# FRM-0449: Sperm and ova establishment annual attestation form

## When to use this form

As per section 20 of the *Safety of Sperm and Ova Regulations* (Safety Regulations), all primary establishment and any other establishment that distributes or imports sperm or ova must send to Health Canada an annual attestation:

- on or before April 1 of the calendar year following the year of registration or the year in which the notice of distribution or importation is sent; and
- on or before April 1 of each subsequent calendar year.

The following legend shows the two 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.

Please refer to the Sperm and ova primary establishment registration application (FRM-0446) or the Sperm and ova establishment notification form (FRM-0448) if you wish to register or submit a notification to Health Canada

Pub: 210661

Canada

## 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.

All fields indicated by an asterisk (*) are mandatory.

## Part 1: Establishment information *

| | |
|---|---|
| Primary establishment registration number (if applicable): | |
| Establishment name: | |

### Primary contact information

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

### Emergency contact information (if different from primary contact)

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

## Part 2: Signature and attestation *

This section must be completed by your establishment's senior executive officer.

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

hereby certify that

(i) the establishment named in this form has evidence demonstrating that it meets the requirements of the *Safety of Sperm and Ova Regulations*,

(ii) in the case of a primary establishment, any other establishment that processes sperm or ova on its behalf meets the requirements of the *Safety of Sperm and Ova Regulations*,

(iii) all information submitted in support of the attestation is accurate and complete, and

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

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

| | |
|---|---|
| E-mail: | Telephone: |

## How to submit your form

**Before submitting this form,** please ensure that the senior executive officer has signed part 2 Signature and attestation.

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 attestation 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

When you send your attestation form to the Biological Product Compliance Program, we recommend:

- that you include your establishment name as it appears on the attestation 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

If you do not submit your annual attestation by April 1, additional compliance and enforcement measures may be taken. For example, cancellation of a registration under section 16 of the Safety Regulations, in accordance with the *Compliance and enforcement policy for the Assisted Human Reproduction Act* (POL-0100).