.

Under SWI, release requests will be submitted utilizing new LPCO requirements.

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

Definitions

Under Safety of Human Cells, Tissues and Organs for Transplantation Regulations a cell means the fundamental biological unit of a human organism that is for use in transplantation;

organ means a perfusable human organ for use in transplantation, whether whole or in parts, and whose specific function is intended to return after revascularization and reperfusion. It includes any adjunct vessels that are retrieved with the organ for use in organ transplantation and,

tissue means a functional group of human cells for use in transplantation. It includes the cells and tissues listed in the definition tissue in section 3.1 of the general standard.

The Establishment Registration Number for CTO is a six (6) digit numerical code beginning in a one (1) assigned to an approved establishment under the Safety of Human Cells, Tissues and Organs for Transplantation Regulations.

Under the Safety of Human Cells, Tissues and Organs for Transplantation Regulations a Source Establishment for CTO includes:

a. Subject to paragraph (b), in the case of an organ from a deceased donor, the relevant organ donation organization;
b. In the case of adjunct vessels that are retrieved with an organ and not used immediately in the organ transplantation, the relevant tissue bank;
c. In the case of an organ from a living donor or lymphohematopoietic cells that are not banked, the relevant transplant establishment;
d. In the case of tissues or banked lymphohematopoietic cells, the relevant cell or tissue bank; &
e. In the case of islet cells, the establishment that prepares the cells for use in transplantation.

Links to the regulations and guidance documents are listed in the Reference Section of this document.

Harmonized System (HS) Codes

The HS Classification numbers for Cells, Tissues and Organs include those listed under heading 3001 and/or 3002.

A complete list of HS codes and ranges applicable to goods regulated by Health Canada (including Cells, Tissues and Organs) is found at **https://www.cbsa-asfc.gc.ca/prog/sw-gu/regcom-marreg/hc-sc-eng.html**

Data Element Rationales

The following data element rationales provide additional information of the specific data element requirements under the Single Window Initiative.

Importer Contact Name	PGAs to contact the importer for IID clarification.
Importer Contact Telephone Number	PGAs to contact the importer for IID clarification.
Importer Contact Email Address	PGAs to contact the importer for IID clarification.
LPCO Type / Authorization Type	Importer must ensure that the product meets the appropriate licensing type to be imported.
LPCO Number	Importer must ensure that the product has a valid licensing number demonstrating its authorization for sale/use in Canada as applicable (DIN, No Objection Letter, etc.)
File	Optional but allows for clearer identification of the product and may ease need for referral.
Exception Process	Importer to indicate exception from the licensing requirements if applicable. For example, importers of medical devices do not require a Medical Device Drug Establishment if they are retailers, clinics, etc. In addition, lymphophematopoietic cells and organs do not need to be processed by a registered establishment.
GTIN Number	Optional but allows for clearer identification of the product and may ease need for referral.
Intended Use	The Intended Use, declared by the broker/importer, will impact the LPCO Type and LPCO Reference Number.
Commodity Type	The Commodity type, declared by the broker/importer, will impact the LPCO Type and LPCO Reference Number.
Expiry Date	Identifies any concern with use.

Intended use and Program conditions for Cells, Tissues and Organs:

Intended use	**Description**
HC01	HC01 - Generic - Human Therapeutic Use

Electronic Commerce Client Requirements Document (ECCRD)

The following table provides the specific rules and conditions associated to each of the data elements for HC Declarations. 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 Health Canada, an importer contact name must be provided for this declaration.
Contact method	Importer Contact Telephone Number	C	For Health Canada, either an importer contact telephone number or an importer contact e-mail address must be provided.
Contact method	Importer Contact Email Address	C	For Health Canada, either an importer contact telephone number or an importer contact e-mail address must be provided.
Document Type (Licence, Permit, Certificate, Other)	LPCO Type/ 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 a list of document types, intended uses and Canadian product categories.
Document Reference Number	LPCO Number	C	For each document provided at the declaration level, the associated reference number related to that document must be provided. Refer to Appendix B for Document Types and the associated Reference Number.
Document Source Description	File	O	For each document provided at the declaration level, it is strongly recommended to provide an image that can be accessed by qualified CBSA and Health Canada employees. Providing an image may improve communication in case of a referral.
PGA Exception Processes	Exception Processes	C	ndicate any exceptional processing required for this transaction. The Specific HC exceptional processing that applies to cells, tissues and organs is: • Lymphohematopoietic cells and organs Lymphohematopoietic cells and organs are exempt from having to provide Establishment Registration Numbers. (SG9 and SG121)

Product Identifier	GTIN Number	O	Cells, Tissues and Organs, can be identified through their GTIN GS1 Asset Identifier. Although not required, this information would allow a clearer identification of the product and facilitate communication in case of referrals. The qualifier for GS1 Global Trade Identification Number (GTIN) must be provided in the 7402, 2 field.
Intended End Use	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 A for list of intended end-use and required additional details.
Canadian Product Category	Commodity Type	M	A Canadian Product Category must be provided depending on the Intended End-Use Code entered in SG117 APP. Refer to Appendix C for the Intended Use and Canadian Product Category. The qualifier for field 5389 should be the code for HC – Cells Tissues Organs.
Production/ Expiry Date	Expiry Date	O	It is strongly recommended to provide the Expiry Date for Tissues. If a format without time zone information is provided the time must be in CBSA Headquarters time (EST, e.g., GTM -5).
Document Type (Licence, Permit, Certificate, Other)	LPCO Type/ 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). Refer to Appendix A for a list of document types, intended uses and Canadian product categories.
Document Reference Number	LPCO Number	C	For each document provided at the commodity level, the associated reference number related to that document must be provided. Refer to Appendix B for Document Types and the associated Reference Number.
Document Source Description	File	O	For each document provided at the commodity level, it is strongly recommended to provide an image that can be accessed by qualified CBSA and Health Canada employees. Providing an image may improve communication in case of a referral.

Additional resources

Regulated Commodities:

Reference Code Tables

Legislation:

For more information on the importation of Human Cell Tissues and Organs for Transplantation, refer to Health Canada's website in the **Guidance Document on the Import Requirements for Health Products under the Food and Drugs Act and its Regulations.**

The **Safety of Human Cells, Tissues and Organs for Transplantation Regulations** contains additional definitions and clarification.

For links concerning the Importation and Exportation - Compliance and Enforcement - Drugs and Health Products see Health Canada's website at: **https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation.html**

Appendix A: Document types, intended uses and Canadian product categories

Intended Use	Canadian Product Category	Document Type(s)
Human Therapeutic Use	Cells	Importer Establishment Registration (optional) AND Exporter Establishment Registration (optional)
Human Therapeutic Use	Tissues	Exporter Establishment Registration (mandatory) AND Importer Establishment Registration (optional)
Human Therapeutic Use	Organs	Importer Establishment Registration (optional) AND Exporter Establishment Registration (optional)

Appendix B: Document type and reference number

Document Type	Reference Number
Importer Establishment Registration	Importer Establishment Registration Number
Exporter Establishment Registration	Exporter Establishment Registration Number

Appendix C: Intended use and Canadian product category	
Intended Use	**Canadian Product Category**
Human Therapeutic Use	Cells
Human Therapeutic Use	Tissues
Human Therapeutic Use	Organs

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**.