HEALTH CANADA

Program: Donor Semen

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PGA: Health Canada

Program: Donor Semen

Implementation of the CBSA Single Window Initiative (SWI)

Semen for Assisted Conception is regulated by Health Canada under the authority of the Food and Drugs Act and the Processing and Distribution of Semen for Assisted Conception Regulations.

The Canada Border Services Agency (CBSA) assists Health Canada with the administration of **The Food and Drugs Act** as well as regulations made thereunder.

Under the Single Window Initiative, release requests will be submitted via the Integrated Import Declaration (IID), which allows custom brokers to submit and obtain electronic release for goods also regulated by participating department and agencies. Release requests for donor semen may be provided to the CBSA electronically by submitting an IID. The physical presentation of a signed declarations or Letters of Authorization (LOA) is no longer needed when using the SWI IID process.

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

About the Donor Semen Special Access Program

The Donor Semen Special Access Program (DSSAP) is a special access program, via Part 2 of the **Processing and Distribution of Semen for Assisted Conception Regulations**, which provides access, in exceptional circumstances, to donor semen that has not been processed in accordance with the Regulations. If authorization is granted, Health Canada will provide a Letter of Authorization (LOA) to the exporter, which must accompany the shipment.

The chart below includes the special documentation requirements for the importation of Semen for Assisted Conception:

Product	Health Canada requirements
Importer's Contact Email	Semen imported for distribution must meet the requirements of the Semen Regulations. Importers must notify Health Canada 10 days in advance of commencing importation. The shipment must have the name and business address of the foreign processor on the outer shipping container, as well as a signed declaration certifying that the semen has been processed in accordance with the Processing and Distribution of Semen for Assisted Conception Regulations and quarantined for a minimum of six months.
Importer Contact Email	A Letter of Authorization (LOA), issued by the Biologics and Genetics Therapies Directorate (BGTD) of Health Canada, must accompany the shipment. In addition, the outer shipping container must clearly display the name and business address of the foreign processor, as well as an indication that the semen may only be distributed in accordance with the authorization.

Harmonized System (HS) Codes

List of HS codes applicable to goods/substances that may be regulated by Health Canada:
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.
File	Optional but allows for clearer identification of the product and may ease need for referral
Commodity Type	The Commodity type, declared by the broker/importer, will impact the LPCO Type and LPCO Reference Number.
Intended Use	The Intended Use, declared by the broker/importer, will impact the LPCO Type and LPCO Reference Number.
LPCO Type / Authorization Type	Importer must ensure that the product meets the appropriate licensing type to be imported.
File	Optional but allows for clearer identification of the product and may ease need for referral
Processor Declaration	Required labelling requirement

Intended use and Program conditions for Donor Semen:

Intended use	**Description**
HC01	HC01 – Generic – Human Therapeutic Use
HC02	HC02 – Generic – Special Access

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. Please refer to Appendix A for acceptable document types and intended use.
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. Please refer to Appendix B for document types and associated reference numbers.
Document Source Description	File	C	If provided at the declaration level, the unique identifier of a related image for the following documents must be provided: • HC – Semen Processor Declaration • HC – Donor Semen Letter of Authorization (LOA)
Canadian Product Category	Commodity Type	M	A Canadian Product Category must be provided depending on the Intended End-Use Code entered in SG117 APP. The Canadian Product Category for intended use (SG117 APP: Human Therapeutic Use and Special Access) is: Donor Semen The qualifier for field 5389 should be the code for HC – Donor Semen
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. Please refer to Appendix A for additional details.
Document Type (License, 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 document types depend on the Intended Use (SG117 APP) and Canadian Product Category (SG117 PGI) provided. Please refer to Appendix A for acceptable document types.
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. Please refer to Appendix B for document types and associated reference numbers.

Document Source Description	File	C	If provided at the declaration level, the unique identifier of a related image for the following documents must be provided: • HC – Semen Processor Declaration • HC – Donor Semen Letter of Authorization (LOA)
PGA Compliance Statement	Processor Declaration	C	For importations intended for human therapeutic use (SG117 APP), the code indicating the semen processor's certification of the product (as indicated below) must be provided. "The outer shipping container in which the semen is transported displays clearly, on the outside surface of that container, a declaration, signed by the processor or an authorized agent of the processor, certifying that the semen has been processed in accordance with the Processing and Distribution of Semen for Assisted Conception Regulations and quarantined for a minimum of six months."

Additional Resources

Reference Code Tables

Legislation

Importation of Donor Semen is referred to in **The Food and Drugs Act** and the Processing and **Distribution of Semen for Assisted Conception Regulations**

Health Canada Guidance Document

Guidance Document on the Import Requirements for Health Products under the Food and Drugs Act and its Regulations (GUI-0084)

Appendix A: Document types and intended uses

Intended Use	Canadian Product Category (SG117 PGI)	Document Type(s) (SG9 or SG121)
Human Therapeutic Use	Donor Semen	Semen Processor Declaration
Special Access	Donor Semen	Donor Semen Letter of Authorization (LOA)

Appendix B: Document types and reference numbers

Document Type(s)	Reference Number
Semen Processor Declaration	(none) Provide generic LPCO Number 'XXX'
Donor Semen Letter of Authorization (LOA)	(none) Provide generic LPCO Number 'XXX'

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**.

www.livingstonintl.com

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