FRM-0448: Sperm and ova establishment notification form

When to use this form

Prior to importing or distributing sperm or ova for the purpose of assisted human reproduction (AHR), establishments must submit a notification to Health Canada as per section 18 of the *Safety of Sperm and Ova Regulations* (Safety Regulations).

This form must be completed by establishments that intend to import or distribute in Canada donor sperm or ova for the purpose of AHR to comply with the notification requirements under the Safety Regulations. Notifications under section 18 of the Safety Regulations apply to activities conducted in Canada, therefore establishments distributing or importing sperm or ova for the purpose of AHR outside of Canada are not required to notify. You will find Instructions on how to complete the sperm and ova establishment notification form at the end of this form. For any questions or clarifications, please email the Biological Product Compliance Program ahrregistration-enregistrementpa@hc-sc.gc.ca

Privacy notice

The personal information you provide to Health Canada will be used by the Biological Product Compliance Program under the Safety of Sperm and Ova Regulations *under the Assisted Human Reproduction Act* and handled in accordance with the *Privacy Act* (https://laws-lois.justice.gc.ca/ENG/ACTS/P-21/index.html).

Why are we collecting your personal information? We require your personal information to administer the Safety of Sperm and Ova Regulations under the *Assisted Human Reproduction Act*.

Will we use or share your personal information for any other reason? In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*.

What happens if you don't want to provide your personal information? Failure to provide the requested information will result in delays in processing your request and may result in the refusal of your application.

What are your rights? You have the right to access and request a correction and/or notation to your personal information. You also have a right to complain to the Privacy Commissioner of Canada if you feel your personal information has been handled improperly. For more information about these rights, or about how we handle your personal information, please contact the Biological Product Compliance Program.

For more information: The collection of your personal information is described in Info Source at infosource.gc.ca. A Personal Information Bank is under development and will be included on Info Source.

Pub: 210659

Canada

Depending on the type of application, fields indicated with an asterisk (*) may be mandatory

Part 1: Type of notification *

Initial notification for importation and/or distribution (complete parts 2 and 3)

☐ **Initial notification**: Select this if you are submitting a notice to Health Canada that your establishment intends to import or distribute donor sperm or ova for the purpose of AHR (refer to section 18 of the Safety Regulations for more information).

Establishments that have already notified and wish to amend their notification** (complete parts 2 and 3)

☐ **Add importation or distribution**: Select this if you intend to begin conducting a new activity (importation/ distribution) subject to section 18 notification requirements under the Safety Regulations.

☐ **Add a new gamete**: Select this if you import or distribute for one of sperm or ova and intend to begin importing or distributing the other subject to section 18 notification requirements under the Safety Regulations.

**A notification to add a new activity or gamete must be submitted using this form prior to the commencing of these activities.

Change of information (complete parts 2 and 3)

☐ **Submit a change of information**: Select this if you previously notified Health Canada and wish to modify the information provided. This change must be submitted within 30 days of the change (refer to section 19 of the Safety Regulations for more information).

Notice of cessation for notification (complete parts 2A and 4)

☐ **Cessation of activities**: Select this if you have ceased all importation or distribution activities at your establishment. This change must be submitted within 30 days of the change, refer to section 19 of the Safety Regulations for more information.

Part 2: Notification of importation or distribution activities *

A) Establishment information

Establishment name:		
Previous name(s) of the establishment (if applicable):		
Registration number (if you are also a primary establishment):		

Civic address

Building name (if applicable):		
Street number:	Street name:	Suite:
City:	Province/State:	Postal/Zip Code:
Country:		

Mailing address

☐ same as above

Street number/ P.O box:	Street name:	Suite:
City:	Province/State:	Postal/Zip code:
Country:		

Primary contact information

Contact's first name, last name and title:	Language: ☐ English ☐ French
Telephone:	E-mail:

Emergency contact information (if different from primary contact)

Contact's first name, last name and title:	Language: ☐ English ☐ French
Telephone:	E-mail:

B) Activities and building information

Select all activities that your establishment conducts. Please submit a separate entry for Part B for each building where activities are conducted.

Address where activities are conducted

☐ same as above

Building name (if applicable):		
Street number:	Street name:	Suite:
City:	Province/State:	Postal/Zip code:
Country:		

Activities	Gamete	
	Sperm	Ova
Distributing	☐	☐
Projected start date (yyyy-mm-dd)		
Importing	☐	☐
Projected start date (yyyy-mm-dd)		

C) Primary establishment that processes the sperm or ova that you are importing or distributing.

Repeat this part C as needed.

Primary establishment name	Registration number	Activities	
		Distribution	Importation
		☐ Sperm ☐ Ova	☐ Sperm ☐ Ova
		☐ Sperm ☐ Ova	☐ Sperm ☐ Ova
		☐ Sperm ☐ Ova	☐ Sperm ☐ Ova
		☐ Sperm ☐ Ova	☐ Sperm ☐ Ova
		☐ Sperm ☐ Ova	☐ Sperm ☐ Ova
		☐ Sperm ☐ Ova	☐ Sperm ☐ Ova

D) List any third parties that facilitate the importation of donor sperm or ova or that provide administrative support to identify donors (for example, egg bank coordinators) (optional)

Part 3: Signature and attestation *

This section must be completed by your establishment's senior executive officer before submitting the form to Health Canada.

I, _____ (print) as the senior executive officer,
(Name and Title)

hereby certify that

(i) the establishment that imports or distributes sperm or ova named in this application has evidence demonstrating that it is able to meet the requirements of the *Safety of Sperm and Ova Regulations*,

(ii) all information submitted in support of the notice is accurate and complete, and

(iii) I have the authority to bind the establishment.

Signature: _____ Date: _____
(yyyy-mm-dd)

E-mail:	Telephone:

Part 4: Notice of cessation *

Activity	Gamete	
Importation	☐ Sperm	☐ Ova
Cessation date (yyyy-mm-dd)		
Distribution	☐ Sperm	☐ Ova
Cessation date (yyyy mm dd)		

Details of the disposition of the sperm or ova in the possession or control of the establishment:

Signature and attestation for notice of cessation

I, _____ (print), as the senior executive officer,
(Name and Title)

hereby certify that

(i) that the establishment named in this notification has evidence, if it is still distributing or importing sperm or ova, demonstrating that it meets the requirements of the *Safety of Sperm and Ova Regulations*,

(ii) all information submitted in support of the notice is accurate and complete, and

(iii) I have the authority to bind the establishment.

Signature: _____ Date: _____
(yyyy-mm-dd)

E-mail:	Telephone:

Instructions on how to complete the sperm and ova establishment notification form

Before completing this form, we recommend that you read the relevant sections of the:

- *Safety of Sperm and Ova Regulations* (Safety Regulations) (https://laws-lois.justice.gc.ca/eng/regulations/SOR-2019-192/index.html)
- *Guidance Document – Safety of Sperm and Ova Regulations* (https://www.canada.ca/en/health-canada/programs/consultation-safety-sperm-ova-regulations/document.html).
  https://www.canada.ca/en/health-canada/services/drugs-health-products/
- Registration and notification guide for sperm and ova establishments under the *Safety of Sperm and Ova Regulations.*
  (https://www.canada.ca/en/health-canada/programs/consultation-safety-sperm-ova-compliance-enforcement/registration-notification-guide-donor-sperm-ova-establishments-gui-0128.html

The following legend shows the three types of icons used in this document, and the way they are intended to be used.

Important: Key or cautionary information for people to know.

Information: Supplementary information like quotes and legal references.

Tip: Things for people to do or understand.

Primary establishments are responsible for all of the processing of sperm or ova for the purpose of AHR and are required to register with Health Canada.

A primary establishment that processes sperm or ova must be registered by submitting a completed application for registration to Health Canada, using the Sperm and ova primary establishment registration application (FRM-0446).

Notification checklist (optional) – FRM-0448

It is not mandatory to complete the checklist, however it is provided for your convenience and it is recommended that you complete it to ensure that all fields have been filled out as required.

Type of notification		To be completed
☐ Initial notification:		☐ Cover letter (recommended) ☐ Notification checklist (recommended) ☐ Part 1 ☐ Part 2 ☐ Part 3
Establishments that have already notified and wish to update their notification	☐ Add importation or distribution	☐ Cover letter (recommended) ☐ Notification checklist (recommended) ☐ Part 1 ☐ Part 2 ☐ Part 3
	☐ Add a new gamete:	☐ Cover letter (recommended) ☐ Notification checklist (recommended) ☐ Part 1 ☐ Part 2 ☐ Part 3
☐ Change of information (Information update)		☐ Cover letter (recommended) ☐ Notification checklist (recommended) ☐ Part 1 ☐ Part 2 ☐ Part 3
☐ Cessation of activities		☐ Cover letter (recommended) ☐ Notification checklist (recommended) ☐ Part 1 ☐ Part 2A ☐ Part 4

General Instructions

Establishments that intend to import or distribute sperm or ova for the purpose of AHR must submit a notification as per section 18 of the Safety Regulations.

An establishment that wishes to add a new activity or gamete, for example, an establishment that has previously notified for the distribution of sperm or ova and wishes to begin importing sperm or ova, or an establishment that imports sperm and wishes to begin importing ova must meet the notification requirements of section 18 of the Safety Regulations. The aforementioned changes are subject to a notification and a notification must be submitted to Health Canada prior to commencing these additional activities.

As per section 19 of the Safety Regulations, a notice of change or cessation of distribution or importation is required to be submitted within 30 days.

For example, an establishment has notified Health Canada that they wish to distribute sperm from primary establishment “A”, with registration number “XXXXXX”, and during the year receives a request to distribute sperm that was processed by primary establishment “B”, with registration number “XXXXYZ”. This would be considered a change and is required to be submitted to Health Canada within 30 days of that change (i.e. when the distribution occurred).

The requirement under paragraph 18(1)(f) of the Safety Regulations is to list the registered primary establishments, and their associated registration numbers, that are actually responsible for the processing of the sperm or ova that is being imported. Third parties that facilitate the importation of donor sperm or ova or that provide administrative support to identify donors (for example, egg bank coordinators) must not be listed on notifications in Part 2C unless they conduct a processing activity on the sperm or ova. If a third party is facilitating or providing administrative support, please include this information in Part 2D.

Third party coordinators should work with the Canadian importers to ensure that they have all of the names and registration numbers of the primary establishments that are processing the sperm or ova for which they are coordinating the donation and subsequent distribution.

There may be cases where a registered primary establishment is importing from a foreign establishment that is conducting activities on their behalf. If you are registered with Health Canada as a primary establishment and you are importing from a foreign establishment conducting activities on your behalf, include your primary establishment name and registration number in this Part 2C.

How to submit your form

Before submitting this form, please ensure that the senior executive officer has signed part 3 Signature and Attestation. In the case of notice of cessation, the senior executive officer must sign part 4. Only signed and dated applications will be accepted.

You may submit your application using an e-signature if applicable.

When ready to submit your form, the preferred method of submission is to email the Biological Product Compliance Program with your completed notification form attached at ahrregistration-enregistrementpa@hc-sc.gc.ca. If you are unable to submit by email, you may submit using the following:

Fax: (613)-960-2156
Mail: Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
3rd floor, Jeanne Mance Building
200 Eglantine Driveway, Tunney's Pasture
Address Locator 1903D
Ottawa, Ontario
K1A 0K9

In order to facilitate the review of the information provided in your notification, we recommend:

- that you include your establishment name as it appears on the notification form in the subject line of the email
- that you send an e-mail to ahrregistration-enregistrementpa@hc-sc.gc.ca if you are submitting by fax or mail to inform us of your submission

As per section 20 of the *Safety of Sperm and Ova Regulations*, a primary establishment and any other establishment that distributes or imports sperm or ova must send to the Minister, in the form established by the Minister, an annual attestation

(a) on or before April 1 of the calendar year following the year in which the notice of distribution or importation is sent; and

(b) on or before April 1 of each subsequent calendar year.

The annual attestation can be submitted using the Sperm and ova establishment annual attestation form (FRM-0449).