Safety of Sperm and Ova Regulations: SOR/2019-192

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ASSISTED HUMAN REPRODUCTION ACT

P.C. 2019-750 June 9, 2019

Whereas, pursuant to subsection 66(1) of the *Assisted Human Reproduction Act* [a], the Minister of Health has laid a copy of the proposed *Safety of Sperm and Ova Regulations* before each House of Parliament, substantially in the annexed form;

Therefore, Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to section 65 [b] of the *Assisted Human Reproduction Act* [a], makes the annexed *Safety of Sperm and Ova Regulations*.

Safety of Sperm and Ova Regulations

Interpretation

Definitions

1 (1) The following definitions apply in these Regulations.

accident means an unexpected event that is not attributable to a deviation from the standard operating procedures or applicable laws, including these Regulations and that could compromise human health and safety or the safety of sperm or ova. (*accident*)

activity, in respect of sperm or ova, means any of the following activities:

(a) processing, which means

(i) performing the donor suitability assessment,

(ii) obtaining the sperm or ova from a donor,

(iii) preparing,

(iv) identifying,

(v) testing,

(vi) preserving,

(vii) assessing quality,

(viii) labelling,

(ix) quarantining, or

(x) storing;

(b) distributing; and

(c) importing. (*activité*)

adverse reaction means the unexpected presence of an infectious disease agent or the unexpected occurrence of an infectious disease in a recipient of sperm or ova or a child created from that sperm or those ova. (*effet indésirable*)

Directive means the document entitled *Technical Requirements for Conducting the Suitability Assessment of Sperm and Ova Donors*, published by the Department of Health, as amended from time to time. (*directive*)

donation code means the unique group of numbers, letters, symbols or a combination of any of them that identifies the sperm or ova donation. (*code d'identification du don*)

donor identification code means the unique group of numbers, letters, symbols or a combination of any of them that is assigned to a donor. (*code d'identification du donneur*)

donor suitability assessment means an assessment of a donor that is based on the following:

(a) donor screening;

(b) physical examination of the donor; and

(c) donor testing. (*évaluation de l'admissibilité du donneur*)

error means a deviation from the standard operating procedures or applicable laws, including these Regulations, that could compromise human health and safety or the safety of sperm or ova. (*manquement*)

establishment means a person, partnership, unincorporated entity or a part of any of them that conducts an activity but only includes a health professional if the health professional conducts an activity that is not referred to in the definition *health professional*. (*établissement*)

health professional means a person who is authorized under the laws of a province to make use of sperm or ova in that province and who

(a) makes use of sperm or ova or distributes sperm to a recipient for their personal use;

(b) prepares, quarantines, labels or stores sperm or ova for the purpose of their use by that person; or

(c) prepares, quarantines, labels or stores sperm for the purpose of its distribution by that person to a recipient for their personal use. (*professionnel de la santé*)

human health and safety means the health and safety of a recipient of sperm or ova or a child created from that sperm or those ova to the extent that their health and safety relate to the safety of the sperm or ova. (*santé et sécurité humaines*)

medical director, in respect of a primary establishment, means a person who is authorized under the laws of the jurisdiction in which the primary establishment is situated to practise the profession of medicine and who is responsible for all medical and technical procedures carried out during the processing of sperm or ova. (*directeur médical*)

primary establishment means an establishment that conducts all processing activities in respect of sperm or ova, whether it conducts them itself or another establishment conducts any of the activities on its behalf. (*établissement principal*)

quarantine, with respect to sperm and ova, means the quarantine described in subsection 28(2) conducted by an establishment or a health professional. (*mise en quarantaine*)

standard operating procedures means the component of a quality management system that comprises instructions that set out the processes applicable to the components of the system and to the activities carried out by an establishment. (*procédures opérationnelles normalisées*)

Amendments to Directive

(2) The document referred to in the definition of *Directive* is deemed to be amended for the purposes of these Regulations if the amendment is not inconsistent with the purpose of reducing risks to human health and safety.

General Requirements

Primary establishment — conformity of processing

2 (1) A primary establishment must ensure that sperm or ova are processed in accordance with these Regulations before distributing or making use of them.

Primary establishment — activities on its behalf

(2) The primary establishment must ensure that every establishment that conducts any processing on its behalf meets the requirements of these Regulations.

Establishment that imports

3 An establishment that imports sperm or ova must ensure that the sperm or ova are processed by a primary establishment that is registered in accordance with these Regulations.

Registration and Notification

Registration

Application, Issuance and Refusal

Requirement to register — primary establishment

4 A primary establishment that processes sperm or ova must be registered and may process sperm or ova, subject to any change under paragraph 11(1)(a), only in accordance with its registration.

Application

5 (1) A primary establishment must submit an application for registration to the Minister, in the form established by the Minister, that contains the following information:

(a) the applicant's name, telephone number, email address, postal address and, if different from the postal address, civic address;

(b) in the case of an applicant that previously conducted its activities under another name, either under these Regulations or the *Processing and Distribution of Semen for Assisted Conception Regulations*, that other name;

(c) the first name, last name, telephone number and email address of a person to contact for further information concerning the application and, if different, a person to contact in case of emergency;

(d) a statement indicating whether the applicant proposes to process sperm or ova;

(e) a list of the processing activities that the applicant proposes to conduct in each building and, if not already provided, the civic address of the respective buildings;

(f) a statement indicating whether the applicant proposes to have another establishment process sperm or ova on its behalf; and

(g) the name and civic address of any other establishment that the applicant proposes to have conduct any of the processing activities on its behalf, a list of the processing activities that are proposed to be conducted in each building and, if not already provided, the civic address of the respective buildings.

Signature and attestation

(2) The application must

(a) be signed and dated by a senior executive officer; and

(b) include an attestation from that senior executive officer of the following:

(i) that the applicant has evidence demonstrating that it is able to meet the requirements of these Regulations,

(ii) that any other establishment that is proposed to process sperm or ova on its behalf is able to meet the requirements of these Regulations,

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

(iv) that the senior executive officer has the authority to bind the applicant.

Additional documents and information

(3) The applicant must provide to the Minister, on or before the date specified in the Minister's written request to that effect, any documents or information that the Minister considers necessary to complete the Minister's review of the application.

Registration number

6 If the Minister determines, after reviewing an application for registration, that the information provided in the application is complete, the Minister must register the primary establishment and issue a registration number.

Refusal

7 The Minister may refuse to register an applicant if

(a) the Minister has reasonable grounds to believe that the applicant has submitted, in the application for registration, false, misleading, inaccurate or incomplete information;

(b) the applicant has not complied with subsection 5(3) or the documents and information that the applicant has provided under subsection 5(3) are not sufficient to complete the review of the application; or

(c) the Minister has reasonable grounds to believe that registering the primary establishment could compromise human health and safety or the safety of sperm or ova.

Amendments

Amendments — application

8 (1) A primary establishment that processes only one of sperm or ova and proposes to begin processing the other must, before doing so, submit an application to the Minister to amend its registration, in the form established by the Minister, that contains a description of the proposed amendment, as well as the information referred to in section 5 that is relevant to the proposed amendment.

Signature and attestation

(2) The application must

(a) be signed and dated by a senior executive officer; and

(b) include an attestation from that senior executive officer of the following:

(i) that the applicant has evidence demonstrating that it is able to meet the requirements of these Regulations,

(ii) that any other establishment that is proposed to process sperm or ova on its behalf is able to meet the requirements of these Regulations,

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

(iv) that the senior executive officer has the authority to bind the applicant.

Additional documents and information

(3) The primary establishment must provide to the Minister, on or before the date specified in the Minister's written request to that effect, any documents or information that the Minister considers necessary to complete the Minister's review of the application.

Amendment

9 If the Minister determines, after reviewing the application for the amendment to the registration, that the information provided in that application is complete, the Minister must amend the registration.

Refusal

10 The Minister may refuse to amend the registration of the primary establishment if

(a) the Minister has reasonable grounds to believe that the primary establishment has submitted, in the application for amendment, false, misleading, inaccurate or incomplete information;

(b) the primary establishment has not complied with subsection 8(3) or the documents and information that it has provided under subsection 8(3) are not sufficient to complete the review of the application; or

(c) the Minister has reasonable grounds to believe that the amendment of the registration could compromise human health and safety or the safety of sperm or ova.

Changes or Cessation

Notice to Minister

11 (1) A primary establishment must notify the Minister in writing, in the form established by the Minister, within 30 days after the day on which

(a) there is any change to the information provided in the application for registration — other than a change that is the subject of an application for an amendment to the registration — including the cessation of all activities with respect to either sperm or ova if the registration is for both sperm and ova; or

(b) the primary establishment has ceased all of its activities.

Contents of notice

(2) The notice must contain the following information:

(a) the primary establishment's name, telephone number, email address, postal address and, if different from the postal address, civic address;

(b) the primary establishment's registration number;

(c) the date on which the change or cessation became effective; and

(d) in the case of cessation, details of the disposition of the sperm or ova that are in the possession or control of the primary establishment.

Signature and attestation

(3) The notice must

(a) be signed and dated by a senior executive officer; and

(b) include an attestation from that senior executive officer of the following:

(i) that if the primary establishment has not ceased all of its activities, it has evidence demonstrating that it meets the requirements of these Regulations,

(ii) that if the primary establishment has not ceased all of its activities, any other establishment that processes sperm or ova or is proposed to process sperm or ova on its behalf meets the requirements of these Regulations,

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

(iv) that the senior executive officer has the authority to bind the primary establishment.

Update to registration

12 The Minister must update the registration to reflect the notice.

Suspension

Suspension without notice

13 (1) The Minister may suspend, in whole or in part, without prior notice, a primary establishment's registration, if the Minister has reasonable grounds to believe that human health and safety or the safety of the sperm or ova has been or could be compromised.

Notice

(2) If the Minister suspends a registration, the Minister must send a notice to the primary establishment that

(a) gives the reasons for the suspension and its effective date;

(b) indicates that the primary establishment has an opportunity to be heard; and

(c) if applicable, indicates that corrective action must be taken by the primary establishment and the date by which it must do so.

Action following suspension of registration

(3) On the suspension of its registration, the primary establishment must immediately notify every establishment, health professional or recipient to which it has distributed the implicated sperm or ova during the period specified in the notice of the reasons for its suspension, the effective date of the suspension and the parts of the registration that are the subject of the suspension.

Action upon notice

(4) An establishment that has been notified under subsection (3) or under this subsection must immediately notify to the same effect any establishment, health professional or recipient to which it distributed the implicated sperm or ova.

Written notice

(5) If the Minister or the establishment gives a notice verbally under this section, that notice must be confirmed in writing as soon as feasible.

Reinstatement of registration

14 (1) The Minister must reinstate a registration, in whole or in part, if the primary establishment makes a request to the Minister, in the form established by the Minister, and provides evidence that demonstrates that

(a) the primary establishment has corrected the situation that gave rise to the suspension; or

(b) the situation that gave rise to the suspension did not exist.

Notice

(2) The reinstatement takes effect immediately after the Minister sends to the primary establishment a notice to that effect.

Exception — compliance history

(3) The Minister may refuse to reinstate a primary establishment's registration if its compliance history demonstrates an inability to consistently conduct its activities in accordance with these Regulations.

Partial reinstatement

(4) If the Minister does not reinstate any part of a registration that was suspended, the Minister must remove that part of the registration.

Cancellation

Cancellation Initiated by Primary Establishment

Cessation of activities

15 The Minister must cancel a registration if the Minister receives a notice under section 11 that the primary establishment has ceased carrying out all of the activities that are the subject of its registration.

Cancellation Initiated by Minister

Circumstances

16 (1) The Minister may cancel a registration in any of the following circumstances:

(a) the primary establishment has not provided the annual statement that is required under section 20;

(b) the primary establishment has not complied with the requirements set out in section 21 to provide additional documents or information;

(c) any information provided by the primary establishment to the Minister in accordance with these Regulations proves to be false or misleading;

(d) the primary establishment fails to take corrective action, within the required period, in accordance with subsection (2) or paragraph 13(2)(c);

(e) the corrective action that was taken by the primary establishment in accordance with subsection (2) or paragraph 13(2)(c) has not corrected the situation that gave rise to a notice of suspension or cancellation of the registration;

(f) the registration has been suspended for a period of more than 12 months;

(g) the Minister has reasonable grounds to believe that the primary establishment does not meet the requirements of these Regulations.

Notice

(2) Before cancelling a registration, the Minister must send to the primary establishment a notice that

(a) gives the reasons for the proposed cancellation and its effective date;

(b) indicates that the primary establishment has an opportunity to be heard; and

(c) if applicable, indicates that corrective action must be taken by the primary establishment and the date by which it must do so.

Action following cancellation of registration

17 (1) If the registration is cancelled under section 16, the primary establishment must immediately take the following action:

(a) cease carrying out all of the activities that are the subject of its registration; and

(b) notify any establishment, health professional or recipient to which it has distributed the implicated sperm or ova during the period specified in the notice of the cancellation and the effective date.

Action upon notice

(2) An establishment that has been notified under paragraph (1)(b) or under this subsection must, in turn, immediately notify to the same effect any establishment, health professional or recipient to which it distributed the implicated sperm or ova.

Written notice

(3) If an establishment gives a notice verbally under this section, that notice must be confirmed in writing within 24 hours after it is given.

Notification

Notice before distribution or importation

18 (1) Before distributing or importing sperm or ova, an establishment must send to the Minister a notice, in the form established by the Minister, that contains the following information:

(a) the establishment's name, telephone number, email address, postal address and, if different from the postal address, civic address;

(b) in the case of an establishment that previously conducted its activities under another name, either under these Regulations or the *Processing and Distribution of Semen for Assisted Conception Regulations*, that other name;

(c) the first name, last name, telephone number and email address of a person to contact for further information concerning the notice and, if different, a person to contact in case of emergency;

(d) a statement indicating whether the establishment proposes to distribute or import sperm or ova and the projected start date;

(e) the civic address of the buildings in which the establishment proposes to conduct the activities, if not already provided; and

(f) the name and registration number of each primary establishment that processes that sperm or those ova.

Signature and attestation

(2) The notice must

(a) be signed and dated by a senior executive officer; and

(b) include an attestation from that senior executive officer of the following:

(i) that the establishment has evidence demonstrating that it is able to meet the requirements of these Regulations,

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

(iii) that the senior executive officer has the authority to bind the establishment.

Change or cessation

19 (1) An establishment that distributes or imports sperm or ova and makes any change to the information provided under section 18, including the cessation of distribution or importation, must send to the Minister, within 30 days after the day on which the change occurs, a notice, in the form established by the Minister, that contains the following information:

(a) the name of the establishment, telephone number, email address, postal address and, if different from the postal address, civic address;

(b) the date on which the change or cessation became effective; and

(c) in the case of cessation, details of the disposition of the sperm or ova that are in the possession or control of the establishment.

Signature and attestation

(2) The notice must

(a) be signed and dated by a senior executive officer; and

(b) include an attestation from that senior executive officer of the following:

(i) that the establishment has evidence, if it is still distributing or importing sperm or ova, demonstrating that it meets the requirements of these Regulations,

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

(iii) that the senior executive officer has the authority to bind the establishment.

Annual Attestation

April 1

20 (1) 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 of registration or the year in which the notice of distribution or importation is sent; and

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

Signature and attestation

(2) The attestation must

(a) be signed and dated by a senior executive officer; and

(b) certify that

(i) the establishment has evidence demonstrating that it meets the requirements of these Regulations,

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

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

(iv) the senior executive officer has the authority to bind the establishment.

Additional documents and information

21 An establishment must provide to the Minister, on or before the date specified in the Minister's written request to that effect, any additional relevant documents or information to demonstrate that the activities it conducts are in compliance with these Regulations.

Donor Suitability

Regular Process

Donor Suitability Assessment and Determination

Donor suitability assessment

22 In order to determine whether a donor is suitable, a primary establishment must ensure that a donor suitability assessment is conducted.

Donor screening

23 An establishment that performs donor screening must do so in accordance with the requirements set out in the Directive under the heading "Donor Screening".

Physical examination

24 An establishment that performs physical examinations on donors must do so in accordance with the requirements set out in the Directive under the heading "Physical Examination".

Donor testing

25 An establishment that performs donor testing must do so in accordance with the requirements set out in the Directive under the heading "Donor Testing".

Donor reassessment

26 In order to determine whether a repeat donor is suitable, a primary establishment must ensure that

the donor is reassessed in accordance with the requirements set out in the Directive under the heading “Donor Reassessment”.

Determination of donor suitability

27 (1) A primary establishment must ensure that its medical director determines whether a donor is suitable by reviewing the information obtained from the donor suitability assessment and, if applicable, from the donor reassessment.

Donor unsuitability

(2) A primary establishment must ensure that its medical director determines a donor to be unsuitable if

(a) the donor meets any criteria set out in the Directive under the heading “Donor Exclusion”; or

(b) the donor suitability assessment is not complete.

Summary document

(3) If a donor has been determined to be suitable, the primary establishment must ensure that its medical director creates and signs a summary document that confirms this determination and that contains

(a) the age of the donor;

(b) a statement that the donor suitability assessment and, if applicable, donor reassessment have been conducted in accordance with these Regulations; and

(c) the dates and results of the donor testing and the assessment of the risk of genetic disease transmission.

Quarantine

Requirement

28 (1) An establishment must quarantine all sperm and ova that it processes in the manner set out in subsection (2) until the medical director of the primary establishment that is responsible for the quarantine of that sperm and those ova has

(a) determined the donor to be suitable; and

(b) determined and documented that the sperm and ova can be released from quarantine.

Segregation

(2) The establishment must quarantine the sperm and ova by

(a) clearly indicating that they are quarantined;

(b) segregating them from sperm and ova that are not quarantined; and

(c) ensuring that they are not distributed or used.

Release from quarantine — exceptional access

29 (1) Despite paragraph 28(1)(a), an establishment may release sperm or ova from quarantine if the primary establishment that is responsible for their quarantine receives a request from a health professional for exceptional access to that sperm or those ova and if one of the following conditions is met:

(a) the recipient has previously been exposed to sperm or ova from that donor and the risk profile of the requested sperm or ova, based on the results of any part of the donor suitability assessment, is at least equivalent to the risk profile of the sperm or ova to which the recipient has previously been exposed, based on the results of any of the donor suitability assessment that was conducted at that time; or

(b) sperm or ova from that donor have previously been used to create a child for an individual or

a couple and the requested sperm or ova are to be used for the purpose of creating another child for that individual or couple.

Summary document

(2) Before the sperm or ova are released from quarantine, the primary establishment must ensure that its medical director creates and signs a summary document that contains the following information:

(a) the age of the donor, if known;

(b) the conditions that have been met;

(c) the dates and results of any donor screening, physical examination or donor testing; and

(d) the reasons the donor was determined to be unsuitable and a detailed explanation for each reason.

Storage

(3) An establishment and a health professional must ensure that sperm or ova that are in their possession or control and are intended for exceptional access are segregated from sperm and ova that are not intended for exceptional access.

Communication of risk

(4) A health professional must meet the following requirements before making use of the sperm or ova or distributing the sperm to a recipient for their personal use:

(a) create a document that states that, based on the summary document and any risk mitigating measures with respect to that sperm or those ova, in their medical opinion, the use of the sperm or ova would not pose a serious risk to human health and safety; and

(b) create a document that states that the health professional has informed the recipient of the risks that the use of the sperm or ova could pose to human health and safety and that the health professional has obtained written consent from the recipient.

Directed Donation Process

Donor Suitability Assessment and Confirmation

Application

30 Despite sections 22 to 29, the requirements set out in sections 31 to 40 with respect to sperm or ova that are intended for directed donation may instead be met if

(a) the donor and recipient know each other; and

(b) the health professional requests the sperm or ova from a primary establishment in the context of a directed donation.

Donor suitability assessment

31 A primary establishment, in the context of a directed donation, must ensure that a donor suitability assessment is conducted.

Donor screening

32 An establishment that performs donor screening, in the context of a directed donation, must do so in accordance with the requirements set out in the Directive under the heading “Donor Screening”.

Physical examination of donor

33 An establishment that performs physical examinations on donors, in the context of a directed donation, must do so in accordance with the requirements set out in the Directive under the heading “Physical Examination”.

Donor testing

34 An establishment that performs donor testing, in the context of a directed donation, must do so in accordance with the requirements set out in the Directive under the heading “Donor Testing”.

Donor reassessment

35 A primary establishment, in the context of a directed donation, must ensure that a repeat donor is reassessed in accordance with the requirements set out in the Directive under the heading “Donor Reassessment”.

Review by primary establishment

36 (1) A primary establishment, in the context of a directed donation, must ensure that its medical director reviews the information obtained from the donor suitability assessment and, if applicable, the donor reassessment.

Summary document

(2) A primary establishment must ensure that its medical director creates and signs a summary document that confirms the review and that contains

(a) the age of the donor;

(b) a statement that the donor suitability assessment and, if applicable, donor reassessment have been conducted in accordance with these Regulations;

(c) the dates and results of the donor testing and the assessment of the risk of genetic disease transmission; and

(d) a list of any criteria set out in the Directive under the heading “Donor Exclusion” that have been met.

Donor suitability assessment cannot be conducted

37 (1) Despite sections 31, 35 and 36, a primary establishment, in the context of a directed donation, must ensure that its medical director meets the requirements set out in subsection (2) if

(a) a donation of sperm or ova has previously been obtained from the donor;

(b) the donor suitability assessment in respect of the donation was not conducted in accordance with these Regulations; and

(c) it is not medically possible to obtain another donation of sperm or ova from the donor or obtaining another donation of sperm or ova would pose a serious risk to the donor.

Requirements — medical director

(2) The medical director must meet the following requirements:

(a) review any available medical information about the donor;

(b) review any available results of any donor screening, physical examination or donor testing that was previously conducted;

(c) unless it is not medically possible to do so, take appropriate measures to complete the donor suitability assessment; and

(d) create and sign a summary document that confirms the medical director’s review and that contains

(i) the age of the donor,

(ii) the medical reasons for which another donation cannot be obtained or an explanation of the risk,

(iii) the dates and results of any donor screening, physical examination or donor testing,

(iv) a list of any criteria set out in the Directive under the heading “Donor Exclusion” that

have been met, and

(v) a list of any parts of the donor suitability assessment that have not been conducted and, for each one, an explanation of the reasons it was not conducted.

Quarantine

Requirement

38 An establishment that processes sperm or ova in the context of directed donation must quarantine that sperm or ova until the medical director of the primary establishment that is responsible for the quarantine of that sperm and those ova has

(a) confirmed the review of the donor suitability assessment and, if applicable, the donor reassessment; and

(b) determined and documented that the sperm and ova can be released from quarantine.

Storage

39 An establishment and a health professional must ensure that sperm or ova that are in their possession or control and are intended for directed donation are segregated from sperm and ova that are not intended for directed donation.

Communication of Risk

Before distributing or making use

40 A health professional must meet the following requirements, in the context of directed donation, before making use of sperm or ova or distributing sperm to a recipient for their personal use:

(a) create a document that states that, based on the summary document and any risk mitigating measures with respect to that sperm or those ova, in their medical opinion, the use of the sperm or those ova would not pose a serious risk to human health and safety; and

(b) create a document that states that the health professional has informed the recipient of the risks that the use of the sperm or ova could pose to human health and safety and that the health professional has obtained written consent from the recipient.

Quality Management

Risk reduction

41 An establishment that conducts an activity must do so in such a way as to reduce the risks to human health and safety and the safety of sperm or ova by having appropriate quality management measures, including the taking of measures

(a) to prevent contamination or cross-contamination;

(b) to prevent the transmission of an infectious disease; and

(c) to maintain the quality of the sperm or ova.

Quality Management System

Organizational structure

42 An establishment must have an organizational structure that sets out the responsibility of management for all activities that it conducts and all measures that it takes in order to meet the requirements related to quality management.

Components of system

43 An establishment must, with respect to the activities that it conducts and the measures that it takes in order to meet the requirements related to quality management, establish and maintain a quality management system that includes the following components and must name an individual to be

responsible for that system:

(a) standard operating procedures;

(b) a process control program that includes a system for verifying and validating any change to a process;

(c) a system that allows for process improvement and that includes complaint monitoring and the implementation of corrective and preventative actions including recalls; and

(d) a document control and records management system.

Standard operating procedures

44 (1) The standard operating procedures must meet the following requirements:

(a) they are in a standardized format;

(b) they are approved by the individual responsible for the quality management system;

(c) they are easily accessible at each location where the relevant activities are conducted;

(d) all changes to them are approved by the individual responsible for the quality management system before they are implemented; and

(e) they are kept up-to-date.

Review of procedures

(2) An establishment must review its standard operating procedures every two years or after either of the following events and every two years after that event:

(a) following any amendment to these Regulations; and

(b) when a deficiency in the standard operating procedures is revealed as a result of an investigation into an error, accident or adverse reaction or as a result of an internal audit.

Internal audit

45 An establishment must establish and maintain an internal audit system for quality management purposes and must carry out an internal audit every two years of the activities that it conducts to ensure that those activities comply with these Regulations and with its standard operating procedures, to be carried out by a person who is qualified to do so and who does not have direct responsibility for the activities being audited.

Tracing and Identifying

Tracing system

46 An establishment must establish and maintain a system for tracing sperm and ova.

Donor identification code

47 A primary establishment must ensure that a donor identification code is assigned to each donor.

Donation code

48 A primary establishment must ensure that a donation code is assigned to each donation of sperm and ova that indicates the date of the donation and links the donation to the donor.

Labelling and Storing

Establishment that labels

49 An establishment that labels an immediate container of sperm or ova must

(a) establish and maintain a labelling control system; and

(b) ensure that the donor identification code and the donation code appear on the label in a clear

and indelible manner.

Label verification — primary establishment

50 A primary establishment must ensure that the immediate container of sperm or ova is already labelled in accordance with the requirements of paragraph 49(b) and that it is accompanied by documentation that contains the following documents and information in English or French before distributing or making use of the sperm or ova:

(a) the donor identification code and the donation code;

(b) the type of content, whether sperm or ova, unless this information already appears on the label of the immediate container;

(c) in the case of exceptional access, a statement that indicates that the donation is for exceptional access only;

(d) in the case of a directed donation, a statement that indicates that the donation is for directed donation only;

(e) the name of the primary establishment, its registration number and contact information;

(f) a copy of any summary document; and

(g) instructions for the handling and storage of the sperm or ova.

Containers

51 (1) An establishment that distributes, imports or makes use of sperm or ova must

(a) verify the integrity of the immediate containers and the shipping containers as well as the accuracy and legibility of their labels; and

(b) ensure that the documentation that accompanies the immediate containers contains the following information in English or French:

(i) the donor identification code and the donation code,

(ii) the type of content, whether sperm or ova, unless this information already appears on the label of the immediate container,

(iii) in the case of exceptional access, a statement that indicates that the donation is for exceptional access only,

(iv) in the case of a directed donation, a statement that indicates that the donation is for directed donation only,

(v) the name of the primary establishment, its registration number and contact information,

(vi) a copy of any summary document, and

(vii) instructions for the handling and storage of the sperm or ova.

Shipping

(2) An establishment that ships sperm or ova must

(a) establish and maintain shipping standards;

(b) verify the integrity of the immediate containers and the shipping containers before shipping as well as the accuracy and legibility of their labels; and

(c) use shipping containers that are capable of resisting damage, maintaining the safety of the sperm or ova and maintaining adequate environmental conditions during shipping.

Storage

52 An establishment that stores sperm or ova must establish and maintain standards for acceptable storage temperature ranges and ensure that sperm and ova are stored at a temperature within that range.

Personnel, Facilities, Equipment and Supplies

Qualified personnel

53 In order to conduct its activities, an establishment must

(a) have sufficient personnel who are qualified by their education, training or experience to perform their respective tasks; and

(b) establish and maintain a program for the initial and ongoing training of personnel and for evaluating their competency.

Facilities

54 The facilities in which an establishment conducts its activities must be constructed and maintained in a manner that allows for the following:

(a) the carrying out of its activities;

(b) the cleaning, maintaining and disinfecting of the facilities in a way that prevents contamination and cross-contamination; and

(c) controlled access to all areas where its activities are conducted.

Environmental control system

55 An establishment must

(a) establish and maintain a system for controlling and monitoring appropriate environmental conditions for all facilities and areas in which activities are conducted; and

(b) periodically inspect those systems in order to verify that the systems function properly and must take any necessary corrective action.

Program — procurement and maintenance

56 An establishment must establish and maintain a program for procuring and maintaining all critical equipment, supplies and services.

Equipment — general requirements

57 An establishment must ensure that the critical equipment that it uses is cleaned and maintained and that, whenever applicable, it is

(a) qualified for its intended purpose;

(b) calibrated;

(c) disinfected or sterilized before each use; and

(d) requalified or recalibrated, as appropriate, after any repair or change is made to it that results in a change to its specifications.

Supplies

58 An establishment must ensure that the critical supplies that it uses are qualified or validated, as applicable, for their intended use and that they are stored under appropriate environmental conditions.

Errors and Accidents

System — investigation by establishment

59 An establishment must establish and maintain a system that allows for the identification, investigation and reporting of errors and accidents.

Error or accident by another establishment

60 (1) An establishment and a health professional that have reasonable grounds to believe that an

error or accident by another establishment has occurred during the processing, distributing or importing of sperm or ova must immediately

(a) determine the donor identification codes and donation codes of the implicated sperm or ova;

(b) quarantine any implicated sperm or ova that are in their possession or control;

(c) notify the following:

(i) the establishment from which they received the implicated sperm or ova, and

(ii) in the case of an establishment, every establishment, health professional or recipient to which it distributed the implicated sperm or ova; and

(d) in the case of a primary establishment that has reasonable grounds to believe that the error or accident occurred during the processing of sperm and ova conducted on its behalf, initiate an investigation into the suspected error or accident.

Contents of notice

(2) The notice must include the following information:

(a) the donor identification code and the donation code associated with the implicated sperm or ova; and

(b) the reason for the belief that an error or accident has occurred.

Action upon notice

(3) An establishment or health professional that is notified under subparagraph (1)(c)(ii) or under this subsection must immediately

(a) quarantine all implicated sperm or ova in its possession or control; and

(b) in the case of an establishment, notify to the same effect every establishment, health professional and recipient to which it distributed the implicated sperm or ova.

Written notice

(4) If an establishment or a health professional gives a notice verbally under this section, that notice must be confirmed in writing within 24 hours after it is given.

Establishment or health professional — own error or accident

61 (1) An establishment and a health professional that have reasonable grounds to believe that an error or accident has occurred during the processing, distributing or importing of sperm or ova that they conducted must immediately

(a) determine the donor identification codes and the donation codes of the implicated sperm or ova;

(b) quarantine any implicated sperm or ova that are in their possession and control; and

(c) subject to subsection (2), initiate an investigation into the suspected error or accident.

Exception

(2) An establishment that conducts a processing activity on behalf of a primary establishment that has or previously had in its possession or control any implicated sperm or ova can request that the primary establishment conduct the investigation by providing a notice to them that contains the following information:

(a) the donor identification codes and donation codes of all implicated sperm or ova; and

(b) the reason for the belief that an error or accident has occurred.

Notice of investigation

62 (1) An establishment that initiates an investigation must immediately notify either the primary

establishment that has or previously had in its possession or control any implicated sperm or ova and on whose behalf the processing activity was conducted or every establishment, health professional or recipient to which it distributed implicated sperm or ova and must include the following information in the notice:

(a) the donor identification codes and donation codes of all implicated sperm or ova; and

(b) a description of the suspected error or accident and an explanation of how human health and safety or the safety of the sperm or ova might have been compromised.

Action upon notice

(2) An establishment or health professional that is notified under subsection (1) or under this subsection must immediately

(a) quarantine all implicated sperm or ova in its possession or control; and

(b) in the case of an establishment, notify to the same effect every establishment, health professional or recipient to which it distributed implicated sperm or ova.

Written notice

(3) If an establishment or a health professional gives a notice verbally under this section, the notice must be confirmed in writing within 24 hours after it is given.

Requirement to cooperate

63 An establishment and a health professional must, on request, provide to any establishment or health professional that is conducting an investigation any relevant documents or information in its possession in respect of implicated sperm or ova.

Results of investigation

64 (1) An establishment that conducts an investigation must notify in writing either the primary establishment that has or previously had in its possession or control any implicated sperm or ova and on whose behalf the processing activity was conducted or every establishment, health professional or recipient to which it distributed implicated sperm or ova of the results of the investigation and of any action that is required to be taken.

Action on receipt of notice

(2) An establishment that receives a notice under subsection (1) or a copy of such a notice under this subsection must send a copy of the notice to every establishment, health professional or recipient to which it distributed implicated sperm or ova.

Release from quarantine

65 An establishment or health professional that quarantines implicated sperm or ova must continue to do so until the results of the investigation reveal that the safety of the implicated sperm or ova is not compromised.

Release from quarantine — exceptional access

66 (1) Despite section 65, an establishment and a health professional may release sperm or ova from quarantine if the establishment or health professional that is responsible for their quarantine receives a request from a health professional for exceptional access to that sperm or those ova and if one of the following conditions is met:

(a) the recipient has previously been exposed to sperm or ova from that donor and the risk profile of the requested sperm or ova, based on the results of any part of the donor suitability assessment is at least equivalent to the risk profile of the sperm or ova to which the recipient has previously been exposed, based on the results of any part of the donor suitability assessment that was conducted at that time; or

(b) sperm or ova from that donor have previously been used to create a child for an individual or

a couple and the requested sperm or ova are to be used for the purpose of creating another child for that individual or couple.

Summary document

(2) Before the sperm or ova are released from quarantine, the establishment or health professional that is responsible for the quarantine must create and sign a summary document that contains the following information:

(a) the age of the donor, if known;

(b) the condition that has been met;

(c) the dates and results of any donor screening, physical examination or donor testing; and

(d) a description of the suspected error or accident and an explanation of how human health and safety or the safety of the sperm or ova might have been compromised.

Storage

(3) An establishment and a health professional must ensure that sperm or ova that are in their possession or control and are intended for exceptional access are segregated from sperm and ova that are not intended for exceptional access.

Communication of risk

(4) A health professional must meet the following requirements before making use of the sperm or ova or distributing the sperm to a recipient for their personal use:

(a) create a document that states that, based on the summary document and any risk mitigating measures with respect to that sperm or those ova, in their medical opinion, the use of the sperm or ova would not pose a serious risk to human health and safety; and

(b) create a document that states that the health professional has informed the recipient of the risks that the use of the sperm or ova could pose to human health and safety and that the health professional has obtained written consent from the recipient.

Preliminary and interim reports

67 The establishment or health professional that conducts an investigation into a suspected error or accident that could lead to an adverse reaction must send the following reports to the Minister, in the form established by the Minister, at the following times:

(a) within 72 hours after the start of the investigation, a preliminary report that includes a detailed description of the suspected error or accident and any relevant information that is available at that time; and

(b) within 15 days after the start of the investigation and every 15 days after that until the final report is made, an interim report that contains

(i) any new information with respect to the suspected error or accident,

(ii) the progress of the investigation, and

(iii) any measures taken during those 15 days to mitigate further risk.

Final report

68 An establishment or health professional that conducts an investigation into a suspected error or accident that could lead to an adverse reaction must send, within 72 hours of completing the investigation, a detailed final report to the Minister, in the form established by the Minister, that contains the following information:

(a) the results of the investigation;

(b) any corrective action taken; and

(c) details concerning the disposition of the implicated sperm or ova.

Adverse Reactions

System — investigation by establishment

69 An establishment must establish and maintain a system that allows for the identification, investigation and reporting of adverse reactions.

Action to be taken

70 (1) An establishment and a health professional that have reasonable grounds to believe that an adverse reaction has occurred must immediately

(a) determine the donor identification codes and donation codes of any implicated sperm or ova in their possession;

(b) quarantine any of the implicated sperm or ova in their possession and control; and

(c) notify the following:

(i) the primary establishment that processed the implicated sperm or ova, and

(ii) if the sperm or ova were imported, the establishment that imported the sperm or ova.

Contents of notice

(2) The notice must include the following information:

(a) the donor identification code and the donation code of the implicated sperm or ova;

(b) a description of the adverse reaction;

(c) the name of any suspected infectious disease or disease agent, if known; and

(d) an explanation of how the safety of the implicated sperm or ova might have been compromised, if known.

Action upon notice

(3) An establishment that is notified under subsection (1) or under this subsection must immediately

(a) quarantine any of the implicated sperm or ova that are in its possession or control; and

(b) notify to the same effect every establishment, health professional and recipient to which it distributed the implicated sperm or ova.

Written notice

(4) If an establishment or a health professional gives a notice verbally under this section, the notice must be confirmed in writing within 24 hours after it is given.

Investigation

71 (1) On receipt of a notice, a primary establishment must immediately initiate an investigation into the adverse reaction.

Requirement to cooperate

(2) An establishment and a health professional must, on request, provide to any primary establishment that is conducting an investigation any relevant documents or information in its possession in respect of implicated sperm or ova.

Results of investigation

72 (1) A primary establishment that conducts an investigation must notify in writing every establishment, health professional or recipient to which it distributed implicated sperm or ova of the results of the investigation and of any action that is required to be taken.

Action on receipt of notice

(2) An establishment that receives a notice under subsection (1) or a copy of such notice under this

subsection must send a copy of the notice to every establishment, health professional or recipient to which it distributed implicated sperm or ova.

Release from quarantine

73 An establishment or health professional that quarantines implicated sperm or ova must continue to do so until the results of the investigation reveal that the safety of the implicated sperm or ova is not compromised.

Release from quarantine — exceptional access

74 (1) Despite section 73, an establishment and a health professional may release sperm or ova from quarantine if the establishment or health professional that is responsible for their quarantine receives a request from a health professional for exceptional access to that sperm or those ova and if one of the following conditions is met:

(a) the recipient has previously been exposed to sperm or ova from that donor and the risk profile of the requested sperm or ova, based on the results of any part of the donor suitability assessment, is at least equivalent to the risk profile of the sperm or ova to which the recipient has previously been exposed, based on the results of any part of the donor suitability assessment that was conducted at that time; or

(b) sperm or ova from that donor have previously been used to create a child for an individual or a couple and the requested sperm or ova are to be used for the purpose of creating another child for that individual or couple.

Summary document

(2) Before the sperm or ova are released from quarantine, the establishment or health professional that is responsible for the quarantine must create and sign a summary document that contains the following information:

(a) the age of the donor, if known;

(b) the condition that has been met;

(c) the dates and results of any donor screening, physical examination or donor testing;

(d) a description of the adverse reaction;

(e) the name of any suspected infectious disease or disease agent, if known; and

(f) an explanation of how the safety of the implicated sperm or ova might have been compromised, if known.

Storage

(3) An establishment and a health professional must ensure that sperm or ova that are in their possession or control and are intended for exceptional access are segregated from sperm and ova that are not intended for exceptional access.

Communication of risk

(4) A health professional must meet the following requirements before making use of the sperm or ova or distributing the sperm to a recipient for their personal use:

(a) create a document that states that, based on the summary document and any risk mitigating measures with respect to that sperm or those ova, in their medical opinion, the use of the sperm or ova would not pose a serious risk to human health and safety; and

(b) create a document that states that the health professional has informed the recipient of the risks that the use of the sperm or ova could pose to human health and safety and that the health professional has obtained written consent from the recipient.

Preliminary and interim reports

75 A primary establishment that is conducting an investigation into an adverse reaction must send the

following reports to the Minister, in the form established by the Minister, at the following times:

(a) within 72 hours after the start of the investigation, a preliminary report that includes a detailed description of the adverse reaction and any relevant information that is available at that time; and

(b) within 15 days after the start of the investigation and every 15 days after that until the final report is made, an interim report that contains the following information,

(i) any new information with respect to the adverse reaction,

(ii) the progress of the investigation, and

(iii) any measures taken during those 15 days to mitigate further risk.

Final report

76 A primary establishment must send, within 72 hours of completing the investigation, a detailed final report to the Minister, in the form established by the Minister, that contains the following information:

(a) the results of the investigation;

(b) any corrective action taken; and

(c) details concerning the disposition of the implicated sperm or ova.

Records

General

77 (1) An establishment and a health professional must keep records that contain all the documents and information required under these Regulations and all other records that demonstrate that they meet the requirements of these Regulations.

Donor identification codes and donation codes

(2) An establishment and a health professional must ensure that the donor identification code and the donation code are components of all of their records that relate to the processing, distribution, importation or making use of sperm or ova.

Retention period — general

78 (1) An establishment and a health professional must keep records for 10 years after their creation unless otherwise specified in these Regulations.

Retention period — employees

(2) An establishment must keep records containing records of the qualifications, training and competency of its employees for 10 years after the day on which an individual ceases to be an employee of the establishment.

Retention period — standard operating procedures

(3) An establishment must keep a copy of every version of its standard operating procedures for 10 years after the day on which they are superseded by a new version.

Processing

79 (1) A primary establishment must keep records that contain the following documents and information with respect to the sperm or ova it processes:

(a) the donor identification code and the donation code that appear on the label of each immediate container of sperm or ova;

(b) the number of immediate containers on which the same donation code appears;

(c) the type of donation, whether sperm or ova;

(d) the date of the donation;

(e) any documents and information with respect to the suitability of the donor;

(f) a copy of all documentation that is required under these Regulations to accompany the immediate container of the sperm or ova; and

(g) any information with respect to the disposition of the sperm or ova.

Establishment to cooperate

(2) An establishment that processes sperm or ova on behalf of a primary establishment must provide to the primary establishment all of the documents and information that it possesses to update the primary establishment's records.

Distribution and importation

80 An establishment that distributes or imports sperm or ova and a health professional who distributes sperm to a recipient for their personal use must keep records that contain the following documents and information with respect to that sperm or those ova:

(a) the donor identification code and the donation code that appear on the label of each immediate container of sperm or ova;

(b) the number of immediate containers on which the same donation code appears;

(c) the contact information for the establishment from which the establishment or health professional received the sperm or ova, if applicable;

(d) a copy of all documentation that is required under these Regulations to accompany the immediate container of the sperm or ova;

(e) the contact information for each establishment, health professional or recipient to which the establishment or health professional distributes the sperm or ova, if applicable; and

(f) any information with respect to the disposition of the sperm or ova.

Making use

81 (1) An establishment and a health professional must keep records that contain the following documents and information with respect to the sperm or ova of which it makes use:

(a) the donor identification code and the donation code that appear on the label of each immediate container of sperm or ova;

(b) the number of immediate containers on which the same donation code appears;

(c) the contact information and registration number of the primary establishment that processed the sperm or ova;

(d) if applicable, the contact information for the establishment from which the establishment or health professional received the sperm or ova, if they were not received from a primary establishment;

(e) a copy of all documentation that is required under these Regulations to accompany the immediate container of the sperm or ova;

(f) any information that allows for the identification of the recipient; and

(g) any information with respect to the disposition of the sperm or ova.

Establishment to cooperate

(2) An establishment must provide to the establishment and health professional all of the documents and information that it possesses to update the establishment and health professional's records.

Retention period — processing, distribution, importation and making use

82 An establishment and a health professional must keep records in respect of each immediate container of sperm or ova for a period of 10 years after the day on which they distribute, make use of or effect the disposition of the sperm or ova.

Investigation

83 (1) An establishment or health professional that has conducted or received a notice of an investigation respecting an accident, error or adverse reaction must keep records that contain

(a) any documents and information with respect to the investigation;

(b) any notices that were received and copies of those that were sent and a list of all the establishments, health professionals or recipients to which they were sent; and

(c) a copy of any reports sent to the Minister.

Retention period

(2) An establishment and a health professional must keep records for a period of 10 years after the date of the last recording in that record.

Record qualities

84 (1) Records containing documents and information must be complete and kept in a manner that allows them to be audited at any time.

Information qualities

(2) The information must be accurate, legible and indelible.

Storage of records

85 An establishment and a health professional must store records in a location that has appropriate environmental conditions and that is secure against the entry of unauthorized persons.

Transitional Provisions

Primary establishment not registered

86 (1) A primary establishment that, before the day on which these Regulations come into force, processes sperm or ova may, despite section 4, continue to do so without having been registered, if it submits an application for registration under section 5 within 90 days after that day.

Duration

(2) Subsection (1) applies until the day on which the determination of the application submitted under section 5 is made.

Registration number

87 Despite paragraphs 11(2)(b), 18(1)(f) and 50(e), subparagraph 51(1)(b)(v) and paragraph 81(1)(c), a primary establishment’s registration number does not have to be provided before the 180th day after the day on which these Regulations come into force.

Distribution or importation before coming into force of these Regulations — notice

88 An establishment that, before the day on which these Regulations come into force, distributes or imports sperm or ova may continue to do so, despite section 18, if it sends a notice to the Minister that meets the requirements of that section within 90 days after that day.

Distribution or importation — requirements

89 (1) An establishment that, on or before the day on which these Regulations come into force, distributes or imports sperm or ova must ensure that

(a) the sperm or ova were processed in accordance with these Regulations by a primary establishment; and

(b) the primary establishment has submitted an application for registration under section 5 within 90 days after the day on which these Regulations come into force.

Duration

(2) Subsection (1) applies until the day on which the determination of the application submitted under section 5 is made.

Sperm obtained before these Regulations come into force

90 (1) This section applies to sperm that is obtained before the day on which these Regulations come into force and that may be distributed, imported and used — despite the requirements set out in sections 22 to 40 – only if

(a) the sperm is processed, within the meaning of the *Processing and Distribution of Semen for Assisted Conception Regulations*, in accordance with those Regulations; or

(b) the sperm is the subject of a special access authorization under section 20 of those Regulations.

Special access authorization

(2) Despite subsection (1), sperm that is the subject of a special access authorization may only be distributed and used for the purpose for which the authorization is granted.

Immediate container

(3) Before distributing or making use of the sperm, an establishment and a health professional must ensure that the identification code, within the meaning of the *Processing and Distribution of Semen for Assisted Conception Regulations,* appears in a clear and indelible manner on the label of the immediate container.

Documentation

(4) Before distributing or making use of the sperm, an establishment and a health professional must ensure that the immediate container of sperm is accompanied by documentation that contains the following information in English or French:

(a) the donation code;

(b) the name and business address of the processor within the meaning of the *Processing and Distribution of Semen for Assisted Conception Regulations*;

(c) the date of the donation, the tests performed in respect of the donor, the dates and results of the tests and, if necessary, an interpretation of the results; and

(d) a copy of the special access authorization, if any.

Records

91 An establishment and a health professional must keep records of all documents and information as required under the *Processing and Distribution of Semen for Assisted Conception Regulations*, in respect of each immediate container of sperm, unless otherwise required by these Regulations, for a period of 10 years after the day on which they distribute, make use of or effect the disposition of the sperm.

Consequential Amendment to the Safety of Human Cells, Tissues and Organs for Transplantation Regulations

92 Paragraph 3(1)(j) of the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* [1] is repealed.

Repeal

93 The *Processing and Distribution of Semen for Assisted Conception Regulations* [2] are repealed.

Coming into Force

Coming into force of section 10 of Act

94 (1) Subject to subsection (2), these Regulations come into force on the day on which section 10 of the *Assisted Human Reproduction Act* comes into force.

180th day

(2) Section 3 comes into force on the 180th day after the day on which section 10 of the *Assisted Human Reproduction Act* comes into force.

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the regulations*.)

Executive summary

Issues: There is a need to strengthen the federal regulatory framework governing assisted human reproduction (AHR) in Canada and address several regulatory gaps. These gaps are due to outdated regulations under the *Food and Drugs Act* as well as provisions in the *Assisted Human Reproduction Act* (AHRA) that are not yet in force and require regulations to operate. These include provisions related to the risks to human health and safety arising from the use of third-party donor sperm and ova in AHR, the reimbursement of expenditures, and the administration and enforcement of the AHRA.

The use of third-party donor sperm and ova in AHR can pose risks to human health and safety, as sperm and ova can transmit disease to the recipient as well as to children born through AHR. The safety of donor sperm is currently regulated under the *Food and Drugs Act* with regulations that require modernization, and there are no federal safety regulations for donor ova. The AHRA permits reimbursement of expenditures related to AHR under specified circumstances, and regulations are needed to set out what may be reimbursed and how to do so. Regulations are also needed to set out procedures and requirements for certain administration and enforcement provisions of the AHRA. Issues related to donor anonymity and to record keeping with the AHRAs existing regulations on consent have additionally been identified.

Description: The *Safety of Sperm and Ova Regulations* establish a human health and safety framework for donor sperm and ova for AHR. The *Reimbursement Related to Assisted Human Reproduction Regulations* set categories of allowable expenditures that may be reimbursed for certain parties involved in AHR, and how loss of work-related income may be reimbursed for surrogate mothers. The *Administration and Enforcement (Assisted Human Reproduction Act) Regulations* set out procedures and requirements regarding seized or forfeited information or material. In addition, amendments to the *Assisted Human Reproduction (Section 8 Consent) Regulations* revise provisions that could unintentionally compromise donor anonymity, require record keeping, and make minor updates. Finally, the *Processing and Distribution of Semen for Assisted Conception Regulations* will be repealed, and a consequential amendment to the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* will be made.

Cost-benefit statement: The incremental costs for the AHR industry to meet the regulations are estimated at $4,579,273 over a 10-year period. It is also expected to cost Health Canada $6,677,430 over a 10-year period to administer the compliance and enforcement program associated with this initiative. As a result, the total anticipated costs associated with the initiative translate to a present value cost (discounted by 7%) of $11,256,703 over a 10-year period.

These costs will be offset by a number of qualitative benefits, including an increased ability to avoid disease transmission from donor sperm or ova to the recipient or donor-conceived person; greater confidence in the safety of donor sperm and ova in Canada; an increased ability to identify, trace and remove from the supply chain donor sperm or ova that are the subject of an

error, accident or adverse reaction; and the increased accountability of regulated parties. The qualitative benefits of the regulations to permit the reimbursement of certain expenditures to sperm and ova donors, surrogate mothers, and persons involved in maintaining and transporting in vitro embryos include providing clarity to those offering and receiving such reimbursements so that they can undertake those transactions without concerns that they could be contravening the AHRA.

"One-for-One" Rule and small business lens: This initiative is an "IN" for the purpose of the "One-for-One" Rule, as the anticipated administrative burden to the AHR industry is estimated to be approximately $39,225 (2012 dollars) annually, or $353 per business. The small business lens also applies as there are approximately 111 small businesses in Canada that may be affected by this initiative. The registration and notification requirements in the *Safety of Sperm and Ova Regulations* were developed with the intent of reducing the burden on small business, where possible, without compromising the safety objectives.

Domestic and international coordination and cooperation: The *Safety of Sperm and Ova Regulations*' infectious disease testing and genetic disease screening requirements will better align Canadian regulations with regulations in the United States and Europe, as well as industry practices in the United States, Europe, and Canada.

Background

Canadians are increasingly using assisted human reproduction (AHR) — such as intrauterine insemination and surrogacy — to help them have children and build their families. [3], [4] This trend is driven by a number of factors, including infertility among heterosexual couples, [5] scientific advances in cryopreserving ova, and the increasing use of AHR by the LGBTQ2+ community and single parents to have children. Health Canada is committed to making sure the rules governing AHR help protect Canadians' safety and reflect their needs.

In 2004, the *Assisted Human Reproduction Act* (the AHRA, or the Act) received royal assent. The AHRA, which was informed by recommendations from the 1993 Royal Commission on New Reproductive Technologies, [6] is a legislative framework that helps protect and promote the health, safety, dignity and rights of people who use or are born of AHR in Canada. Among the provisions of the AHRA that are in force, section 2 provides key principles that underpin the Act, including those that recognize that the health and well-being of children born of AHR technologies must be a priority in decisions related to the technology's use, and that persons who seek to undergo AHR procedures must not be discriminated against. Sections 5 to 9, which are also in force, set out prohibited activities related to AHR that may pose significant human health and safety risks, that may compromise the dignity and rights of individuals, or that have been deemed to be ethically unacceptable. In December 2007, the first regulations under the Act, the *Assisted Human Reproduction (Section 8 Consent) Regulations* [7] (the Consent Regulations), came into force. These Regulations set out, among other things, requirements for how consent is provided or withdrawn with respect to the use of human reproductive material [8] for the purpose of creating an embryo or in vitro embryos (IVE) for any purpose.

In 2010, the Supreme Court of Canada found that certain sections of the legislation exceeded the legislative authority of the Parliament of Canada under the *Constitution Act, 1867* and were therefore unconstitutional. In 2012, Parliament repealed those sections, and a new prohibition was enacted in the AHRA (section 10) that has as its purpose the reduction of the risks to human health and safety arising from the use of third-party donor sperm and ova for the purposes of AHR. Third-party donor sperm or ova (referred to hereafter as donor sperm or ova) is sperm or ova that has been obtained from a donor and is meant for use by a female person other than a spouse, common-law partner or sexual partner of the donor. Donor sperm or ova may be from a donor that the recipient does not know, a donor who also acts as a surrogate mother, or may be from a donor who is known to the recipient but who is not their spouse, common-law partner, or sexual partner.

Section 10 and several other sections of the AHRA were not brought into force immediately as they require regulations to operate. The Consent Regulations provided the first set of regulations under the AHRA, allowing section 8 to be brought into force, and this initiative includes the remainder of the required regulations, now allowing all sections of the AHRA to be brought into force.

The safety of donor sperm is currently regulated under the *Processing and Distribution of Semen for Assisted Conception Regulations* (the Semen Regulations) under the *Food and Drugs Act*. Any person who processes, imports for distribution or distributes donor sperm used or intended for use in assisted conception in Canada must comply with the Semen Regulations. Currently, donor ova are not subject to specific safety requirements under federal law.

The AHR industry includes, among others, sperm and ova banks, importers and distributors, fertility clinics, lawyers, consultants, surrogates, sperm and ova donors, and health care providers. The majority of donor sperm and, Health Canada believes, the majority of donor ova used in Canada for AHR are imported from the United States, where sperm and ova may be purchased from a donor. In Canada, donor sperm and ova may be purchased from a sperm or ova bank, provided that the bank is not acting as an agent or representative of the donor. However, the AHRA prohibits in Canada the purchase, offer to purchase, or advertisement for the purchase of sperm or ova from a donor or a person acting on behalf of a donor.

Issues

There are federal regulatory gaps with respect to AHR, due to the outdated Semen Regulations, and because the AHRA's provisions related to the safety of donor sperm and ova (section 10), reimbursement (section 12), and administration and enforcement (sections 45–58) are not in force. In addition, issues have been identified related to the existing Consent Regulations.

1. Safety oversight of donor sperm and ova

Donor sperm

Currently, donor sperm in Canada are subject to the Semen Regulations. The Semen Regulations were made under the *Food and Drugs Act* in 1996 to mitigate the risk of infectious disease transmission from the use of donor semen in assisted conception. At the time, a driver for regulatory oversight was cases of HIV transmission through donor sperm. Under the Semen Regulations, the donor screening (e.g. medical records review, physical exam, questionnaires) and donor testing (e.g. laboratory tests) requirements include screening and testing for certain infectious diseases.

There is a need to modernize the federal regulatory requirements for the safety of donated sperm. Keeping such a scheme up to date is important, as donor sperm carries a risk of transmitting disease to the recipient as well as the child conceived. Human health and safety oversight will be strengthened by adding diseases to the screening and testing requirements to reflect the increased spread of certain infectious diseases (e.g. West Nile and Zika viruses), and to make allowances for advances in testing methods.

As the Semen Regulations include out-of-date screening and testing practices, they are misaligned with U.S. and European requirements and industry standards and act as a barrier to the import of donor sperm from the United States and other jurisdictions. This is the case for infectious disease screening criteria as well as microbiological testing requirements. In addition, all test kits used to test donor specimens for the presence of infectious disease agents are required to be licensed in Canada, and as a result donor sperm that has been tested by equivalent kits licensed in other jurisdictions, but not in Canada, cannot be imported.

Oversight of donated sperm will benefit from adding donor screening requirements for genetic diseases. There are currently no such requirements in the Semen Regulations, but it is increasingly considered an industry best practice given the continued advances in knowledge of inheritable conditions. While Health Canada is not aware of any reported cases of serious genetic disease transmission through AHR in Canada, there have been cases of serious genetic diseases (e.g. cystic fibrosis, neurofibromatosis) passed onto donor-conceived persons in the United States and Europe.

[9], [10], [11], [12] Information on a donor's known family history of genetic disease can increase the opportunities to mitigate the risk of transmitting such diseases to children born of AHR.

Internal analysis, as well as consultation with stakeholders and AHR experts, has pointed to the need to modernize the regulatory oversight of "directed donations," when the donor and the recipient know each other. Under the Semen Regulations, donors must meet all screening and testing criteria, even if they are known and chosen by the recipient to become their donor, as the Regulations do not distinguish between unknown and directed donors. It may be possible to use a directed donor who would otherwise be excluded from donation through an application to Health Canada's Donor Semen Special Access Programme (DSSAP), which provides access in exceptional circumstances to sperm that has not been processed in accordance with certain requirements of the Semen Regulations. Applications are each evaluated, and, where they meet the DSSAP requirements, are provided with a special access authorization issued by the Minister of Health. The DSSAP was first put in place primarily to allow access to donor sperm donated prior to 2000, and did not originally accommodate directed donations. Recognizing that individuals wished to build their families using sperm from known donors who would otherwise be excluded from donating, Health Canada expanded the scope of the DSSAP to consider such requests. The expansion of the DSSAP, combined with considerable stakeholder feedback, identified the need to introduce a directed donation process into regulations.

Under the Semen Regulations, there are gaps in Health Canada's ability to provide health and safety oversight of the establishments participating in Canada's donor sperm supply chain. Currently, domestic donor sperm processors and importers are required to notify Health Canada of their intent to process or import for distribution before they begin their activities. This approach has presented a number of challenges. For instance, sperm distributors are not required to identify themselves to Health Canada. This gap in oversight of a section of the supply chain makes it more difficult for the Department to verify that recipients have access to donor sperm that complies with the Regulations. It also makes it more difficult for Health Canada to trace donor sperm in the event of a safety issue.

In addition, the Semen Regulations do not include a registration requirement as a prerequisite to the processing of sperm, nor is there any requirement for the processor or importer to attest to their compliance with the Semen Regulations. This leaves Health Canada with limited options for compelling processors to comply with the screening and testing requirements of the Semen Regulations. The Department can seize and prosecute for violations of the *Food and Drugs Act* or the Semen Regulations, but lacks the regulatory tools necessary to encourage processors to come into compliance when, for example, minor deficiencies in operating procedures are noted.

Under the current framework, the onus is on the importer to ensure that the donor sperm they are importing from foreign processors meets the requirements of the Semen Regulations. Issues identified with donor screening or testing of imported sperm are usually detected upon inspection of the importer after the import has occurred and distribution of the sperm may have already commenced. This increases the possibility that non-compliant sperm could be used in Canada before any issues are identified by Health Canada. To verify a foreign processors' compliance with the Regulations, Health Canada has to currently work through the Canadian importer and, if issues are identified, seek to influence the foreign processor to implement voluntary corrective actions.

Donor ova

To date, there are no federal regulatory requirements for the safety of donor ova, and Health Canada has no oversight over its supply chain. When the Semen Regulations were enacted in the mid-1990s, the field of ova donation was less advanced. However, as with donor sperm, donor ova used in AHR carries with it the potential risk of transmitting diseases to the recipient and the child conceived from that ovum.

Recent advancements in the field, such as ova cryopreservation technology, as well as the increased availability of donors via the Internet, have made it easier to access donor ova. This includes increased accessibility to donor ova from countries without robust safety oversight for ova donations. Potentially unsafe ova may be readily imported and made available to people in Canada, putting recipients and children born of AHR at increased risk of disease transmission. Although the

Department is not aware of any reported cases of infectious disease transmission through donor ova in Canada, scientific studies have demonstrated that certain infectious disease agents can be detected in ova obtained from women infected with those diseases. This, combined with the risk of transmitting a serious genetic disease to a child born from using donor ova, compels Health Canada to take steps to mitigate potential risks to human health and safety that could result from the use of donor ova.

2. Reimbursement of expenditures permitted under the AHRA

The absence of regulations respecting reimbursements permitted under the AHRA has led to confusion for parties involved in sperm and ova donation and surrogacy arrangements. The AHRA prohibits reimbursing donors, surrogates and persons who maintain and transport IVEs except in accordance with the regulations. The reimbursement provision of the AHRA is not, however, in force. As a result, persons in Canada using AHR and who are reimbursing donors and surrogates are doing so in the absence of regulations. Health Canada provides, via fact sheets, some guidance as to what, in its view, may be reimbursed. [13] There has, nonetheless, been significant criticism of the absence of reimbursement regulations and the resulting lack of clarity. [14] Regulations are required to clarify what constitutes allowable reimbursable expenditures.

3. Administering and enforcing the AHRA

The administration and enforcement provisions in the AHRA set out a framework for enforcement activities. The power includes provisions that set out the activities that inspectors designated by the Minister of Health can undertake to verify that parties are in compliance, or to prevent non-compliance, with sections 8, 10 and 12 of the AHRA and their associated consent, safety and reimbursement regulations.

Among these activities, the AHRA gives inspectors the power to seize material [15] or information that they have reasonable grounds to believe is related to a contravention of the Act. Seized material or information is forfeited to the Crown if no application for restoration is made within 60 days, if an application for restoration is denied, or if the owner or the person in whose possession it was at the time of seizure consents in writing to its forfeiture. The AHRA requires a “designated officer” within Health Canada to make reasonable efforts to preserve any viable seized sperm, ova or IVE.

Before these provisions can be brought into force, regulations are needed to define the “designated officer” mentioned in subsection 52(3) and section 54, and to set out the requirements in relation to taking further measures with respect to seized sperm, ova or IVE, when the consent of the donor is impossible to obtain.

Subsection 51(1) of the AHRA sets out that a person from whom material or information was seized may apply within 60 days after the date of seizure to a provincial court judge within whose jurisdiction the seizure was made for an order to have the material or information restored, provided they send a notice to the Minister of their intention to do so. As the AHRA sets out no further details regarding this process, it is in regulations that the notice requirements will be set out.

4. Gaps in the Consent Regulations

The Consent Regulations specify the basic requirements in relation to the consent obtained from a donor for the use of human reproductive material or an IVE, as required by section 8 of the AHRA.

Currently, the Consent Regulations may unintentionally compromise the anonymity of third-party donors of reproductive material and IVEs by requiring the disclosure of information that may reveal their identity. While a temporary administrative solution is in place, regulatory amendments are necessary to fully respond to the concerns raised by sperm banks.

The Consent Regulations do not currently include a requirement for the retention of records. A fixed record-keeping period will better support compliance and enforcement in matters of consent. In addition, the Standing Joint Committee for the Scrutiny of Regulations has identified in the Consent Regulations certain provisions that warrant clarification as well as discrepancies between the French

and English versions.

Objectives

These regulations will assist in reducing the risks to human health and safety that may arise from using donor sperm and ova for the purpose of AHR, including the risk of disease transmission. It will also provide clarity to stakeholders on the allowable reimbursements for certain expenditures involved in AHR, help maintain donor anonymity for persons who choose to donate on the basis of anonymity, and set out procedures and requirements regarding measures related to seized or forfeited information and material.

Description

These regulations, which support the bringing into force of sections 10, 12, and 45 to 58 of the AHRA, will

1. **establish a health and safety regulatory framework** for donor sperm and ova used for the purpose of AHR;
2. **set categories of allowable expenditures that may be reimbursed** in relation to the donation of sperm and ova, the maintenance and transport of IVEs, and surrogacy, as well as set out requirements for the reimbursement of loss of work-related income for surrogate mothers;
3. **set out procedures and requirements for measures related to information or material** that is seized or forfeited under the AHRA;
4. **amend the Consent Regulations** to preserve the anonymity of donors, introduce a record-retention requirement, align the English and French versions of provisions, and clarify certain terms and phrases;
5. **repeal the Semen Regulations** and make a consequential amendment to another set of regulations that references the Semen Regulations; and
6. **establish coming-into-force dates** that will balance the need for increased safety oversight with the need to allow sufficient time for stakeholders to update their practices to comply with the regulations.

1. Safety of Sperm and Ova Regulations

The Regulations [16] introduce a regulatory framework focused on reducing the risks to human health and safety arising from donor sperm and ova intended for use in AHR in Canada. This will be done through a set of requirements for establishments that conduct the activities of processing, importing or distributing donor sperm and ova, including measures related to the traceability of the sperm or ova. Health professionals, as defined in the Regulations, will be subject to limited regulatory requirements.

The Regulations take a risk-based approach to the different activities conducted by persons along the supply chain for donor sperm and ova for use in AHR. This approach recognizes that the level of oversight for an activity should be proportionate to its health and safety risk level.

1.1 Establishments

An establishment is defined in the Regulations to include persons that process, import, or distribute donor sperm and ova, and to exclude health professionals. Processing means any of the following activities in respect of donor sperm or ova: performing donor suitability assessments, obtaining sperm or ova from a donor as well as preparing, identifying, testing, preserving, assessing the quality of, labelling, quarantining or storing donor sperm or ova. A health professional will not be considered an establishment, unless he or she conducts an activity beyond those listed in the definition of health professional, as described below.

Establishments will be subject to specific requirements primarily dealing with quality management

related to the activities that they conduct and, as applicable, to their processing of donor sperm and ova activities.

Two types of establishments will be required to identify themselves to Health Canada: primary establishments will be required to register with Health Canada, and establishments that distribute or import donor sperm or ova will be required to notify Health Canada prior to the distribution or importation. All other establishments, which include facilities (e.g. laboratories or clinics) that perform any processing activities such as testing or storage, will not be required to register or notify.

1.1.1 Primary establishments

Primary establishments are defined as establishments that conduct (themselves or through another establishment acting on their behalf) all of the processing activities in respect of donor sperm or ova for use in AHR in Canada. They will be responsible for ensuring that donor sperm or ova have been processed in accordance with the Regulations prior to distributing or making use of them. Considering the higher level of risk associated with their responsibilities, these primary establishments will have to register with Health Canada.

An application for registration of a primary establishment will be required to contain certain information, including the following: the applicant's name, address and contact information; a statement indicating whether the applicant proposes to process sperm or ova; a list of the processing activities that are proposed to be conducted in each building; and a statement as to whether the applicant intends to have another establishment process sperm and ova on its behalf as well as the name and address of those establishments and a list of processing activities and the buildings in which they will be conducted. In addition, an attestation signed by a senior executive officer will be required.

If the Minister of Health determines that the information in the application is complete, the Minister will be required to register the primary establishment and issue a registration number. The Minister will have the authority to refuse to register a primary establishment in certain situations, including where the Minister has reasonable grounds to believe that the information provided by the applicant in the application was false, misleading, inaccurate or incomplete, or where the issuance of the registration could compromise human health and safety or the safety of the donor sperm or ova. The Minister will have the power to suspend a registration, in part or in whole, without prior notice when he or she has reasonable grounds to believe that the safety of sperm or ova or human health and safety has been or could be compromised. The Minister may also cancel a registration under certain circumstances. Primary establishments will also be required to provide the Minister with an annual attestation that will include certifying that they have evidence to demonstrate that they are in compliance with the Regulations.

Registration is considered necessary to identify and monitor primary establishments, as the activities they conduct are integral to the safety of donor sperm and ova. Given that primary establishments will need to attest to, and have evidence to demonstrate, compliance with the Regulations to maintain registration, Health Canada will be provided with the regulatory tools needed to help determine if the requirements of the Regulations are being met and to take enforcement actions if they are not.

Primary establishments will be responsible for the processing activities conducted by other establishments on their behalf. These activities could include, for instance, testing and preparing donor sperm and ova. The primary establishment will, however, always remain responsible for determining that donor sperm or ova can be released from quarantine. Establishments that conduct activities on behalf of primary establishments will not be required to register with Health Canada; primary establishments will be required to identify them in their registration applications. The establishments that perform processing activities on behalf of a primary establishment will be subject to applicable requirements related to the activities they perform on behalf of the primary establishment as well as to the requirements that apply to all establishments, and, like other establishments, they could be subject to inspection to verify compliance with the Regulations.

The current limitations on Health Canada's ability to provide safety oversight on imported sperm collected and processed in other countries will be addressed, in part, by the registration scheme and

the general requirement placed on establishments that import. The Regulations require that establishments that import donor sperm and ova ensure that the sperm or ova have been processed by a registered primary establishment. Given the requirements on primary establishments, Health Canada will have the regulatory tools needed to determine if the Regulations are being met, and the Department will be allowed to work directly with the establishments to help ensure compliance. If the facility that processed the donor sperm or ova was not registered under the Regulations, then the importing establishment will have to be registered as, and meet the requirements of, a primary establishment, including ensuring that the donor sperm or ova is processed in accordance with the Regulations.

1.1.2 Importing or distributing establishments

Due to the requirements placed on primary establishments and the relatively lower level of risk for importing and distributing activities, establishments will be required to notify the Minister prior to importing or distributing donor sperm or ova for use in AHR. An importing establishment will be required to ensure that the donor sperm or ova were processed by a registered primary establishment. The Regulations also require establishments that import or distribute donor sperm or ova for use in AHR to provide the Minister with an annual attestation that includes certifying they have evidence to demonstrate that they are in compliance with the Regulations.

1.2 Health professionals

As defined in the Regulations, a health professional, as a person who is authorized by the laws of their province or territory to make use of donor sperm or ova in AHR, will not be considered an establishment when they only conduct the following activities: (i) making use of donor sperm or ova, or distributing donor sperm to a recipient for their personal use; (ii) preparing, quarantining, labelling or storing donor sperm or ova only for the purpose of making use of that sperm or ova; or (iii) preparing, quarantining, labelling or storing donor sperm only for the purpose of distributing that sperm to a recipient for their personal use. As an integral part of the health and safety framework, health professionals will be required to meet certain regulatory requirements with regard to records to permit the traceability of the donor sperm or ova, related to errors, accidents, and adverse reactions and related to exceptional access and directed donations.

Where a person that is authorized by the laws of their province or territory to make use of donor sperm or ova in AHR conducts any activity other than those listed in the definition of a health professional, that person will be considered an establishment and will be subject to the relevant establishment requirements that correspond to the activities being carried out.

1.3 Donor suitability

The Regulations provide two distinct processes for assessing donor suitability: regular process and directed donation process.

1.3.1 Regular process for donor sperm and ova

The regular process will establish the standard requirements of assessing donor suitability, it will apply to all donor sperm and ova by default. However, in cases where the donor and the recipient know each other, the directed donation process requirements may be followed instead.

For the regular process, the primary establishment will be responsible for ensuring that the donor suitability assessment is conducted. The Regulations lay out the required steps for the donor suitability assessment, and the technical requirements for conducting them are set out in a directive incorporated by reference into the Regulations. The technical requirements include screening and testing sperm and ova donors to reduce the risk of infection and genetic disease transmission from the donor to the recipient or to the child born from the use of the donor’s sperm or ova. The directive also sets out the exclusion criteria that will be used to establish whether a donor is suitable or not for the purpose of the regular process. Health Canada will have the ability to amend this directive from time to time, with amendments that are consistent with the purpose of reducing risks to human health and safety.

Establishments will be required to quarantine all donor sperm and ova that they process, which includes, among other things, segregating the sperm and ova and ensuring that they are not distributed or used. Establishments will be required to continue to keep sperm and ova in quarantine until the medical director of the primary establishment responsible for the donor sperm or ova quarantine has taken certain steps, including determining that the donor is suitable and that the donor sperm or ova can be released from quarantine.

Under the regular process, these requirements will have to be met for all donor sperm and ova, with the exception of two exceptional circumstances: (1) previous exposure: if the intended recipient has already been exposed to a donor's sperm or ova and the results of any of the donor suitability assessment completed is at least equivalent to the risk profile of the requested sperm or ova; or (2) genetic sibling: if donor sperm or ova were used to create a child for an individual or couple and the requested sperm or ova from the same donor are to be used to create another child for the same individual or couple. Donor sperm and ova that do not meet all the requirements under the regular process, but that meet one of these circumstances, could still be considered for release from quarantine through exceptional access.

For the specific sperm or ova to be released from quarantine through exceptional access, certain requirements will need to be met. First, a health professional will need to initiate exceptional access on behalf of a recipient. The primary establishment will then be required to ensure the creation of a summary document that contains detailed information regarding that sperm or ova and the donor. The donor sperm or ova will have to be accompanied by a document that states that it is for exceptional access, and it will have to be segregated from other donor sperm and ova. Finally, prior to making use of the sperm or ova, a health professional will need to document that, based on the summary document and any risk mitigation measures with respect to the sperm or ova in their medical opinion, using the donor sperm or ova does not pose any serious human health and safety risks. A health professional will also be required to document that he or she has informed the recipient of the risk that the use of the donor sperm or ova could pose to human health and safety and that he or she has obtained the recipient's written consent.

1.3.2 Directed donation process for donor sperm and ova

The directed donation process will provide a means for the use of donor sperm or ova when the recipient and the donor know each other but are not each other's spouse, common-law partner, or sexual partner. While such donors may proceed through the regular process, the option to use the directed donation process instead will make it easier for Canadians who know their donor to proceed with building their families.

The directed donation process will also allow sperm or ova from a known donor to be imported, distributed and used, even if that donor does not meet all of the donor suitability requirements under the regular process, as any associated health risks could be individually assessed and mitigated in such circumstances.

The directed donation requirements are largely similar to the regular process requirements, with certain differences. Specifically, a health professional will need to initiate the process for directed donation on behalf of a recipient. The assessment of the donor will not require that the donor be retested and a donor will not be automatically excluded if they meet certain screening or testing results. Instead, a primary establishment will have to ensure that information regarding the donor is reviewed by its medical director who uses it to create a summary document. Prior to making use of the donor sperm or ova, a health professional will be required to document that, based on the summary document and any risk mitigation measures with respect to the sperm or ova in their medical opinion, using the donor sperm or ova does not pose a serious risk to human health and safety. The health professional will also be required to document that he or she has informed the recipient of the risk that the use of the sperm or ova could pose to human health and safety, and that he or she obtained the recipient's written consent. The sperm or ova will also have to be accompanied by a document that states that it is for directed donation, and it will have to be segregated from other donor sperm and ova.

1.4 Quality management

To reduce risks to the safety of donor sperm and ova as well as to human health and safety, all establishments, which includes primary establishments, will be required to meet quality management requirements in respect of the processing, importing and distributing activities that they conduct. Health professionals will be subject to limited quality management provisions regarding error, accident and adverse reaction investigation and reporting, as well as records.

1.4.1 Quality management system

Establishments will be required to establish and maintain a quality management system for the activities they conduct and for the measures that they take in order to satisfy the requirements related to quality management. The requirements of a quality management system include standard operating procedures, a process control program, a system for process improvement, and a document control and records management system.

Establishments must also have an internal audit system and are required to conduct internal audits every two years of the activities they carry out to verify that those activities comply with the Regulations and their own standard operating procedures.

Establishments will be required to have standard operating procedures for all components of their quality management systems and for all activities that they conduct. The procedures will be required to meet certain requirements, and establishments will have an obligation to review them every two years, following any regulatory amendments, and when a deficiency is revealed.

1.4.2 Tracing, identifying, labelling, and storing

The Regulations include tracing, identification, labelling, and storing requirements that support the safety and traceability of donor sperm and ova, and assist inspectors with compliance and enforcement activities.

These requirements include that primary establishments must ensure that a donor identification code is assigned to each donor, and that a donation code is assigned to each donation of sperm and ova. An establishment that labels will be responsible for ensuring that each container of donor sperm or ova is labelled with a donation code and a donor identification code to link it to its date of donation and donor. The Regulations also provide the requirements for documentation that must accompany each container of donor sperm or ova as the material goes through the distribution chain to help verify that it complies with the Regulations, including donor suitability assessment information and information needed for traceability.

Establishments that distribute, import or make use of donor sperm or ova will also be required to examine both immediate containers and shipping containers for compliance with the Regulations. As well, the Regulations set out that an establishment that ships donor sperm or ova will be required to use shipping containers that are capable of resisting damage, maintaining the safety of the sperm or ova, and maintaining adequate environmental conditions during the duration of the shipping.

1.4.3 Personnel, facilities, equipment and supplies

Establishments will be required to have sufficient and qualified personnel, as well as suitable facilities, environmental control systems, equipment, and supplies.

1.4.4 Errors, accidents and adverse reactions

The Regulations include requirements such that donor sperm or ova that are the subject of an error or accident or that may be the cause of an adverse reaction can be quickly identified and quarantined.

Establishments and health professionals will be required to take certain actions in the event of an error, accident or adverse reaction, which will depend on the circumstances. They will include initial measures such as the quarantine of any donor sperm or ova implicated in an error, accident, or adverse reaction, and sending notices to other establishments or health professionals that may have any of the implicated donor sperm or ova. They can progress to, for instance, reporting to Health Canada, as well as implementing corrective measures to prevent further errors, accidents or adverse

reactions.

There are also provisions that permit donor sperm or ova implicated in an error, accident, or adverse reaction to be released from quarantine if it is requested for exceptional access, under the same circumstances and meeting the same requirements as the release for exceptional access under the regular process.

1.4.5 Records

The record requirements support the traceability of donor sperm and ova, and assist the designated inspectors in verifying compliance with the Regulations. All establishments and health professionals will be required to maintain these records for a period of 10 years following their creation unless otherwise specified in the Regulations.

Establishments will be responsible for keeping records that contain all documents and information required in the Regulations, as well as all other records that demonstrate their compliance with the Regulations. Among other things, they will need to keep records on all donor sperm and ova that they processed, and on all establishments and health professionals to which they distributed donor sperm and ova.

Establishments and health professionals that conduct an investigation into an error, accident or adverse reaction, or that have received a notice of an investigation, will be required to maintain records of the investigation as well as any action taken.

Establishments and health professionals will also be required to maintain records on all donor sperm or ova that they use, including, among other things, information about the establishment from which they received the donor sperm or ova and the recipient who has undergone an AHR procedure in which the sperm or ova was used. Health professionals who distribute sperm to a recipient for their personal use will also be required to keep specific records.

1.5 Donor sperm and ova obtained prior to the coming into force of the Regulations

Under transitional provisions, the Regulations permit the import, distribution and use of donor sperm processed in compliance with the Semen Regulations that was obtained prior to the coming into force of the Regulations, as well as donor sperm authorized under the Donor Semen Special Access Programme. Certain labelling and documentation requirements of the Regulations will have to be met in that specific situation.

Donor sperm or ova obtained prior to the coming into force of the Regulations may otherwise be imported, distributed or used if they are brought into compliance with the requirements, such as for the directed donation process or exceptional access.

2. Reimbursement Related to Assisted Human Reproduction Regulations

The AHRA permits, in accordance with the regulations, the reimbursement of certain expenditures incurred by a donor in the process of donating sperm or ova, by any person for the maintenance or transport of an IVE, and by a surrogate mother in relation to her surrogacy. The Act also permits a surrogate mother to be reimbursed for loss of work-related income incurred during her pregnancy if a qualified medical practitioner certifies in writing that continuing to work may pose a risk to her health or that of the embryo or foetus.

The Regulations establish broad categories of expenditures that can be incurred by a donor or surrogate and that can subsequently be reimbursed. For example, donors and surrogate mothers may be reimbursed for expenditures for drugs or devices, care of dependents or pets, or incurred as a result of travel or seeking legal or counselling services in the course of their donation or surrogacy. Surrogate mothers may also be reimbursed for expenditures related to her surrogacy, such as maternity clothing, prenatal exercise classes, groceries, the services of a midwife or doula, or the delivery of the child. As established by the AHRA, all expenditures reimbursed to a donor must be in relation to their donation, and all expenditures reimbursed to a surrogate mother must be in relation to her surrogacy.

Where a surrogate mother has a loss of work-related income incurred during her pregnancy, which is considered by Health Canada to include the postnatal period, the Regulations provide detail about the documentation that will be needed for reimbursement. In addition, a person may be reimbursed for expenditures incurred in the maintenance or transport of an IVE, which could include, for example, the storage of an IVE. The Regulations also set out documentation and record-keeping requirements for each reimbursement, and give the Minister of Health the ability to request any record or additional information from persons who must maintain a record in relation to a reimbursement.

3. Administration and Enforcement (Assisted Human Reproduction Act) Regulations

Most of the administration and enforcement provisions in the AHRA that are not in force (sections 45 to 58) do not require regulations to come into force, including sections that authorize the Minister to designate inspectors and sections that set out the powers of inspectors. Two provisions do require regulations to come into force, and regulations are also needed to add detail related to a third provision.

3.1 Designated officer

The AHRA requires that the notion of “designated officer” be defined in the regulations. The designated officer is responsible, among other things, for providing directions regarding the handling of certain seized or forfeited material or information. The Regulations define the “designated officer” as the Director General responsible within the Department for overseeing compliance and enforcement of the AHRA. Health Canada has determined that an individual at that level is appropriate given the sensitive nature of some of the material that could be seized or forfeited. It considers that the definition is general enough to accommodate any future departmental reorganization while being specific enough to allow the designated officer to be identified by referring to an organizational chart.

3.2 Treatment of seized or forfeited material and information

Among the different inspection powers set out in the AHRA, inspectors designated under the Act will have the ability to seize any material and information by means of which or in relation to which they believe, on reasonable grounds, that the AHRA has been contravened. Seizure could be considered, for instance, in the case of certain specific activities prohibited under the AHRA, or if significant issues with the safety of donor sperm or ova occurred. Under the AHRA, seized material or information may be restored to the person from whom it was seized following an application to a provincial court judge. If such application is not made within 60 days after the date of seizure, or if such an application does not result in an order of restoration, then the AHRA specifies that the seized material or information is forfeited to Her Majesty.

If inspectors seize any viable donor sperm, ova or IVEs, the AHRA requires the designated officer to make reasonable efforts to preserve them. The Act also requires that any further measures with respect to seized sperm, ova or IVEs be consistent with the consent of the donor, or, if consent cannot be obtained, that they be in accordance with the regulations. The Regulations set out who the donor is and whose consent will have to be obtained in the case of an IVE; specifically, they specify when an individual or when a couple is considered the donor of an IVE for the purpose of further measures. Health Canada may be unable to locate or determine the identity of the donor of seized sperm, ova or IVEs because, for instance, they donated anonymously and laws prevent the disclosure of the donor’s identity. If donor sperm, ova or IVEs are seized and then forfeited to Health Canada, and if it is impossible to obtain the consent of the donor for further measures, the Regulations will only permit the designated officer to direct the disposal of the forfeited donor sperm, ova or IVEs following 180 days after it has been forfeited.

3.3 Notice seeking restoration of seized material or information

The AHRA sets out the process for a person to apply for an order of restoration of seized material or information, including the requirement that a notice be sent to the Minister. The Regulations add details to this process by setting out the notice requirements that a person from whom material or

information is seized will need to follow if they intend to make an application for an order of restoration.

4. Regulations Amending the Assisted Human Reproduction (Section 8 Consent) Regulations

The amendments to the Consent Regulations make minor modifications to improve the scheme. One amendment helps preserve the anonymity of donors that donated on the condition of anonymity, where the person making use of the donated sperm, ova or IVEs is not the person who originally obtained the consent directly from the donor. Currently, the Regulations state that the person who makes use of sperm, ova or IVEs must have the written consent of the donor prior to their use. The amendments set out that, in cases of anonymous donations, the consent requirements will be met if the person making use of the donor sperm or ova has, prior to making use, a document from the person who originally obtained consent from the donor, attesting, among other things, that written consent was obtained in accordance with the prescribed requirements and specifying the purpose(s) for which the donated sperm, ova or IVEs can be used. For example, a sperm bank will obtain written consent from an anonymous donor, and then provide to a fertility clinic a separate document that attests, among other things, that the sperm bank received the donor's written consent.

The Regulations also add a new record-retention provision that requires that persons who obtain or make use of sperm, ova or IVEs are responsible for keeping copies of all the documents they are required to have under the Consent Regulations for a period of 10 years after the date on which the sperm, ova, or IVEs are used, or sperm or ova are removed from the donor's body.

In addition, certain provisions of the Consent Regulations are amended in order to clarify a number of terms and phrases and improve consistency between the French and English versions. The title will also be changed to *Consent for Use of Human Reproductive Material and In Vitro Embryos Regulations*, to bring it in line with the titles for the other regulations.

5. Repeal of the Processing and Distribution of Semen for Assisted Conception Regulations *and consequential amendment to the* Safety of Human Cells, Tissues and Organs for Transplantation Regulations

The *Safety of Sperm and Ova Regulations* replace the Semen Regulations for donor sperm. As a result, the Semen Regulations will be repealed, concurrent with the coming into force of the Regulations. The Donor Semen Special Access Programme (DSSAP), which is part of the Semen Regulations, will also end at that time. Access to the types of donor sperm that are currently obtained through the DSSAP will be possible, in the majority of cases, through the directed donation process and exceptional access provisions.

A consequential amendment to subsection 3(1) of the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* will be made to repeal the paragraph dealing with semen regulated under the Semen Regulations in the non-application section of those Regulations. Semen and ova that are regulated under the AHRA will continue to not be subject to the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* pursuant to the non-application provision that is currently in those Regulations.

6. Coming into force and transitional provisions

The new and amended regulations include coming-into-force dates. The coming-into-force dates of the new regulations are the same as the coming-into-force dates of the sections of the AHRA that they support, which will themselves be brought into force via orders in council. The regulations also include transitional provisions in the *Safety of Sperm and Ova Regulations* and the Consent Regulations.

6.1 Safety of Sperm and Ova Regulations

The *Safety of Sperm and Ova Regulations* will come into force on the day that section 10 of the AHRA comes into force, which will be the 240th day after the day on which the order in council to

bring into force section 10 is made, with the exception of one provision. This period will provide industry with the time needed to update their practices to come into compliance with the Regulations. The exception, section 3, will come into force on the 180th day after the day the Regulations come into force to provide primary establishments with time to receive and communicate their registration numbers.

Transitional provisions will allow primary establishments that process donor sperm or ova before the day in which these Regulations come into force to continue to process donor sperm or ova without a registration from Health Canada, provided they have filed a registration application within 90 days after the coming into force of the Regulations. This will apply until the registration number is issued or the application for registration is refused. Similarly, transitional provisions will allow establishments that distribute or import donor sperm or ova before the day on which these Regulations come into force to continue conducting those activities without prior notification, provided that they notify Health Canada within 90 days after the coming into force of the Regulations. In addition, regulated parties will not be required to have or provide registration numbers, as set out in certain provisions, until the 180th day after the day that these Regulations come into force, to provide time to primary establishments to receive and communicate their registration numbers.

The Semen Regulations will be repealed at the same time as the *Safety of Sperm and Ova Regulations* come into force. Also at that time, the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* will be amended to remove from the non-application provisions of those Regulations the paragraph dealing with semen regulated under the Semen Regulations. The same order in council that brings section 10 of the AHRA into force will also bring section 4.2 of the AHRA into force at the same time; this provision states that the *Food and Drugs Act* does not apply in respect of sperm and ova to be used for the purpose of AHR.

6.2 Reimbursement Related to Assisted Human Reproduction Regulations

The *Reimbursement Related to Assisted Human Reproduction Regulations* will come into force on the day that section 12 of the AHRA comes into force, which will be one year after the order in council to bring into force section 12 of the AHRA is made. This will provide stakeholders with the time needed to transition to the new reimbursement regime.

6.3 Administration and Enforcement (Assisted Human Reproduction Act) Regulations

The *Administration and Enforcement (Assisted Human Reproduction Act) Regulations* to support subsections 51(1) and 52(3) and section 54 of the AHRA come into force on the day that the order in council that brings into force sections 45 to 58 of the AHRA is made.

6.4 Regulations Amending the Assisted Human Reproduction (Section 8 Consent) Regulations

The amendments to the Consent Regulations will come into force six months after publication of the Regulations in the *Canada Gazette*, Part II. These include transitional provisions in the case of anonymous donations of sperm or ova obtained, or IVE created prior to December 1, 2007, the day on which the Consent Regulations came into force, which are consistent with the scenarios provided for in the existing transitional provisions found in section 16 of the Consent Regulations.

Regulatory and non-regulatory options considered

Option 1: Do not introduce regulations under the AHRA and leave existing regulations in place (maintain the status quo)

The status quo is not considered to be a viable option, as it would not address the gaps in the oversight of safety of donor sperm and ova. The safety of donor sperm would remain regulated by out-of-date requirements under the Semen Regulations that are insufficiently aligned with those in other jurisdictions. Donor ova would be subject to no federal safety oversight, with Canadians remaining at risk of exposure to infectious diseases through their use. There would be no regulations to clarify the expenditures that may be reimbursed for certain parties involved in AHR, leaving those parties in confusion on what is permitted. The Consent Regulations would continue to include a

number of gaps, including provisions that could result in the unintentional compromise of the anonymity of donors.

Furthermore, not bringing into force the reimbursement and administration and enforcement provisions of the AHRA that were enacted in 2004, due to a lack of supporting regulations, would lead to the automatic repeal of those provisions, as per the *Statutes Repeal Act*, unless a request for deferral from repeal is granted every year.

In addition, this option would fail to fulfill the intent of Parliament as expressed in the Act.

Option 2: Develop the regulations necessary to bring into force the reimbursement and administration and enforcement sections of the AHRA, and regulate donor sperm and ova under the Food and Drugs Act

Health Canada considered the feasibility of maintaining the safety requirements for donor sperm in their current location under the *Food and Drugs Act* and adding safety requirements there for donor ova. This would continue to use the authorities of the *Food and Drugs Act* while permitting modernization of the requirements.

This is not, however, considered an adequate option, as it would fail to fulfill the intent of Parliament as expressed in section 10 of the AHRA. The purpose of section 10 of the AHRA is to reduce the risks to human health and safety from donor sperm and ova used for the purpose of assisted human reproduction.

Option 3: Propose a new set of regulations under the AHRA (recommended approach)

This approach is preferred as it provides for a cohesive, consistent regulatory framework that oversees the safety of donor sperm and ova, reimbursement, and consent, with administration and enforcement authorities. Furthermore, this option will fulfill parliamentary intent.

Benefits and costs

Scope and baseline scenario

The cost-benefit analysis (CBA) seeks to explain the qualitative and quantitative costs and benefits of the regulations. All calculated costs and benefits have been calculated over a 10-year period, and the present value figures have been discounted by 7% as required by the Treasury Board Secretariat. [17] A conservative approach to the costs and benefits has been taken whereby Health Canada is of the view that the benefits in this analysis are understated and the costs are overstated. This approach was taken due to the limited data available on the AHR industry as well as the use of AHR in Canada. The data used in this CBA were collected through costing surveys distributed to the Canadian AHR industry and stakeholders, drawn from published literature, or based on Health Canada's operational experience. Despite these multiple sources of information, there were several data gaps on the state of AHR in Canada, which stakeholders have also identified. The CBA, in some instances, provides and explains estimates for figures that lack robust data, while in other instances, it acknowledges the lack of data. The full cost-benefit analysis is available upon request.

The focus of this CBA are the costs and benefits associated with the *Safety of Sperm and Ova Regulations*, as only these Regulations have significant cost implications to industry and government. These Regulations will impose costs on Canada's AHR industry, principally on its members that would meet the definition of an establishment. Establishments are anticipated to consist of sperm and ova banks and other donor sperm and ova processors that meet the definition of primary establishments; importers and distributors of donor sperm or ova; facilities that perform processing for donor sperm or ova; and health care providers that meet the definition of establishment. They are located across Canada, most commonly in cities. Health Canada estimated that there are 111 establishments, consisting of 105 final distributors and 6 processors and importers of donor semen, that will be subject to the *Safety of Sperm and Ova Regulations*. Based on the best available historical industry data, Health Canada opted against assuming growth in the number of

establishments in Canada's AHR industry in the CBA. According to Health Canada's inspection database, the number of regulated final distributors under the Semen Regulations has ranged between 102 and 105, from 2011 to 2016, with no identified trend. This low variability in regulated parties suggests a lack of growth in AHR facilities involved in donor sperm, and due to the low amount of activity in ova donations in Canada, it is assumed to be similarly flat. Absent any data showing industry growth, Health Canada assumed that the number of establishments is likely to remain steady, and that existing establishments will meet any growth rate by increasing their capacity by adding staff and space. In addition, no data is available on the current operating costs of members of the AHR industry. No additional industry and costing information emerged during the *Canada Gazette*, Part I, consultation period and therefore this assumption holds.

Given the lack of precise figures on the quantity of donor sperm and ova used in Canada, a study and an industry report were used to estimate these metrics. The potential number of recipients of donor sperm was used to estimate the quantity of donor sperm used annually. A 2017 study using demographic data broadly estimated that 7 866 persons in Canada may seek donor sperm for their reproductive needs at any one time. [18] An annual report prepared by the Canadian Fertility and Andrology Society in 2012 found that, on an annual basis, approximately 617 donor ova were used in Canada. [19] Using these values, Health Canada estimated that roughly 9 000 Canadians seek donor sperm or ova to meet their reproductive needs each year.

Similarly, an estimated growth rate was used to calculate costs that are dependent on the number of donor sperm or ova used annually in AHR. The number of AHR procedures in Europe, Australia and the United States has seen growth rates of 5% to 10% annually in recent years. [20] Assuming a similar growth rate in Canada, Health Canada estimated an increase in demand for AHR at the high end of that range, at 10% annually.

Given the existing Semen Regulations, and based on Health Canada's knowledge of the AHR industry, establishments are believed to already be meeting several of the requirements. The Semen Regulations include requirements for donor suitability assessments for donor sperm, including screening and testing, and establishments are believed to already be performing the incremental requirements in these Regulations. Health Canada also believes that establishments currently operating already meet the minimum requirements for facilities, equipment, supplies, and appropriate environmental monitoring.

Overview

It is projected that the incremental cost to industry to meet the requirements will be $4,579,273 over a 10-year period. Health Canada anticipates that its compliance and enforcement program costs will be $6,677,430 over a 10-year period. The total costs translate to a present value (PV) cost (discounted by 7%) of $11,256,703 over a 10-year period.

There are quantitative and qualitative benefits associated with the *Safety of Sperm and Ova Regulations*. The quantitative benefits include the anticipated cost savings to Health Canada associated with ending the Donor Semen Special Access Programme (DSSAP), representing a present value cost (discounted by 7%) of $103,949 over a 10-year period.

The qualitative benefits of the *Safety of Sperm and Ova Regulations* are significant. These include an increased ability to avoid infectious or genetic disease transmission from donor sperm or ova to the recipient or donor-conceived person, as well as greater confidence in the safety of donor sperm and ova in Canada. Benefits also include an increased ability to identify, trace and remove donor sperm or ova that are the subject of an error or accident from the supply chain, as well as increased accountability of regulated parties.

The qualitative benefits of the *Administration and Enforcement (Assisted Human Reproduction Act) Regulations* as well as the bringing into force of the administration and enforcement sections of the AHRA include an improved ability to help those affected by the use of AHR technologies, especially women using these technologies and children born as a result of the use of these technologies.

The qualitative benefits of the *Reimbursement Related to Assisted Human Reproduction Regulations*,

which permit the reimbursement of certain expenditures to sperm and ova donors, surrogate mothers, and persons involved in maintaining and transporting IVEs, include providing clarity to those offering and receiving such reimbursements so that they can undertake these transactions without concerns that they could be contravening the Act.

Table 1: Cost-benefit analysis (all values in 2017 dollars)

Quantified impacts ($)					
	Stakeholders	**Base Year**	**Final Year**	**Average annual**	**Total (PV)**
Benefits					
Ending DSSAP	Health Canada	$14,800	$14,800	$14,800	$103,949
Total savings		**$14,800**	**$14,800**	**$14,800**	**$103,949**
Costs					
Administrative costs	Establishments	$187,073	$191,294	$188,919	$1,325,094
Regulatory compliance costs	Establishments	$1,313,057	$383,784	$434,552	$3,254,179
Compliance and enforcement	Health Canada	$745,007	$745,007	$745,007	$5,232,616
Administrative enforcement	Health Canada	$205,709	$205,709	$205,709	$1,444,814
Total costs		**$2,450,846**	**$1,525,794**	**$1,574,186**	**$11,256,703**
Net benefits		**−$2,436,046**	**−$1,510,994**	**−$1,559,386**	**−$11,152,754**

Qualitative impacts

Benefits

Strengthened donor suitability assessment requirements regarding donor sperm, including donor screening and testing, to prevent disease transmission to recipients of donor sperm or to persons created from donor sperm.

First-time establishment of federal regulations for the safety of donor ova to prevent disease transmission to recipients of donor ova or to persons created from donor ova.

Increased regulatory oversight and compliance and enforcement activities to support the removal of non-compliant donor sperm and ova from the supply chain.

Greater confidence in the safety of donor sperm and ova from an increased ability to identify, trace and remove donor sperm or ova that are the subject of an error or accident, or the source of an adverse reaction, from the supply chain.

Increased opportunities to mitigate the risk of transmitting genetic diseases to donor-conceived persons through more information about a sperm or ova donor's known family history of genetic disease.

Increased accessibility to donor sperm or ova from a known donor by formalizing directed donation requirements in regulations.

Elimination of wait time associated with Health Canada's reviews and authorizations of the special access application to use, import or distribute donor sperm under the existing Donor Semen Special Access Programme.

Increased clarity to those offering and receiving reimbursements, as permitted under the AHRA, allowing them to undertake these transactions without concerns that they could be contravening the Act.

Improved ability by Health Canada to administer and enforce the AHRA to help protect those affected by the use of AHR technologies, especially women using these technologies and individuals born as a result of the use of these technologies.

Costs

All estimated costs are calculated based on the requirements of the *Safety of Sperm and Ova Regulations*, as Health Canada believes that the costs of the *Reimbursement Related to Assisted Human Reproduction Regulations*, the *Administration and Enforcement (Assisted Human Reproduction Act) Regulations*, and the amendments to the Consent Regulations will be negligible.

Table 2 provides the forecasted total cost for the estimated 111 establishments in Canada that will be directly impacted by the *Safety of Sperm and Ova Regulations*. All costs in the table and in the text are the total estimated costs for all establishments.

Table 2: Total costs to establishments (all values in 2017 dollars)

Quantified Impacts	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
1. Registration/Notification	$ 12,557	$0	$0	$0	$0	$0	$0
2. Annual statement	$ 11,489	$ 11,489	$11,489	$ 11,489	$ 11,489	$ 11,489	$ 11,489
3. Amend or change data *	$ 2,872	$ 2,872	$2,872	$ 2,872	$ 2,872	$ 2,872	$ 2,872

* Administrative costs; all others are compliance costs

4. Additional labelling	$58,500	$64,350	$70,785	$77,864	$85,650	$94,215	$103,636	
5. Record keeping *	$ 3,108	$3, 419	$3,761	$ 4,137	$4, 550	$ 5,005	$5, 506	
6. Information request *	$ 70,138	$ 70,138	$70,138	$ 70,138	$ 70,138	$ 70,138	$ 70,138	
7. Record retrieval *	$ 103,230	$ 103,230	$ 103,230	$ 103,230	$ 103,230	$ 103,230	$ 103,230	
8. Develop quality management measures/SOPs	$ 366,300	$0	$0	$0	$0	$0	$0	
9. Update and review SOPs	$ 74,856	$0	$149,711	$0	$149,711	$0	$149,711	
10. Self-audit	$ 163,205	$163,205	$0	$163,205	$0	$163,205	$0	
11. Employee training	$ 555,000	$0	$0	$0	$0	$0	$0	
12. Investigation — General	$ 34,375	$ 34,375	$ 34,375	$ 34,375	$ 34,375	$ 34,375	$ 34,375	
13. Investigation — Quarantine	$ 25,669	$ 25,669	$ 25,669	$ 25,669	$ 25,669	$ 25,669	$ 25,669	
14. Investigation — Communication	$ 11,107	$ 11,107	$ 11,107	$11,107	$ 11,107	$ 11,107	$ 11,107	
15. Investigation — Error reporting *	$7,725	$7, 725	$7, 725	$7, 725	$7, 725	$7, 725	$7, 725	
Total	**$1,500,130**	**$497,578**	**$490,862**	**$511,810**	**$506,516**	**$529,030**	**$525,458**	

* Administrative costs; all others are compliance costs

Industry costs

The estimated costs are calculated either using the average cost per establishment multiplied by the number of establishments, or using the average cost per unit of donor sperm or ova multiplied by the number of units. The average cost per establishment or per unit is the average of the cost estimates provided by stakeholders in response to the costing survey. Some costs required further assumptions such as the percentage of establishments to which the cost is applicable, or the frequency of the incurred cost. These assumptions are described with each cost below.

Nos. 1–3. The first three costs in Table 2 are for requirements of certain establishments to inform Health Canada that they are participating in Canada's AHR industry. Primary establishments would have to register with Health Canada by submitting an application for registration, while establishments that import or distribute donor sperm or ova would need to notify the Minister of Health prior to undertaking the activity of import or distribution. In the absence of data regarding how many establishments would need to register versus notify, Health Canada has estimated a one-time registration and notification cost of $113 per establishment based on the wage hours required for the establishments to conduct their registration or notification process. The total overall costs will be $12,557 for all 111 establishments in the first year the Regulations are in force.

The Regulations will also require primary establishments and establishments that import or distribute

donor sperm or ova to provide the Minister with an annual statement certifying that they have sufficient evidence to demonstrate that they comply with the Regulations. The annual cost of these activities is estimated to be $11,489. It is assumed that in a given year, 25% of establishments would change data, so the cost was calculated as the average cost per establishment multiplied by the number of establishments (111), multiplied by 25%. The annual cost of data changes is estimated at $2,872.

No. 4. Establishments that label units will be required to label each unit of donor sperm and ova, and provide accompanying documentation. The cost is calculated as the average cost for labelling and documentation per unit multiplied by the number of units of donor sperm and ova (9 000 in the first year). The number of units is projected to increase by 10% each year. The estimated incremental cost associated with the labelling requirements is $58,500 in the first year, and the cost increases by 10% annually as per the estimated growth rate. As a result, the average incremental cost for labelling is estimated to be $93,234 annually in the 10-year period.

Nos. 5–7. Under the Regulations, establishments and health professionals will be responsible for the record keeping of specific documentation, including on the donor sperm and ova they process or receive, and any investigations they undertake that are required by the Regulations. Record-keeping requirements throughout the distribution chain are necessary to permit the traceability of donor sperm and ova as well as to demonstrate compliance with the Regulations. The cost is calculated as the average cost of record keeping for each unit multiplied by the number of units of donor sperm and ova. Based on figures provided through survey responses, it is estimated that the total industry cost to maintain records electronically and physically would be $3,108 in the first year. This cost is expected to increase by 10% annually as it takes into account the number of sperm or ova used.

The Regulations will permit the Minister to ask for any relevant information in support of a primary establishment’s application for registration or to demonstrate that the activities that it conducts, or is responsible for, are being carried out in compliance with the Regulations. Health Canada could also ask any establishment to provide it with any relevant information to demonstrate that its ongoing activities are being conducted in compliance with the Regulations. Based on current data, it is assumed that the Minister may make up to three requests per establishment per year for information. The cost is calculated as the average cost per establishment multiplied by the number of establishments, multiplied by three, for an average annual cost to industry estimated at $70,138.

On the assumption that establishments will need to retrieve physical records to respond to each of the three information requests from the Minister, it is estimated that there would be an additional annual cost of $103,230 for record retrieval.

Nos. 8–11. The Regulations require establishments to have in place a set of quality management measures, including a quality management system with standard operating procedures (SOPs), as well as processes and procedures related to labelling, storing, personnel, facilities, equipment and supplies, among other things. It is estimated that half of all establishments currently have these measures in place. Therefore, Health Canada estimates that half of establishments would incur a one-time expenditure to develop and implement quality management measures to comply with the Regulations, at a total cost of $366,300. The cost is calculated as the average cost per establishment multiplied by the number of establishments, multiplied by 50%.

The Regulations require establishments to review their SOPs every two years, following an amendment to the Regulations, or when a deficiency is revealed through an investigation or audit. The estimated average annual cost for establishments to review their SOPs every two years is $67,370. In the first year, the cost is calculated as the average cost per establishment multiplied by the number of establishments, multiplied by 50%, as it is assumed that the half of establishments with existing SOPs would review and update them in order to comply with the new Regulations. Subsequently, in every other year (years three, five, seven, and nine) the cost is calculated as the average cost per establishment multiplied by the number of establishments.

The Regulations will also place a requirement on establishments to perform an audit every two years of their activities. The estimated annual cost for all establishments to perform a self-audit is $163,205, and the estimated average cost for establishments to self-audit the first year and then every two

years is $97,923. Regarding the timing of the reviews and self-audits, it is assumed it would be standard industry practice to perform a self-audit in the first year that the proposed Regulations are in force, and then begin biennial self-audits beginning in year two. It is also assumed that establishments would subsequently alternate the biennial audits with the SOP reviews and updates to distribute these costs more evenly.

Under the Regulations, establishments will also be required to have qualified personnel and a system in place to provide personnel with initial and ongoing training. It is estimated that this requirement will impose a one-time compliance cost of $555,000 on establishments in the first year, to train staff in accordance with the Regulations. Health Canada assumes that the cost associated with the ongoing training of personnel will be attributed to the establishment's own operational cost of doing business.

Nos. 12–15. The final four costs in Table 2 are for activities that establishments and, in some instances, health professionals will be required to undertake in the event of an error, accident, or adverse reaction. Health Canada has identified four incremental costs related to investigation and reporting requirements, and for each has assumed that 25% of establishments would participate in an investigation into an error, accident or adverse reaction on an annual basis. These four costs were calculated as the average cost per establishment multiplied by the number of establishments, multiplied by 25%.

In the event of a suspected error, accident or adverse reaction related to their activities, establishments and, in some instances, health professionals would be required to investigate. The average annual cost associated with 25% of establishments performing an investigation is $34,375. Under the Regulations, establishments and health professionals may also be required to quarantine donor sperm or ova implicated in an error, accident or adverse reaction. The average annual cost to quarantine implicated donor sperm or ova will be $25,669.

In the event of an error, accident or adverse reaction, the Regulations require communication among the establishments and health professionals that processed or received donor sperm or ova implicated in an error, accident or adverse reaction. Health Canada estimates the average annual cost for this communication at $11,107. Finally, for specific cases of errors, accidents or adverse reactions, establishments and, in some instances, health professionals will be required to provide reports to the Minister on, among other things, the event that triggered the investigation and the progress of the investigation. The average annual cost associated with 25% of establishments reporting to the Minister is estimated at $7,725.

Sensitivity analysis

Through the costing survey administered by Health Canada, AHR organizations were asked to provide Health Canada with all of the costs associated with the Regulations. Survey participants were asked to provide cost estimates based on the actions they would need to take to meet the regulatory requirements. To produce the most accurate estimate for the CBA, the data collected was analyzed and synthesized into a lower cost scenario (alternative scenario) and a higher cost scenario (current scenario) to formulate an industry average cost for each activity.

Table 3: Impact scenarios — Costs for AHR establishments and health professionals (in 2017 dollars)

Scenario Analyzed	Estimated Number of Establishments	Estimated Number of Health Professionals	Year 1	Year 10	Average	Total (PV)
Alternative scenario	52	59	$746,341	$315,226	$336,634	$2,457,249
Current scenario	111	0	$1,500,130	$575,078	$623,471	$4,579,273

Of the 111 establishments estimated for costing purposes, as informed by Health Canada's inspection database for the Semen Regulations over 2011–2016, six are Canadian processors and importers of donor semen that have notified Health Canada of their activities. These six processors and importers are expected to be establishments under the Regulations. The remaining 105 of the 111 represent health care providers (e.g. fertility clinics, doctors) who are expected, based on Health Canada's understanding of their activities, to be health professionals as defined in the Regulations. To be conservative, the cost-benefit analysis assumes that they are all establishments. It is also noted that Health Canada does not have data on donor ova processing, importation or facility use in Canada.

Although Health Canada has applied all estimated costs that arise from the Regulations to 111 establishments, Health Canada is aware that not all health care providers currently regulated under the Semen Regulations would be likely to assume all costs associated with the regulatory requirements. This is because an organization would need to comply with the regulatory requirements particular to the activities they conduct, as an establishment or as a health professional.

In Table 3, costs for the higher cost, current scenario and a lower cost, alternative scenario are provided. The alternative scenario estimates that 52 establishments, which consists of the 6 known establishments as well as 46 health care providers that are also assumed to be conducting activities that can only be performed by establishments, thereby assuming the full cost burden associated with these activities. The remaining 59 health care providers are assumed to meet the definition of health professionals. The alternative scenario is lower cost as health professionals would only assume costs related to the limited requirements that are stipulated for them associated with record keeping and investigation; these costs are included in Table 2 as No. 5 and Nos. 12–15. The estimated industry cost for the alternative scenario is a lower $2,457,249 (PV) over a 10-year period, compared to the CBA's current scenario estimate of $4,579,273 (PV).

For the purposes of the cost-benefit analysis, Health Canada had chosen to apply the conservative, higher impact scenario to all costing figures, thereby assuming that all 111 AHR persons will meet the definition of an establishment and be subject to the costs of all activities associated with establishments. This approach was selected to account for the possibility that each health care provider is conducting activities that can only be performed by establishments that under the Regulations would result in them assuming costs related to establishment requirements.

The higher cost scenario also provides the most suitable estimate of the potential costs for industry to comply with the Regulations given the lack of available data on the AHR industry, including the number of establishments that process, import or distribute only donor ova in Canada; the number of establishments, other than primary, importing or distributing, that may assume costs to meet the requirements; and the potential impact on the fees for imported donor sperm and ova.

Government costs

Table 4: Health Canada costs for administering and enforcing the AHRA

Health Canada	Year 1	Year 2 to Year 10	Average	Total (PV)
Compliance and enforcement	$745,007	$745,007	$745,007	$5,232,616
Administrative enforcement	$205,709	$205,709	$205,709	$1,444,814
Total	$950,716	$950,716	$950,716	$6,677,430

The administration and enforcement provisions in the AHRA set out a framework through which designated inspectors will verify that parties comply with the Act.

Health Canada estimates the annual cost of implementing a compliance and enforcement program to oversee the new AHR regulatory framework at $950,716. The annual administration and enforcement cost of $745,007 includes four inspectors, one regulatory compliance and enforcement advisor and a

registration officer. An additional annual expenditure of $205,709 includes the cost associated with inspections as well as information management and information technology development.

Other costs considered

As it is believed that most donor sperm and ova used in Canada are imported from the United States, it is likely that any increased costs assumed by U.S. and other foreign primary establishments that choose to register with Health Canada would be included in the fees associated with obtaining donor sperm and ova. While the Regulations have been designed to match U.S. and Canadian industry practice to the extent possible, there will nonetheless likely be incremental costs. Due to a lack of data at this time, the cost analysis did not estimate a potential increase in fees charged to Canadian establishments or consumers. The recognition of these circumstances, however, contributed to the decision to use a conservative, higher impact estimate for overall costs, in an effort to better capture the impact of the Regulations.

The *Reimbursement Related to Assisted Human Reproduction Regulations* only apply where, following a request for reimbursement, a person chooses to reimburse a sperm or ova donor or surrogate mother for expenditures assumed in relation to their donation or surrogacy or to any person for the maintenance or transport of an IVE as per the categories of allowable expenditures. There is no regulatory requirement for reimbursement to occur but, should individuals voluntarily opt to do so, the reimbursement must be in compliance with the Regulations. The principal information requirements in the Regulations include the following items:

1. Sperm and ova donors, surrogates, and persons that maintain or transport an IVE will be required to collect receipts and prepare a declaration, including a list of expenditures;

2. Sperm and ova donors, surrogates, and persons that maintain or transport an IVE will be required to provide these documents to the person providing the reimbursement;

3. The person providing the reimbursement will be required to affirm and sign the declaration;

4. The person providing the reimbursement will be required to keep these records for six years; and

5. The person providing the reimbursement may receive a records request from the Department and be required to send specified records for verification.

Health Canada believes that the time required for sperm and ova donors, surrogates and persons that maintain or transport IVEs to complete item 1 in the list above, the preparation of a declaration, is negligible. This is because the declaration requirements were purposely kept light in recognition that Health Canada assumes that it will primarily be private citizens preparing the declaration for reimbursement. Further, Health Canada has no way of knowing how many people will choose to opt into reimbursement activities. Data about existing reimbursement activities is unavailable because, in the absence of regulations, any reimbursements that are happening now are not subject to Health Canada compliance and enforcement activities. Given that Health Canada has no way of estimating how many reimbursements would take place, the costs associated with item 1 could not accurately be described in the CBA. Only an estimated cost for item 5 in the list above has been calculated, as it is required as part of the administrative costs under the “One-for-One” Rule: three annual record requests would cost industry/private citizens an estimated $217 (PV) over 10 years.

While most of the costs for requirements are attributable to the *Safety of Sperm and Ova Regulations*, the AHRA has provisions that specifically deal with the seizure and storage of information and material, including those that give designated inspectors the ability to seize and store information and material. The *Administration and Enforcement (Assisted Human Reproduction Act) Regulations* are required to operationalize three of the administration and enforcement provisions in the AHRA, which will thereby permit all administration and enforcement provisions of the Act to be brought into force. These Regulations include details on the notice requirements should a person apply for the restoration of seized material or information. The incremental costs associated with the notification requirements are attributable to the Regulations. However, they have not been estimated because Health Canada believes that the time required for a person to complete such a notice will be negligible. This is because the notice requirements were purposely limited to only those basic

elements that would typically be found in this type of notice and are not onerous. Further, Health Canada has no way of forecasting how often information or material may be seized nor any way of knowing how many people may apply for restoration of seized material or information by following the notice requirements. Given that the costs are negligible, and given that Health Canada has no way of estimating a multiplier, the costs associated with the notice requirements could not accurately be described in the CBA.

The government costs for the administration and enforcement provisions related to seized material in the regulations have not been estimated separately. They are part of the full cost provided for Health Canada's compliance and enforcement program. The cost includes salary and other operating expenditures for all activities that will be required to enforce the Act and the regulations, including seizures and storage. Health Canada notes that in the final *Administration and Enforcement (Assisted Human Reproduction Act) Regulations* the period only after which the designated officer may direct the disposal of forfeited sperm, ova or IVEs, when consent of the donor is impossible to obtain, increased to 180 days from the 60 days proposed in the pre-published regulations. However, given the moderate increase in this period of time, the government costs have not been revised.

The amendments to the Consent Regulations include new provisions dealing with consent for the purposes of section 8 of the AHRA in cases where donations were made on the condition of anonymity as well as record-keeping requirements. As it is believed that these activities are already in practice by the AHR industry, the incremental costs are considered negligible.

Cost summary

The projected total cost to all establishments would be $4,579,273 over a 10-year period; this number includes costs for all activities associated with administration and compliance. Health Canada anticipates that its compliance and enforcement program costs would be $6,677,430 over a 10-year period. The total costs would translate to a present value cost (discounted by 7%) of $11,256,703 over a 10-year period.

Benefits

Qualitative benefits

The objective of the safety framework for donor sperm and ova in Canada is to reduce the risks to human health and safety that arise from using donor sperm and ova for the purpose of AHR, including the risk of disease transmission. Based on the precautionary principle, the health and safety oversight of donor sperm and ova requires modernization to address emerging diseases, changes in the industry, genetic diseases, as well as the addition of requirements for donor ova.

Through a document incorporated by reference, the *Safety of Sperm and Ova Regulations* indicate the infectious diseases for which a sperm or ova donor will need to be screened and tested prior to donation. The Regulations also require additional genetic disease screening of prospective donors by requiring them to undergo a questionnaire to help determine the presence of known genetic diseases in the donor or in their family history. This will help mitigate the risk of genetic disease transmission to donor-conceived persons. It is believed that existing establishments in Canada currently meet these requirements.

The testing requirements are justifiable, as Health Canada relies on the precautionary principle when it comes to the prevention of disease transmission. While the CBA does not attempt to quantify the benefits of avoided disease transmission due to the difficulty in estimating potential reductions, an example is provided to illustrate the type of benefit that could result from these reductions. Health Canada has analyzed the costs associated with the avoidance of one specific infectious disease that could be transmitted (hepatitis C) to determine a baseline for current expenses being carried. These savings in expenses only measure the current spending on hepatitis C; however, there are other similar diseases that could be used in this analysis such as the West Nile virus or HIV, among others. Looking at hepatitis C specifically as an example disease, a study estimated the lifetime cost for a patient with chronic hepatitis C at $64,694 in 2013, noting that this cost varied substantially according

to the state of the disease, ranging from a low-cost scenario of $51,946 for a patient with no fibrosis, to a high-cost scenario of $327,608 for a patient requiring a liver transplantation. [21] The study also noted that while the prevalence of chronic infection with hepatitis C in Canada is projected to decrease, advanced liver disease and associated costs are projected to continue to rise over the next 20 years. Preventing disease transmissions will result in benefits to the health care system due to these avoided costs.

Quantitative benefits

Table 5: Reduced Health Canada costs by ending the Donor Semen Special Access Programme (in 2017 dollars)

	Year 1	Years 2–10	Average	Total (PV)
Reduced DSSAP costs	$14,800	$14,800	$14,800	$103,949

Currently, through the Donor Semen Special Access Programme (DSSAP) in the Semen Regulations, doctors can apply to the Minister of Health to obtain access to non-compliant sperm. The Minister of Health currently has the authority to grant or refuse each special access application. Under the Regulations, an application to the Minister of Health will not be a requirement for the replacements to the DSSAP: the directed donation process and exceptional access. It is anticipated that health professionals will spend the same amount of time to prepare documents for the directed donation process and exceptional access as they currently do for the DSSAP, as the documentation requirements are similar. The reduction in mailing costs resulting from the elimination of an application requirement will be negligible. As a result, no reduction in costs for health professionals has been estimated.

It is anticipated that ending the DSSAP will reduce program costs for Health Canada. In 2017, under the DSSAP, the Minister of Health received 74 applications. Health Canada estimates that each application costs the Department approximately $200 to review, authorize and file. The Department will thus save approximately $14,800 annually by eliminating the need to review and authorize applications under the DSSAP, which represents a present value benefit of $103,949 over the same 10 years, discounted at 7%.

Small business lens

The small business lens applies to regulatory proposals that affect small business and would impose a nationwide cost over $1 million annually. The Treasury Board Secretariat defines a small business as any business, including its affiliates, which has fewer than 100 employees or between $30,000 and $5 million in annual gross revenues. Health Canada considers all establishments in the AHR industry as small businesses. As a result, there are 111 small businesses operating in Canada that will be affected by the Regulations.

Regulatory flexibility analysis statement

Health Canada considered two options for how establishments would be required to inform the Department of their activities, when developing the health and safety framework for donor sperm and ova. The first option considered was registration for all establishments that process, import, or distribute donor sperm and ova. The second option, which was selected, would only require registration for establishments that are responsible for conducting all processing activities with regard to donor sperm and ova. Establishments that import or distribute donor sperm and ova would need to instead notify Health Canada prior to commencing these activities. As notification is less administratively burdensome than registration, establishments that distribute or import donor sperm or ova would save on costs by having only to notify rather than register with Health Canada.

The second option was selected because it will achieve the objective of providing safety oversight on

establishments participating in Canada's donor sperm and ova supply chain without unduly imposing unnecessary administrative burden costs on Canadian small businesses. Further, under this option, health professionals who are not undertaking activities that are performed by primary establishments or establishments that import or distribute donor sperm or ova will not be required to register or notify Health Canada.

The selected option will place the most regulatory oversight and administrative burden upstream in the supply chain on those establishments responsible for the activities that bear the most health risk (i.e. screening and testing of sperm and ova donors). Regulatory oversight and administrative burden will decrease down the supply chain commensurate with the level of health risk associated with each activity, as regards the safety of donor sperm and ova.

The alternative option that was not selected would require all establishments to register with Health Canada, no matter what activities they engaged in along the supply chain. This option would also have required health professionals conducting activities that are not reserved for establishments to register with Health Canada and be subject to all of the same regulatory requirements as a primary establishment. This option would have imposed significant compliance and administrative burden on health professionals, even when they would have been only making use of donor sperm or ova.

Ultimately, the second option was selected because it reduces burden on small businesses where possible without compromising the safety oversight objective of the framework.

Table 6: Comparison of alternate and chosen options for registration, notification and related requirements

	Alternate Option	**Current Option**	
Short description	Registration for all establishments and health professionals	Registration of primary establishments and notification for establishments that import or distribute	
	Average costs for all establishments and health professionals ($)	Average costs for primary establishments and establishments that import or distribute ($)	Average costs for establishments that perform processing activities and health professionals ($)
Compliance cost — Registration/Notification	$113 one-time cost	$113 one-time cost	$0
Compliance cost — Annual statement	$104 annually	$104 annually	$0
Administrative cost — Amend or change data	$26 annually	$26 annually	$0
Total cost per small business	Year 1: $243 Years 2–10: $130	Year 1: $243 Years 2–10: $130	$0

"One-for-One" Rule

The current initiative is an "IN" ("One-for-One" Rule).

Annualized administrative costs (constant $2012)	$39,225
Annualized administrative costs per business ($2012)	$353

The “One-for-One” Rule applies to the regulations, and the anticipated administrative burden to establishments is estimated at $39,225 (2012 dollars) annually. This calculation includes costs associated with record keeping, information requests, record retrieval, amending or changing data, reporting errors, accidents and adverse reactions, and reimbursement records requests. The cost estimates associated with the “One-for-One” Rule are reported in 2012 dollars and discounts values to a base year of 2012.

As a way to partially reduce the administrative burden on industry, Health Canada allows those establishments that only import or distribute sperm and ova to be required to notify Health Canada before they commence these activities, rather than having to register with Health Canada. As registration is a somewhat more administratively burdensome process than notification, this would have the effect of reducing the administrative burden on those establishments that only engage in importation and distribution of donor sperm and ova.

These regulations create three new sets of regulations and repeal one set of regulations. Two of the new sets of regulations (safety, and reimbursement) will impose administration burden and so will be considered “IN” regulatory titles under the “One-for-One” Rule. The repeal of the Semen Regulations will be considered an “OUT” regulatory title. Overall, these Regulations will result in a total “IN” of one regulatory title, and it will carry the obligation under the *Red Tape Reduction Act* to repeal an additional regulatory title within the next two years from within the health portfolio, unless a regulation has already been repealed in accordance with that Act at the time the new regulations are made.

Gender-based analysis plus (GBA+)

While all persons may be affected by the use of AHR technologies, the AHRA itself notes that women who use donated sperm or ova, women who act as surrogates, and children born as a result of the use of these technologies are more directly and significantly impacted by their application than men. Gender and diversity issues were initially assessed as part of the original legislative process surrounding the AHRA.

Gender and diversity issues were also considered during regulatory development based on feedback received from diverse stakeholder groups during policy consultations. It is recognized that women using AHR technologies and children born of AHR face an increased health risk due to existing safety gaps in Canada’s regulatory framework. The *Safety of Sperm and Ova Regulations* will help to reduce this risk with the introduction of safety requirements for donor ova and improved safety requirements of donor semen.

The Regulations also benefit Canadians using donor sperm through the inclusion of the directed donation process that will give a person more flexibility in choosing a donor by making it less administratively burdensome for a person (such as a single woman or a woman in a same-sex couple) wanting to make use of a friend’s sperm in AHR.

The *Reimbursement Related to Assisted Human Reproduction Regulations* will put clear rules in place in respect of reimbursement that provide clarity for sperm or ova donors and surrogate mothers who want to be reimbursed for expenditures permitted under the Act.

The *Administration and Enforcement (Assisted Human Reproduction Act) Regulations* support the bringing into force of the administration and enforcement sections of the AHRA. With these sections in force, Health Canada will be better able to administer and enforce the Act and help protect persons affected by the use of AHR technologies, especially women using these technologies and children born as a result of the use of these technologies.

Consultation

There is a range of stakeholders who may be impacted by or have views on the regulations. This includes people in Canada using AHR technologies and children born through AHR; fertility clinics; donor sperm and ova processors such as sperm and ova banks; donor sperm and ova importers and distributors; businesses that provide surrogacy consulting services and arrange sperm and ova donations; professional associations; advocacy and rights associations including LGBTQ2+ groups; health care providers (e.g. doctors performing AHR in clinical settings); lawyers specializing in fertility law/family law; provinces and territories; and academics.

A notice of intent (/rp-pr/p1/2016/2016-10-01/html/notice-avis-eng.php) to introduce regulations under the AHRA was published in October 2016. Subsequently, Health Canada published a consultation paper (https://www.canada.ca/en/health-canada/programs/consultation-assisted-human-reproduction/document.html) in July 2017 and launched a 60-day consultation period that generated 57 sets of comments. Comments were submitted by a range of stakeholders, including individuals as well as representatives of medical professionals, the AHR industry, academics, surrogates, intended parents, advocacy groups, and fertility lawyers. A summary of the feedback (PDF) (https://www.canada.ca/content/dam/hc-sc/documents/services/publications/drugs-health-products/feedback-toward-strengthening-assisted-human-reproduction-act/ahr-what-we-heard-report-2018-eng.pdf) received was published in January 2018.

In general, there was stakeholder support for developing regulations under the AHRA to help protect the health and safety of persons who use AHR technologies or are born through AHR. Many stakeholders emphasized the point that the regulatory scheme under the AHRA should recognize the important role that a health care provider plays in assessing and communicating risks to persons using AHR technologies and should leave room for AHR recipients to make their own decisions about risks in certain circumstances.

Stakeholders were generally supportive of the registration and notification schemes, but were divided as to who should bear which obligations. Most stakeholders agreed with Health Canada’s approach to place the highest level of regulatory oversight on those establishments responsible for processing donations, due to the human health and safety risks associated with their activities. While most stakeholders were of the view that the processing of donations where the donor is known to the recipient (directed donation) should be subject to the same regulatory oversight as the processing of donations from unknown donors, some stakeholders felt it would be appropriate for directed donations to be subject to fewer regulatory obligations. Health Canada agrees with the majority of stakeholders and recognizes that the human health and safety risks associated with the processing of donor sperm and ova merit a similar level of oversight in both circumstances. Similarly, some stakeholders felt that regulatory requirements in respect of personnel, facilities, equipment, and quality management should be equally applicable to all persons engaged in regulated activities, while other stakeholders did not, as they felt the operational and economic burden of complying could be too great to bear.

The majority of stakeholders agreed with Health Canada’s approach to sperm and ova donor screening, testing and donor suitability assessment, and supported the directed donation pathway. For instance, stakeholders agreed with the genetic screening criteria for sperm and ova donors, and were in support of the embedded flexibility to assess a donor based on genetic diseases known to be prevalent in the donor’s ethnic background, in accordance with recognized medical guidelines. Some stakeholders suggested additional infectious disease testing, such as testing for “new or emerging infections,” while other industry stakeholders expressed concern with respect to the availability or accessibility of certain tests, or their relevance in particular geographic regions of Canada. Some also raised concern about the cost and reliability of a few of the currently available tests. Health Canada took into consideration all feedback provided and has made some revisions to the infectious disease testing requirements as a result. For instance, this included revising the testing requirement for West Nile virus so it is done when relevant, rather than year-round. Specifically, it will be required only if the donation is made during the time of year when the virus is potentially transmissible to humans or if the donor has lived in or travelled to an area where the virus was recently endemic.

Many stakeholders indicated support for the categories of reimbursement expenditures, but some suggested additions and modifications to those categories with a view to ensuring the regulations are

flexible enough to accommodate the individual circumstances of each donation and surrogacy situation. Health Canada has assessed all of the feedback provided and made modifications to the categories of expenditures, as appropriate.

Health Canada also received a number of comments that were out of the scope of the regulatory project. These included comments calling on the Government to amend the AHRA to remove the prohibitions on payment to sperm and ova donors and to surrogates, to review the scientific prohibitions and to decriminalize certain aspects of the Act. While these stakeholders advocated for making legislative changes at the level of the AHRA, most were in support of advancing the regulatory project, recognizing the importance of bringing into force the remaining sections of the Act.

In addition to comments received through formal consultations, several stakeholder groups, including provincial and territorial counterparts as well as those representing AHR health care providers and associations, have been generally supportive of the Government's intent to make regulations and bring into force the dormant sections of the AHRA. Some cite the continued importance of the legislation and the fact that action is overdue. Specifically, stakeholders supported Health Canada in addressing the regulatory gaps that have resulted from the outdated Semen Regulations and lack of donor ova regulations. These stakeholders also stressed the importance of having a reimbursement system that is not overly onerous or bureaucratic and advocated for a model that would allow for reasonable compensation, suggesting that a definitive itemized list of reimbursable expenses could be too rigid to account for the individual circumstances of each donation and surrogacy arrangement.

Consultations after prepublication in the *Canada Gazette*, Part I

The proposed regulations were prepublished in the *Canada Gazette*, Part I, on October 27, 2018. The comment period for the regulations was open for a 75-day period, ending on January 10, 2019. Also open for comment during that 75-day period was the proposed Directive, "Technical Requirements for Assessing the Suitability of Sperm and Ova Donors," to be incorporated by reference into the *Safety of Sperm and Ova Regulations*. During the same period, Health Canada also provided an online questionnaire for comments on the proposed regulations, and held five in-person consultation sessions in five provinces.

Across the consultations, Health Canada received a total of 375 written submissions and 82 individuals provided comments at the in-person sessions. Respondents included members of the public, as well as both individuals and groups representing the views of the following: medical professionals in the field of AHR, fertility clinics, donor egg and sperm banks, surrogacy and ova donation agencies and consultants, adoption agencies, academics, surrogates, advocacy groups, intended parents, lawyers, sperm and ova donors, and donor-conceived people.

All comments within the scope of these regulations are summarized and responded to below. A number of comments received were outside of the scope of the initiative and so are not discussed here; however, Health Canada reviewed every comment received from stakeholders, and the issues raised will be further studied and brought to the attention of appropriate parties, including provincial and territorial governments, as applicable. This includes comments on such issues as

- Foreign intended parents: many stakeholders called for putting in place a prohibition on surrogacy arrangements between Canadian surrogates and foreign intended parents to address concerns, among others, that the health care costs associated with such arrangements are subsidized by Canadian taxpayers.
- Compensation to donors and surrogates: some respondents advocated for amendments to the AHRA to remove the prohibitions related to payment of donors and surrogates.
- Donor registries: many respondents expressed the need to establish a national donor registry and ban anonymous donations so that health and genetic information would be available to donor-conceived people.

The AHRA requires that, subject to certain procedures and exceptions, before the regulations are made, proposed regulations must be laid before each House of Parliament and referred to the relevant committee in each House, with any reports they provide to be taken into account by the

Minister of Health. On October 29, 2018, the proposed regulations, as prepublished in the *Canada Gazette*, Part I, were tabled in the House of Commons and in the Senate. The legislated tabling requirement was fulfilled on March 18, 2019. No feedback was received.

I. Comments on the Safety of Sperm and Ova Regulations

Many respondents were generally supportive of these Regulations, noting, among other things, that they will serve to protect women who use assisted human reproduction and children born through it, and better service those in the LGBTQ2+ community as well as single individuals who use AHR to build their families.

Numerous respondents asked for clarification on aspects of the Regulations, and Health Canada will provide more explanation on these Regulations as well as information about complying with the requirements in online guidance material. As needed, general clarifications in guidance documents on the following matters may be provided:

- donor testing requirements;
- donor screening requirements, including genetic screening of sperm and ova donors;
- quarantine and segregated storage requirements for donor sperm and ova;
- circumstances that qualify as a directed donation;
- obtaining informed consent of the donor;
- age-related risks associated with donor sperm and ova;
- how cryopreserved donor ova, collected prior to the Regulations coming into force, could be used under these Regulations;
- requirements for the importation of donor sperm and ova;
- maintaining records;
- quality management requirements;
- reporting errors and accidents; and
- how Health Canada will conduct the administration and enforcement of these Regulations.

Comments on definitions and scope

A number of respondents found the definitions and roles of establishments, primary establishments, health professionals, and medical directors unclear. Some respondents requested revisions to the definitions of establishment and health professional as they found that they overlapped, and did not reflect how the AHR industry operated. Some respondents were unclear on how private practice physicians may be impacted by these Regulations.

Health Canada's view is that the risk-based design of the Regulations is appropriate. As designed, the level of regulatory oversight corresponds to the level of risk an activity poses to the health and safety of Canadians. The Regulations are focused on product safety and were also designed in a way that recognizes the role the provinces and territories play in overseeing the practice of health professionals who are authorized under provincial and territorial laws to make use of sperm or ova.

Health Canada recognizes there are some scenarios where the Regulations equally apply to both the health professional and the establishment that may lead to some potential confusion. These could be where a health professional works for an establishment or where a health professional structures their practice by creating a corporation, in which case the health professional is not considered an establishment when they label, prepare, quarantine or store donor sperm or ova as an individual, yet the corporation is considered an establishment if it conducts any processing activity. The reason for the design of the Regulations is to have certain important requirements that are at the core of the health and safety framework apply to health professionals who only make use of donor sperm or ova or distribute donor sperm to a recipient for their personal use (e.g. a family physician who performs intrauterine insemination or serves as the shipping address for donor sperm to be used in a private

setting). These include requirements related to the communication of risk to the recipient, records to permit the traceability of the donor sperm or ova, as well as those related to errors, accidents, and adverse reactions.

Regulatory obligations imposed on both health professionals and establishments apply equally to both parties in the scenarios described above. However, in these cases, Health Canada's view is that the requirements on both the health professional and the establishment could be satisfied by a single or shared action on the part of both parties. For example, both the health professional and establishment have a requirement to maintain certain records, but this requirement could be satisfied for both parties by a single set of records maintained in the establishment's record management system. Health Canada will also explain these matters in guidance that will be published on the Government of Canada website.

A respondent commented that the definition of adverse reaction is incomplete as it does not include allergic reactions as a result of how the sperm is washed prior to use. Health Canada confirms that in its view allergic reactions in the recipients of donor sperm or ova would typically be considered an error or accident, so are included within the scope of these Regulations.

Several respondents requested that the Regulations include references and content from the CSA Standard, CAN/CSA-Z900-Tissues for Assisted Reproduction, which is a voluntary Canadian standard for donor sperm and ova activities. These suggestions ranged from amending certain definitions or terms to match content in the CSA standard, to incorporating it by reference into the Regulations rather than the Directive. The Directive has been informed by the scientific and technical expertise of the CSA technical subcommittee as well as a number of national and international regulatory frameworks and Health Canada technical subject matter experts. Incorporating the Directive by reference in the Regulations provides the department with more flexibility to quickly update the technical requirements based on emerging scientific advances in the field of AHR and to effectively address urgent circumstances, for example, in the event of an emerging disease. Furthermore, the department is well positioned to receive relevant scientific data that could result in changes to the donor screening criteria, since it reviews relevant information in the context of similar health products, for example, blood and cells, tissues, and organs.

A respondent commented that it was not clear that the proposed Regulations apply only to donor sperm and ova for assisted human reproduction, and therefore that they do not apply to sperm or ova from a spouse or sexual partner. As well, another respondent commented that it was not clear whether someone would be permitted to perform an insemination on themselves at home given these requirements. Health Canada confirms that pursuant to section 10 of the AHRA these Regulations made under the authority of the AHRA set out requirements that only apply to donor sperm and ova meant for use in AHR by a recipient who is not the donor's spouse, common-law partner or sexual partner, as well as to ova intended for the donor's use as a surrogate. Health Canada also confirms that it would be permitted to perform self-inseminations at home.

Some respondents provided specific comments on the language and terminology used in the Regulations and associated documents. For instance, a group of respondents requested that the French Regulations use the female form of recipient (receveuse) and donor (donneuse) when the regulations are referring to activities that only females may undertake, i.e. surrogacy, pregnancy and ova donation. Some respondents requested that the Regulations and associated documents incorporate the language used in the LGBTQ2+ community to describe all parties and reproductive parts. Others requested references to donor-conceived people, rather than children, to more fully reflect all individuals who are donor conceived and avoid infantilizing them. Health Canada notes these comments, but confirms that no revisions on the matter of gendered language will be made to the Regulations as the drafting of regulations, which is done by the Department of Justice, is expected to reflect the Department of Justice's current policy regarding gender-neutral language. Health Canada has reviewed the language of the Regulatory Impact Analysis Statement as well as the guidance the department is developing and revised it to be more inclusive where possible.

A few respondents expressed concerns that facilities in other countries would not spend the money and time needed to meet the requirements, which would introduce new barriers to access and limit

Canada's supply of donor sperm and ova. Health Canada notes that these Regulations increase overall alignment between Canada and the United States, the source of the majority of donor sperm and ova used in Canada, as well as with Europe.

Comments on registration, notification, and attestation

A respondent asked if Health Canada would be providing standard forms for registration, notification and annual attestations. Health Canada confirms that it will be providing standard forms for regulated parties to use to meet these requirements.

A respondent requested clarification on how Health Canada will ensure the effectiveness of the proposed regulatory oversight when most of the establishments that supply donor sperm and ova to Canada are outside of the country. Similarly, another respondent asked how Health Canada will be verifying attestations of foreign processors. Some respondents expressed concerns that it would be difficult to verify foreign compliance with the Regulations or, on the other hand, that donor sperm and ova may be imported that do not meet the safety requirements. Health Canada manages the risks posed to Canadians using assisted human reproductive technologies and persons born through the application of these technologies through various types of compliance and enforcement activities, including compliance promotion, proactive compliance monitoring, and rapid response and enforcement. All donated sperm or ova for use in AHR in Canada must comply with the relevant regulatory requirements in Canada. Foreign establishments who wish to conduct activities in relation to donor sperm or ova to be imported in Canada for use in AHR should ensure that applicable requirements are followed in order for the donated sperm or ova to enter the Canadian market. As part of its compliance and enforcement approach to AHR products and activities, Health Canada may collaborate with trusted international regulatory partners and conduct voluntary inspections of foreign establishments.

Some respondents expressed concerns about how primary establishments would ensure that donor sperm and ova were safely processed in establishments that perform work under their responsibility. Health Canada does not intend to prescribe the manner by which a primary establishment ensures that donor sperm and ova are safely processed by any establishment that conducts an activity on behalf of the primary establishment. Health Canada is of the view that industry is best positioned to determine the mechanisms by which the primary establishment satisfies this requirement (e.g. through a contract with the establishment).

A few respondents commented that a single registration system would be better as, for instance, having two systems (i.e. registration and notification) may be confusing. A respondent requested clarification on the notification process for establishments that import and distribute donor sperm or ova, expressing concern that it may impact on an intended parent's receipt of it. Health Canada believes that the risk-based design of the Regulations is appropriate. As designed, the level of regulatory oversight corresponds to the level of risk an activity poses to the health and safety of Canadians who use AHR to build their families. As primary establishments conduct activities that pose the highest level of risk, they are responsible for registering with Health Canada prior to processing donor sperm and ova for Canadians, or as otherwise required during the transition period after the Regulations come into force. As importation and distribution represent comparatively lower risk activities, establishments conducting these activities are required to notify Health Canada once they commence their activities. As these establishments will only be required to notify Health Canada when they begin operations, and annually thereafter, the Department does not believe that this will negatively impact distribution or importation of donor sperm and ova.

A respondent expressed concern that AHR services could be significantly disrupted as a result of suspension and cancellation of primary establishments' registrations. Health Canada's choice of a particular compliance and enforcement action is informed by a risk-based approach that encompasses identifying, assessing and managing health and safety risks. In determining the most appropriate type of intervention, Health Canada also considers factors related to the conduct of the regulated party and the need to maintain public confidence in the overall integrity of the regulatory regime, including the public's perception of risk.

Comments on the regular process and the Directive

Some respondents recommended that Health Canada review the Regulations every three years to keep pace with changes in the field. Health Canada agrees with the importance of keeping the Regulations up to date with the latest science in the field of assisted human reproduction, including with regards to the evidence-based screening and testing requirements in the Directive. In addition, the 2018 Cabinet Directive on Regulation introduced a new requirement for all departments to regularly review their regulatory stock, including guidance and other policies. Health Canada will regularly review the latest science in the field of AHR and update the Directive so that it reflects the best available science.

A few respondents expressed concern that the Regulations included no minimum requirements for assessing the quality of donations, such as those related to sperm motility or its quality post-thaw, similar to the evaluation requirements under the Semen Regulations. Health Canada is of the opinion that the Regulations address requirements regarding quality assessment of donations. There is a general requirement that establishments must have standard operating procedures (SOPs) for all activities that they perform; as quality assessment is part of the definition for activity, all establishments that assess quality of donations must have SOPs that lay out how they do so and, per the general requirement that quality management measures, including SOPs, must be appropriate, the SOPs for quality assessment will have to include appropriate requirements for assessing the quality of donations. Health Canada will additionally provide further general clarifying information on the quality assessment of sperm and ova in guidance.

A few respondents recommended that a list of genetic diseases be included in the Directive, to ensure transparency and consistency across all donor screenings. A respondent also requested clarification on how the donor assessment should proceed when a proposed donor is unable to provide information regarding the presence of a genetic disorder in three generations of their family history. Health Canada will recommend a list of serious genetic disorders in a guidance document, but will not prescribe them in the Regulations. Health Canada recognizes that genetic screening is a rapidly evolving field. Given the inherent nature of genetic disease transmission, rapid advances in the knowledge of genetic disorders, and the variability in the genetic screening practices in the industry, including a prescriptive list of genetic disorders at the level of the Regulations would not provide Health Canada with sufficient flexibility to respond to advances in the field. The Regulations require that all sperm and ova donors undergo genetic disease screening, based on the donor's medical history and the donor's available family history, for the risk of serious single-gene genetic disorders. Based on the results of genetic screening, the medical director or a qualified professional designated by the medical director is required to assess the risk of genetic disease transmission, including the risk of not obtaining the relevant genetic information in three generations of the donor's family history.

Several respondents asked that genetic testing be made mandatory for sperm and ova donors, in addition to the genetic screening required, to reduce the risk of transmitting a genetic disease to a child born of AHR. A respondent also expressed concern that challenges associated with advances in genetic sciences have not been considered. Health Canada has not added this requirement to the Directive, as it is not permitted under the *Genetic Non-Discrimination Act* to require this information. Under the Directive, relevant genetic test results may be used in lieu of genetic screening to assess the risk of genetic disease transmission. These Regulations, including the Directive, were developed to reflect the latest scientific evidence in assisted human reproduction. Health Canada will continue to closely monitor the field, and as advances are made carefully consider amendments to the Regulations or the Directive, as appropriate.

Some respondents recommended that recipients who use donor sperm and ova from a donor whose suitability was assessed through the regular process also receive medical advice on the risks of using it and provide informed consent. Health Canada has not added this requirement to the regular process, given that only sperm and ova from donors who have been determined suitable based on their screening and testing results can be used under this donation pathway, except in certain limited exceptional circumstances. Further, the summary document that accompanies the donation provides the health professional with the necessary information to determine if, in their medical opinion, any additional risks should be communicated to the recipient.

A number of respondents expressed concern that donor screening will assess a donor's social history, and requested clarifications on what this would entail. Health Canada notes that the scope of donor screening criteria, as outlined in the Directive, does not extend beyond assessing a donor's risks of infectious and serious genetic disease transmission. Although the Directive sets out the minimum screening requirements that must be included in a structured questionnaire, a medical director responsible for developing the questionnaire may choose to include additional criteria, beyond those set out in the Regulations, to assess the donor's overall suitability. A respondent requested that Health Canada create a standard screening questionnaire for sperm and ova donors that establishments may elect to use, as this would promote uniformity and reduce the burden of the new Regulations. Health Canada will not be creating a standard donor screening questionnaire as part of its guidance on the requirements for assessing donor suitability. The minimum requirements set out in the Directive are intended to be sufficiently broad to allow establishments enough flexibility to design their own questionnaire based on the overall donor suitability assessment regime (donor screening, testing, and physical examination) and any operational considerations. Thus, Health Canada is of the view that a standard donor screening questionnaire may be overly prescriptive and as a result, less effective in reducing the risk of disease transmission.

A number of respondents expressed concerns with the donor screening requirements related to sexual behaviour and HIV infections. These included screening criteria that, for the regular process, would screen out a man who has had sex with a man (MSM) in the past six months as well as a person with exposure to or with an active HIV-1 or HIV-2 infection. Respondents noted that there can be a variety of circumstances included within these criteria, such as men in monogamous sexual relationships, as well as persons on antiretroviral drugs with well-managed HIV. For the regular process, a respondent requested that the deferral period for a man who has had sex with a man be replaced with an assessment of the risks of the man's sexual behaviour and a determination of high versus low risk sexual behaviour in line with the assessment of men who have sex with women. Further, respondents noted that sperm-washing can reduce the risk of HIV transmission through donor sperm. On the other hand, other respondents supported the screening and testing requirements, including those for HIV, for the protection of the recipient and the child born of AHR.

Health Canada acknowledges that stakeholders are concerned regarding the MSM donor deferral criteria. At the same time, the donor screening criteria have been informed by national standards, as well as the latest scientific and epidemiological research for similar product lines such as blood. The Regulations require that all sperm and ova donors, including MSM, undergo donor screening to identify risk factors for infectious and genetic disease transmission. The MSM deferral is for donors who are subject to the regular process. In the case where the donor and recipient know each other, a donor is not excluded from donating if they screen positive for the MSM criteria. Health Canada is committed to making policy decisions that are based on scientific evidence. As such, it closely monitors and will take into consideration the outcomes of ongoing donor screening research initiatives in Canada and internationally. Health Canada will update donor screening requirements as they are supported by scientific evidence.

A number of respondents requested that the Directive permit the use of test kits licensed in countries other than Canada and the U.S. One respondent noted that they currently import donor ova from Ukraine and Malaysia, while another respondent noted their plans to begin importation of donor sperm from Denmark and potentially other parts of Europe. Some respondents also expressed concerns with potential issues regarding access to test kits licensed in Canada and the U.S.

At this time, Health Canada will not permit the use of test kits licensed or approved in countries other than Canada and the U.S. Testing of sperm and ova donors for infectious disease agents (i.e. donor testing) is an important component of the donor suitability assessment regime to ensure the safety of donor sperm and ova intended for use in an AHR procedure. Donor testing relies heavily on the availability and use of high quality, safe and effective donor screening test kits. Without the use of such test kits, donor testing could lead to 'false negative' test results that would allow for an infected donor to donate sperm or ova and could lead to infectious disease transmission to the recipient or the child born through AHR. Pre-market approval and post-market surveillance of medical devices, including test kits, that govern the quality, safety and efficacy of medical devices vary internationally.

Allowing the use of test kits from countries that may not have robust medical device regulations would elevate the risk of infectious disease transmission to the recipient or the child born through AHR. In addition to test kits approved in Canada, U.S. test kits will also be permitted as Canada and the U.S. have worked together on pre- and post-market regulatory alignment of medical device regulations, through cooperation in designing regulations and ensuring alignment in their implementation and enforcement. Thus, the use of U.S.-approved test kits that may not be approved in Canada is not expected to increase the risk of infectious disease transmission associated with the use of donor sperm or ova.

A number of respondents made specific recommendations on donor screening and testing criteria in the Directive. These included suggestions on requirements around physical examinations, the timing for testing donors, deferral periods for certain infectious diseases and risk factors, as well as other additional screening criteria for health risks such as diabetes and early onset cancers. Health Canada notes these suggestions, and will take them into consideration. Any changes made to the Directive must be supported by sufficient scientific evidence and assessed in the context of similar health products within Canada, as well as internationally. As such, Health Canada will closely monitor and take into consideration the outcomes of scientific advances in this field and will make decisions on the proposed recommendations as supported by scientific evidence.

Comments on directed donation and exceptional access

Many respondents expressed support for the new directed donation provisions in the Regulations, noting that it is beneficial for those who wish to use a known donor when they access AHR services to help build their families.

A few respondents expressed concern that the Regulations did not require the communication of risk to, and informed consent from, a surrogate who receives an IVE that is created with donor sperm or ova released through exceptional access or through directed donation. Health Canada confirms that surrogates in those circumstances must be informed of the risk and provide their consent. Health Canada will provide general clarifications in guidance on this matter.

Regarding the requirements for directed donation and for exceptional access, some respondents wanted to increase the testing and screening standards while others wanted to decrease them. For instance, some felt that all donations should be subject to the regular process with all screening and testing requirements met, in the interests of the health and safety of the child born of AHR. At the same time, some felt that people pursuing directed donations should be permitted to waive all screening and testing requirements as it is their right to make their own health decisions. A respondent commented that if intended parents have a child born of AHR and seek to use the same donor sperm or ova for another child, they should be exempted from all requirements. A few respondents also expressed concern that some may ‘stretch’ the interpretation of a known donor to beyond what is intended to be permitted. Health Canada recognizes the right of individuals to make an informed decision to accept certain risks in using AHR technologies to build their families and the important role of the treating physician in assessing the risks and counselling their patients. In developing the directed donation and exceptional access provisions, Health Canada has taken into consideration the overall level of risk posed by each type of donation to the recipient and child born of AHR, within the distribution chain as well as years of stakeholder feedback on the Semen Regulations. As such, the tailored requirements for each of the processes are primarily based on the different level of exposure associated with each process, with the intent to make it easier for Canadians to use AHR technologies to build their families while protecting their health and safety.

A respondent commented that the requirements for directed donations would complicate instances where fresh donations are used by a fertility clinic that is not the primary establishment, as quarantine requirements appear to require donations to be sent to a primary establishment. Health Canada confirms that a fertility clinic that conducts all of the processing activities with respect to donor sperm or ova for the purposes of making use of that sperm or ova under the directed donation pathway would be considered a primary establishment under the Regulations. Therefore, the fertility clinic would be required to register with Health Canada. Health Canada notes that all donor sperm and ova, regardless of the donation pathway, must be quarantined until the donor has been screened, tested

and their suitability assessed in accordance with the Regulations. However, the Regulations do not set out a time frame for obtaining the donation. As such, for donor sperm and ova under the directed donation pathway, a donation can be obtained following the completion of a donor suitability assessment, thus allowing for the use of a fresh sample.

Some respondents expressed concerns with permitting the use of fresh sperm, as this could introduce unnecessary risk. Some were similarly concerned that quarantine would not be required for donor sperm or ova, when the donor is known. Health Canada recognizes that the use of fresh sperm may be allowed in the case where the donor and the recipient know each other (i.e. directed donation processing). In such instances, the treating physician plays an important role in assessing the risk based on the results of the donor suitability assessment and the availability of any risk mitigating measures, and must document the recipient's informed consent prior to making use of that donation. These measures along with segregated storage and labelling requirements mitigate the overall risk of using fresh donor sperm to the recipient and the distribution chain.

A number of respondents expressed concern that physicians will bear a greater burden for the directed donation and exceptional access requirements, and as a result may not agree to participate in their use. Health Canada does not agree that these requirements would place a greater burden on physicians as they were modelled on the requirements of the Donor Semen Special Access Program, which has existed since 2001 to provide access, in exceptional circumstances, to semen that has not been processed in accordance with certain requirements of the Semen Regulations. Physicians will have to follow very similar steps for directed donation and exceptional access for donor sperm and ova; one notable difference is that they will no longer have to request approval from Health Canada to use the donor sperm. In addition, physicians who meet the definition of a health professional, and not an establishment, are not required to register or notify Health Canada of their activities.

Some industry respondents expressed concerns about the burden associated with being a primary establishment, which certain clinics would become if they continued performing, under current practices, directed donations. A few respondents commented that they may need to cease performing directed donations, which could limit access to them in their region of Canada. A specific concern raised was the challenge of a smaller clinic having to perform all activities that are the responsibility of a primary establishment. Health Canada notes that the risk-based design of the Regulations and the level of regulatory oversight over primary establishments have been set up to help protect the health and safety of Canadians who use AHR to build their families. As such, Health Canada has not amended the Regulations to reduce these requirements. However, Health Canada confirms that a primary establishment will not be required to itself perform all activities for which it is responsible. The Regulations are set up to align with current industry practices of contracting out many activities to other establishments, and do not prohibit primary establishments from making such arrangements. In addition, Health Canada also notes that the industry costs estimated in the Benefits and costs section are calculated in a conservative manner, to show the upper range of costs for a primary establishment. If a primary establishment or an establishment only itself performs a subset of the full range of activities, it would not be subject to certain requirements and would not have to apply resources to complying with them. As there was some confusion among respondents on these matters, Health Canada will provide further information in guidance.

Comments on quality management

Several respondents commented that the design of the quality management requirements, and the requirements listed under the quality management system in particular, place too high a burden on establishments. A few respondents also found it unclear which quality management requirements applied to their establishments. For instance, it was not clear to some respondents that establishments that only store donor sperm or ova would be required to meet only the quality management requirements for storage. In addition, a respondent recommended adding clearer requirements for the storage, handling, and distribution of donor sperm and ova. Some respondents commented that while the proposed requirements were appropriate, a number of them needed to be separated out from the quality management system as they represented discrete quality management requirements. This is the case as, within the sector, quality management is understood as a broad category encompassing issues such as record keeping, personnel qualifications, sanitation,

cleanliness, equipment verification, process validation, and complaint handling. One specific aspect of quality management is a quality management system, which is composed of certain components related to organizational structure, processes and procedures, change controls and validation, continuous improvement, and document controls. In the current design of the quality management system requirements, a number of other aspects of quality management beyond industry understanding of the scope of a system were included, leading to a concern that the requirements would be excessively burdensome upon regulated parties. In response to these comments, Health Canada has amended the Regulations to distinguish more clearly between the quality management system and other quality management requirements. The requirements are substantively unchanged, but are now in alignment with industry practices. These amendments also make clearer which requirements apply to establishments based on which regulated activities they undertake.

A respondent expressed concern over the lack of explicit requirements surrounding distribution, storage, and handling, including specific requirements related to traceability and labelling, and that there are no quality management requirements for these issues. Health Canada is of the view that the proposed Regulations included complete requirements for traceability, but that the requirements for labelling and storage should be strengthened given how central they are to the safety of donor sperm and ova. As a result, the Regulations have been amended to add an outcome-based quality management requirement for labelling and to broaden the storage requirement to a more complete outcome-based quality management requirement. In addition, the requirements for identifying and labelling have been moved into the quality management section to make clear that these are quality management requirements, as understood by industry.

A respondent commented that health professionals should be required to follow standard operating procedures (SOPs), or equivalent guidelines, for the preparation, handling, storage, and labelling of donor sperm and ova. Health Canada is of the view that sufficient standards are already in place at, for instance, the provincial level for the practices of health professionals, such that it is unnecessary for these Regulations to include requirements for health professionals to have SOPs for activities in relation to donor sperm and ova.

Many respondents commented on the proposed record-retention period of 10 years. Most of these comments requested longer periods from 18 years, to 110 years, to indefinitely, and for a number of reasons, including so that records are available in the event of a late occurring adverse event, such as a genetic disorder; so that a donor-conceived person can receive the donor’s medical history once that person is an adult; or so that contact could be made between donors and their offspring later in life. On the other hand, a few respondents suggested that records be kept for shorter periods of time, such as in cases where donor sperm or ova are disposed of or do not result in pregnancy. One respondent questioned the need to ensure that donations can be traced, including through record-retention, commenting that the value was unclear. A few respondents requested that it be required for a donor’s medical records to be made available to a donor-conceived person once they reach the age of majority. It was also suggested that the records be held centrally by Health Canada or by another organization.

Health Canada confirms that establishments and health professionals are required to keep their relevant records for a minimum of 10 years after their creation, or as otherwise specified. This record-retention period ensures that in the event of a health or safety issue linked to the donation, measures can be taken to trace that donation and identify those who have distributed, imported and made use of the donation. This is especially important in the event that an adverse reaction (due to the transmission of infectious disease for example) has occurred in the recipient or the person born of the donation, and the donation must be traced within the distribution chain. The 10-year retention period provides sufficient time for establishments and health professionals to investigate any safety concerns, and take appropriate risk mitigation measures as a result. Furthermore, the 10-year record-retention period set out in the Regulations has taken into account retention periods in other jurisdictions to ensure that the communication of information, as it relates to the safety of the donation, can occur throughout the distribution chain. However, establishments and health professionals may choose to retain their records for longer periods of time. Concerns related to accessing donor records beyond the 10-year period for the purpose of identifying the donor are

beyond the scope of these regulations.

A group of respondents recommended that anonymized/de-identified information about errors and accidents as well as adverse reactions related to AHR be made publicly available. Once the Regulations are in force, Health Canada confirms that anonymized reports on all adverse reactions related to donor sperm and ova will be made available through the Canada Vigilance Adverse Reaction Online Database. In addition, the department provides access to information regarding compliance and enforcement actions while complying with its legal obligations under the applicable privacy laws. For example, Health Canada currently makes the results of establishment inspections available so that persons using assisted human reproductive technologies in Canada can make informed choices in selecting their source for donor sperm, and intends to include the results of establishment inspections pertaining to donor ova once the Regulations come into force.

Comments on the cost-benefit analysis

A respondent commented that expenses for pregnancy, deliveries and neonatal care were not included in the cost-benefit analysis. Health Canada confirms that is the case, as the cost benefit analysis assesses the direct costs and direct benefits that are anticipated to result from the regulations. As the regulations have no requirements directly pertaining to pregnancy, deliveries and neonatal care, which are health care matters under provincial jurisdiction, there are no costs or benefits on these matters to include.

AHR industry respondents commented that the number of regulated parties seemed, in their view, overestimated. They further expressed concern that, if the number of regulated parties decreased, the cost per facility would increase. Health Canada can confirm that if the number of regulated parties is lower, then the overall costs will decrease and the actual cost per facility would not change. Health Canada also notes the comment on over-estimating the number of regulated parties, but as no additional data was received the cost-benefit analysis remains conservatively estimated using an upper range for the number of regulated establishments.

A respondent noted that it was not clear that the government cost related to preparing and maintaining records has been fully evaluated and included in the proposed costs. Health Canada confirms that these costs are included in the costs for administering and enforcing the AHRA provided in the Benefits and costs section of this document.

II. Comments on the Reimbursement Related to Assisted Human Reproduction Regulations

The comments provided on these Regulations were mixed. Many respondents welcomed the introduction of the proposed Regulations and were generally supportive of their content. There were many others, however, who were critical of the Regulations and its content, often based on their view that payment to donors and surrogate mothers should be permitted. A large number of respondents provided comments, particularly on the lists of proposed reimbursable expenditures for donors and surrogates, the provisions on the reimbursement for loss of work-related income and on the documentation and record-keeping requirements.

There were also some comments on the overall tone and language used in the Regulations and their supporting materials, as some respondents felt that they did not reflect the experiences of people involved, such as the generosity and altruism of donors and surrogate mothers. Health Canada notes these comments. It is not possible to address these comments in the language of the Regulations. Health Canada will take them into consideration as it develops guidance and other supporting documents.

Many respondents asked questions and requested clarifications on the Regulations. Health Canada will provide general clarifications in guidance and other supporting documents that it will publish on the Government of Canada website in advance of the regulations coming into force. These general clarifications will include

- which health care providers can provide recommendations in writing to donors and to surrogates for products and services, and related to loss of work-related income of surrogates;

- how surrogates who are self-employed or commission-based would be able to be reimbursed for loss of work-related income;
- the circumstances under which it would be permitted to request reimbursement for embryo maintenance and transportation, and from whom such a reimbursement could be requested;
- roles and responsibilities of the donor and surrogate requesting reimbursements and the people providing the reimbursement, regarding documentation, attestations, and record keeping; and
- how administration and enforcement of these Regulations would proceed, including seeking records and methods of enforcement, if any.

Comments on reimbursable expenditures for sperm and ova donors

Numerous respondents requested the inclusion of additional types of reimbursable expenditures for ova and sperm donors in the Regulations. Comments typically noted that these expenditures may be experienced by donors, so they should be included to avoid burdening individuals who donate sperm and ova. A number of respondents commented that donors should not have to deal with stress or hardship due to financial matters related to the donation. In three instances, Health Canada agreed that the suggested additions are within the scope of what is permitted by the AHRA, and have added them as permitted reimbursable expenditures in the Regulations. The added items are as follows:

- Expenditures for pet care, related to the donation;
- Expenditures for travel insurance, related to the donation; and
- Expenditures for obtaining the note recommending a product or service from a person authorized under the laws of a province to practise medicine in that province.

Numerous respondents suggested that ova donors should be permitted to be reimbursed for the loss of work-related income, as the process of ova donation is a medical procedure that carries health risks (e.g. ovarian hyperstimulation syndrome) that may result in a woman needing to take time off work. Subsection 12(3) of the Act only deals with reimbursing surrogates for the loss of work-related income and therefore regulations cannot be made to address the respondents' suggestion. Health Canada recognizes this issue; guidance will be developed to provide greater clarity on this matter.

A few respondents suggested adding expenditures incurred both before and after the donor sperm and ova are obtained by an establishment, such as counselling before or afterwards. Expenditures listed in the Regulations that occur during those times are already eligible for reimbursement as they occur in the course of a donation, which typically span a period of time and may encompass appointments, meetings, procedures, and recovery. Health Canada will publish guidance that provides specifics on this.

A respondent requested that food expenditures related to the donation be a permitted reimbursement for ova donors, as there are diets recommended to them while they are in the course of donating. While ova donors may be encouraged to maintain a healthy diet during the process, Health Canada is not aware of any specific dietary requirements associated with donating ova. Accordingly, the Regulations have not been amended to reflect this request.

A respondent requested that more types of health care practitioners be permitted to provide the written recommendation for products and services that a donor may have reimbursed. Health Canada is of the view that persons authorized under the laws of a province to practise medicine in that province are best positioned to provide or recommend in writing products or services to donors that would protect their health and safety or are otherwise related to their donation.

A respondent expressed concern that the list of reimbursable expenditures for sperm and for ova donors is the same, when ova donors generally face additional health risks in the course of a donation. Health Canada notes this but is of the view that no revisions to the Regulations are needed, as donors can only be reimbursed for the expenditures they actually incur in the course of the donation. If the facts of a particular sperm donation lead to the donor incurring an expenditure that is more commonly associated with ova donation (e.g. the donor is out-of-pocket for the cost of a drug, as defined in section 2 of the *Food and Drugs Act*), Health Canada believes it is reasonable that they

be reimbursed.

Several respondents commented that they felt that the list of reimbursable expenditures is too rigid, with the consequence being that donors will be unable to request reimbursements for expenditures that they incur in the course of the donation, which may deter persons from becoming donors. A number of respondents suggested adding an ‘other’ or ‘any reasonable expense’ category to the list of reimbursable expenditures, to provide flexibility so that reasonable but unanticipated expenditures can be reimbursed. Health Canada considered all suggestions for additional expenditures to this list and added several, as noted above. Health Canada also notes that certain items in the list, such as those relating to expenditures for ‘drugs and devices,’ and to ‘products and services’ where recommended in writing, are broad and may permit the reimbursement of many types of items and services.

Comments on reimbursable expenditures for surrogates

Numerous respondents requested the inclusion of additional types of reimbursable expenditures for surrogates in the Regulations. Comments typically noted that these expenditures may be experienced by surrogate mothers due to their pregnancy, so they should be included to avoid burdening women who are acting as surrogates with expenses that they are not able to ask the intended parents to reimburse. A number of respondents commented that surrogates should not have to deal with stress or hardship due to financial matters related to the surrogacy. In several instances, Health Canada agreed that the suggested additions are within the scope of what is permitted by the AHRA, and have added them as permitted reimbursable expenditures in the Regulations. Health Canada will also publish general guidance providing more information about the permitted reimbursable expenditures that will be provided in the Regulations. The added items are as follows:

- Expenditures for prenatal exercise classes;
- Expenditures for pet care related to the surrogacy;
- Expenditures for groceries, excluding non-food items, related to the surrogacy;
- Expenditures for travel insurance related to the surrogacy;
- Expenditures for telecommunications related to the surrogacy;
- Expenditures for the services of a midwife or a doula; and
- Expenditures for obtaining the note recommending a product or service from a person authorized under the laws of a province to assess, monitor and provide health care to a woman during her pregnancy, delivery, or post-partum.

There were also recommendations to add specific items to the list of expenditures that may be reimbursed, where it is Health Canada’s view that those types of expenditures are already sufficiently included in the list. Those suggestions and Health Canada’s response are as follows:

- Several respondents suggested adding expenditures related to the post-partum period, or during the pre-pregnancy period. Expenditures made before the pregnancy or during the post-partum period are already eligible for reimbursement when they are in relation to surrogacy, and provided that such expenditures are one of the permitted types listed in the Regulations. For instance, expenditures related to travel to a medical appointment in preparation for the surrogacy would be permitted to be reimbursed, and breast pumps and pumping supplies would be permitted expenditures as they are a device, as defined in section 2 of the *Food and Drugs Act*. Guidance will provide additional general information on this.
- Several respondents suggested adding expenditures related to personal hygiene. As for the previous example, most of those expenditures, where related to the surrogacy, would be devices and are already included in the list. Guidance will provide additional general information on this.
- Several respondents suggested adding expenditures for home care or household help. Health Canada’s view is that, generally, this type of expenditure is not sufficiently linked to surrogacy to be included in the list. Should it be recommended in writing to a surrogate mother, by a person

authorized under the laws of a province to assess, monitor and provide health care to a woman during her pregnancy, delivery, or post-partum, that she not partake in strenuous activity or requires bed-rest, such home assistance could be a service that is permitted to be reimbursed.

- A number of respondents suggested adding expenditures for items to increase comfort and well-being such as pregnancy pillows, mattress covers, morning sickness remedies, and belly support bands. Health Canada is of the view that these expenditures are already included in items listed, including those related to clothing, drugs and devices, the delivery, and items provided or recommended in writing by a person authorized under the laws of a province to assess, monitor and provide health care to a woman during her pregnancy, delivery, or post-partum.
- Some respondents suggested that adding expenditures for services such as prenatal massage, chiropractor, acupuncture, and physiotherapy during the prenatal and postnatal periods. Health Canada's view is that these are health care services that require a recommendation in writing from a person authorized under the laws of a province to assess, monitor and provide health care to a woman during her pregnancy, delivery, or post-partum, and as such are already covered in the list. Some respondents expressed concerns about the effort required to receive written recommendations, including the expense and time. To address the concern, Health Canada has added the cost that may be charged to provide a written recommendation to the list of reimbursable expenditures. Health Canada also notes that, depending on provincial and territorial rules, the persons who can provide a written recommendation to a surrogate may include their doctor, nurse practitioner, or midwife.

Several respondents commented that they felt that the list of reimbursable expenditures is too rigid, with the consequence being that surrogates will be unable to request reimbursements for expenditures that they incur as a result of the surrogacy. Many had the view that surrogacy should be cost-neutral for the surrogates. Some respondents expressed concerns that, as a result, the Regulations will cause financial strain for surrogates and may discourage surrogacy in Canada if surrogates cannot be reimbursed for all incurred expenditures. A number of those were past or current surrogates who commented that they would not choose to be surrogates given these Regulations. A few respondents commented that there should not be an inclusive list, and that surrogates and intended parents should have the latitude to determine the appropriate reimbursements for their particular circumstances. A number of respondents suggested adding an 'other' or 'any reasonable expense' category to the list of reimbursable expenditures, to provide flexibility so that other reasonable but unanticipated expenditures can be reimbursed. On the other hand, some respondents commented that permitting any 'reasonable expense' in the Regulations could lead to loopholes that would result in commercialization of surrogacy. Health Canada considered all suggestions for additional expenditures to this list and added several, as noted above. Health Canada also notes that certain items in the list, such as those relating to expenditures for 'drugs and devices,' and to 'products and services' where recommended in writing, can encompass a broad range of expenditures. Health Canada has not added a more general item to the list as it is of the view that the chosen approach most effectively balances permitting surrogates to be reimbursed for expenditures incurred in relation to their surrogacy, while supporting the key principles of the Act.

A few respondents suggested that the Regulations set a maximum total reimbursement to a surrogate, so that surrogacy is a financially accessible option for intended parents. Another respondent suggested a schedule of compensation amounts for surrogates, included maximums, that could be reimbursed without receipt, and that any amounts greater than that schedule could be reimbursed with receipt. Maximum reimbursements for certain types of expenditures, such as for the care of dependent, was also suggested. On the other hand, some respondents felt that setting a cap would be artificial and limiting. Health Canada did not implement the suggestion to set a maximum total reimbursement in the Regulations, as there can be considerable variation in the circumstances of women's pregnancies and therefore in the expenditures that may be incurred. Furthermore, the provision of a receipt to receive a reimbursement is a requirement at the level of the AHRA.

Comments on reimbursing loss of work-related income for surrogates

Numerous respondents requested that the Regulations permit the reimbursement of lost work-related income post-delivery for surrogate mothers. Some respondents further requested that the Regulations permit reimbursement for expenses and lost wages related to medical issues caused by the pregnancy, such as surgical/birth complications, loss of reproductive organs, disability, or post-partum depression. Health Canada interprets pregnancy to include a postnatal period and will provide additional general information and clarification in guidance on this matter.

A respondent expressed concern that the requirements around reimbursing lost work-related income for surrogates are prejudicial for self-employed women, which may not have the same evidence of wages as others. Health Canada chose intentionally broad language in setting out the supporting evidence of income that is required by the Regulations, in part to account for various types of employment arrangements that surrogates may be involved in. Health Canada will provide additional general information and clarification in guidance.

A respondent proposed capping reimbursement for lost work-related income at a certain percentage of the surrogate's wages as is done with employment insurance, such as at 55% of their income, up to a maximum amount. As mentioned above, Health Canada is of the view that setting a maximum amount would not respect the individual nature of each surrogacy arrangement. Restricting the reimbursement to a certain percentage of the surrogate's wages is not consistent with the frequently received comment from respondents that surrogates should not have to deal with stress or hardship due to financial matters related to the surrogacy.

Comments on documents and records

Many respondents requested that the reimbursement process not be overly onerous or bureaucratic, and should allow for timely reimbursement of expenditures. Several felt that elements of the process are too arduous and impractical, particularly for surrogates who generally request to be reimbursed multiple times during the surrogacy, such as monthly, and who may already be required to submit documents to employers and the government for time off work. Comments on specific elements of the reimbursement process are as follows:

- Some respondents commented that the declaration statement required by donors and surrogates seeking reimbursement is too difficult and is unnecessary given the required receipts, and will be a deterrent to those seeking reimbursements.
- A few respondents specifically commented that requiring a detailed list of expenditures in the declaration is unnecessary micromanagement of the process.
- A number of respondents commented that the requirement for certain expenditures that specified health care providers provide a written recommendation for products and services will take time away that could be spent on health matters and may lead to reluctance to recommend expenses. It may also place a greater burden on the health care providers. Respondents additionally noted that it could be more difficult for surrogates and donors who have no local health care provider, such as those in rural areas. Respondents suggested removing the requirement for a written recommendation.
- Some respondents commented that the requirement that the person providing the reimbursement must sign the declaration is complicated, adds little benefit, and puts parties at risk of violating law if this step is forgotten.
- A few respondents expressed concern that it is not possible to obtain receipts for some expenditures, such as for the purchase of used maternity clothes or for babysitting.
- Some respondents suggested reducing the length of time to maintain records, such as to 2 years, primarily to facilitate psychological closure. Others felt that 6 years, to align with the period required to keep income tax records, was appropriate.
- A respondent suggested that the declaration only be required when there is no receipt, and another commented that receipts should not be a requirement for any reimbursed expenditure. On the other hand, a respondent felt it was reasonable to require receipts.
- A group of respondents was concerned about the administrative burden on fertility centres and

agencies that provide many reimbursements to donors, and who may have to maintain a new system to track the reimbursements.

Health Canada carefully considered these comments in developing the final Regulations. The chosen approach most effectively balances permitting donors and surrogates to be reimbursed for expenditures incurred in relation to their donation or surrogacy, while supporting the key principles of the Act. Health Canada is of the view that establishing a verifiable process in the Regulations, including the signed declaration, provides stakeholders with clarity that is currently lacking. It also provides a mechanism to enable compliance enforcement efforts undertaken by Health Canada.

In addition, as requested by a number of respondents, Health Canada will publish on its website an example of a declaration form as a sample to help guide stakeholders. This will include a model of how to complete documentation for travel reimbursements, as requested.

A group of academic respondents, including those in law, recommended removing the regulations that permit the Minister of Health to require records from persons who reimburse expenditures, and that new provisions be added pertaining to any criminal liability that persons could be charged with regarding the provision of reimbursements. Their concern with these regulations relates to their view that the AHRA's section 12, under which the regulations are made, is a criminal law provision, and therefore must adhere to certain rights under the *Canadian Charter of Rights and Freedoms*. Health Canada has considered the issue, and is of the opinion that section 12 of the Act instead represents a purely regulatory provision; as a result, it is the department's view that these concerns are not applicable and the present regulations regarding providing records are appropriate within the context of administering section 12 and its associated regulations for the purpose of verifying compliance.

A respondent requested that there be a way for individuals to anonymously report transactions that do not meet these Regulations' requirements. Health Canada encourages Canadians to report to the department any problems they encounter with donor sperm or ova, including reimbursement. Health Canada is committed to verifying complaints from Canadians and industry regarding reimbursements related to assisted human reproduction.

Comments on the coming into force provisions

Several respondents recommended against an immediate coming into force for the *Reimbursement Related to Assisted Human Reproduction Regulations*, and that there be a delay between the publication of the final regulations and their coming into force to give individuals and members of the AHR industry time to transition from current practices to these requirements. Health Canada agrees and has revised the timing of the coming into force such that the Regulations will come into force twelve months after the order in council that brings into force section 12 of the AHRA is made.

III. Comments on the Administration and Enforcement (Assisted Human Reproduction Act) Regulations

Several respondents provided comments in support of the proposed approach for administering and enforcing the AHRA, including its regulations, stating these efforts help ensure that regulated parties have appropriate safety and administrative processes in place.

Many respondents requested clarifications and provided comments on the administration and enforcement regime that Health Canada will put in place for the Act and its regulations, including facility inspections. Several noted the importance of a strong regime, while others had suggestions on the time, resources, and transparency that would be involved. These comments and requests include the following:

- Respondents in the AHR industry noted some concerns around facility inspections and the enforcement of the Act. They requested that the implementation of these elements consider the time and resources of their community, and that the inspection process be a means for quality improvement, and recommended that inspections be no more than every two years unless there is a reason to do so more frequently in particular cases. A few other respondents also asked for more information on the length and frequency of inspections.
- A few respondents asked about the privacy and confidentiality of information collected during

inspections.

- Respondents asked whether inspections would be made in facilities in other countries.
- A few respondents requested that inspection regimes and results be made public.
- A number of respondents expressed concerns about how the possible seizure of materials, including sperm, ova, and embryos, would proceed. Questions included how authorization would be given, how material would be safely transported and stored, and how clinics and owners of the material would be informed and involved in seizure, restoration and disposal.
- A respondent asked how these federal Regulations may interact with provincial jurisdiction, such as in the matters of donor or surrogacy arrangements that take place in multiple provinces and territories.
- A respondent requested that there be systems in place to guarantee that no other use is made of forfeited sperm, ova, or IVEs as a means of fulfilling their disposal.
- A respondent requested more information on Health Canada's use of storage for reproductive materials, should it be required during enforcement activities.

Health Canada acknowledges these comments and requests, and will take them into account in the development of guidance and procedures regarding the administration and enforcement of the Act and its regulations. Clarifications on these matters will be provided in guidance and policies published online.

A number of respondents requested an extension to the period of time that the designated officer must wait before he or she can direct the disposal of seized and forfeited donor sperm, ova or IVEs, in cases where it is impossible to obtain the consent of the donor for further measures. The proposed regulations had set that period as 60 days, and respondents, among other concerns, questioned whether 60 days is an adequate period to determine the impossibility of gaining consent. Comments suggested longer periods ranging from 90 days, to the material's full viability period, to indefinitely. Health Canada has revised this period to 180 days, to address stakeholder concerns and to enable Health Canada to seek fresh consent (i.e. a new statement of consent) from donors regarding the forfeited material if circumstances arise in which it would be appropriate to do so.

A group of respondents requested that these Regulations use certain definitions from the Semen Regulations and the CSA Standard, CAN/CSA-Z900, Tissues for Assisted Reproduction, for consistency. They specifically recommended that the Regulation's definition of a donor, in relation to an in vitro embryo, be amended so it is consistent with the CSA definition, which is more reflective of what practitioners see clinically. Health Canada notes this suggestion, but has made no change to the definition of donor as the Regulations do not have clinical practice as a purpose, but rather address matters of consent for further measures to be taken with respect to seized sperm, ova or in vitro embryos. As a result, the definition of donor, in relation to an in vitro embryo created for reproductive use, takes into account the individual or couple for whose reproductive use the embryo has been created.

Finally, a respondent requested clarification on whether the costs of government storage facilities for reproductive materials, should it be required, is included in the estimated costs. Health Canada can confirm that government costs for storage are included in the estimated costs.

IV. Comments on the Regulations Amending the Assisted Human Reproduction (Section 8 Consent) Regulations

A few respondents commented that the timing of a donor's withdrawal of consent in the proposed regulations are not consistent with industry practice as it does not recognize that consent forms for in vitro fertilization (IVF) are signed prior to the IVF cycle. They noted that the proposed regulations would have required the recipients to return to the clinic to sign an additional form after the ova are obtained but before the IVE is created; otherwise the Regulations would allow the donor to withdraw their consent at any time following donation. Returning to the clinic to sign another form could be burdensome for those who do not live in close proximity to the clinic. Health Canada notes this and has corrected the Regulations to take into account current clinical practices.

A group of respondents recommended against including any provisions that seek to strengthen donor anonymity. Other respondents requested that it no longer be possible to donate sperm or ova anonymously, remarking that the availability of at-home DNA tests have made identifying previously anonymous donors possible. On the other hand, a number of respondents supported the option of donor anonymity. Health Canada notes the recommendation; however, the AHR industry offers anonymous donation in Canada and the U.S., and the amendments put into the Regulations the long-standing administrative policy that responds to concerns raised by sperm banks. As a result, Health Canada has proceeded with the proposed amendments related to anonymity.

Several respondents sought clarifications in the amendments regarding the proposed record-retention period of 10 years. In some comments, respondents felt that keeping records for 10 years following removal of reproductive material may not be long enough, if the material is cryopreserved for more than 10 years following removal. In other instances, keeping records for 10 years may be of no use if the material is destroyed before it is used. Certain stakeholders also requested that the period be extended to 25 years, or longer, as they were also proposing a longer record-retention period for the *Safety of Sperm and Ova Regulations* and suggested they be the same. Health Canada has chosen to retain the 10-year period as it best ensures consistency with provincial requirements.

Some respondents submitted comments regarding the provisions that refer to the situation where a donor has proceeded in a certain manner on the condition of anonymity. They requested that, for clarity, these provisions refer instead to the manner of donation or the entity co-ordinating the donation, rather than the condition of anonymity. Health Canada has not amended these provisions, as this request goes beyond the scope of administrative policy and the intent of the Regulations.

Respondents requested amendments to how certain provisions use the term ‘person,’ to make clearer that, in some instances, they may be employees of a clinic or ova bank and acting as a representative of that facility. Health Canada has not amended the Regulations in response to this comment but will provide general clarification on this matter in guidance.

Summary of changes to the regulations following prepublication

The regulations differ from those prepublished in the *Canada Gazette*, Part I, in the following manner:

Safety of Sperm and Ova Regulations

- There were three minor changes to definitions in the Regulations, for clarification:
    - The definition of ‘activity’ was revised to clarify that processing means one or more of the specified list, rather than including them and thus giving the impression that other things could be part of processing;
    - The French definition for ‘directive’ was revised to incorporate a revised title of the document, to ‘Exigences techniques concernant la tenue de l’évaluation de l’admissibilité du donneur de spermatozoïdes ou d’ovules’; and
    - The French version of ‘standard operating procedures’ in the definition and throughout the Regulations has been revised to ‘procédures opérationnelles normalisées.’
- Revisions were made to provisions under the Regular Process related to re-testing and quarantine:
    - The Regulations were amended to move the requirements for re-testing sperm donors from the Regulations into the Directive’s donor testing requirements. This change has been made so that re-testing requirements can be updated in future as new scientific developments allow, as well as to better align with industry practices in which re-testing is understood to be part of the testing component of the donor suitability assessment, rather than as a condition for release from quarantine.
    - The provisions regarding quarantine were revised to streamline the regulatory text, given the move of the re-testing provisions to the Directive. This involved combining and re-ordering certain sections under the regular process and the directed donation process.
    - The Regulations were amended to correct the condition for release from quarantine under

the exceptional access sections in the case of previous exposure to a donor's sperm or ova to better reflect the policy intent. The revisions will allow, if certain requirements are met, sperm or ova to be released from quarantine if the intended recipient has already been exposed to a donor's sperm or ova and the results of any of the donor suitability assessment that was completed indicate that the risk profile of the requested sperm or ova is at least equivalent.

- A revision was made to the section of the Regulations that sets out quarantine requirements. This section is referred to in the definition of quarantine in the Regulations. The revision makes clear that donor sperm or ova under quarantine cannot be either distributed or used.
- The Regulations were amended to correct three instances where the requirement for a signed summary document was omitted.
- A requirement under directed donation was amended to correct an omitted reference to the donor reassessment as it may be the case for a directed donation that, for a repeat donor, a donor reassessment was conducted and should be reviewed if it is available.
- Portions of the Quality Management section of the Regulations were amended to reorganize and strengthen the quality management requirements, to better align with industry understanding of the scope of quality management systems versus quality management practices and respond to stakeholder comments on labelling and storage.
    - These revisions included relocating provisions originally under Quality Management System into other parts of the Quality Management section to be adjacent to existing quality management provisions on the same general topic.
    - Provisions under Quality Management System were modified to make clearer that establishments only have to have a quality management system appropriate to the specific activities they conduct, as defined in the Regulations, and the measures they take to satisfy the requirements related to quality management.
    - The revisions included moving the provisions originally under Identifying and Labelling into the Quality Management section of the Regulations. A new provision was also added that requires establishments that label to establish and maintain a labelling control system.
    - A requirement related to storage was amended to add that establishments that store sperm and ova must establish and maintain acceptable temperature ranges for storage. The requirement that equipment must maintain appropriate environmental conditions was removed and replaced with a requirement that sperm and ova be stored at a temperature within the acceptable storage temperature range.
- Revisions were made in the Errors and Accidents section to make clear that any establishment with reasonable grounds to believe that an error or accident has occurred during the processing, distribution or importing of donor sperm or ova, either in their establishment or in another one, must, regardless of whether they have had the sperm or ova in their possession, take specified actions. This change has been made as establishments may perform certain processing steps, such as certain tests, without having the donor sperm or ova in their possession.
- The coming into force provisions were reworded such that most of the Regulations come into force on the day that section 10 of the AHRA comes into force. The period of time between the making of the Regulations and their coming into force was lengthened from 6 months, as originally proposed, to 240 days in the final Regulations. Section 3 of the regulations comes into force on the 180th day after the day on which section 10 comes into force. Provisions that delay certain requirements related to registration numbers until the 180th day after the day that the Regulations come into force were moved from the coming into force section into the transitional section to meet regulatory drafting standards.
- In addition, various provisions were revised to increase consistency between English and French versions or improve clarity.

Reimbursement Related to Assisted Human Reproduction Regulations

- The following categories of reimbursable expenditures for donors have been revised or added, as they may be reimbursed when the expenditures are in relation to their donation:
    - An existing category was expanded to include expenditures for the care of pets;
    - An existing category was revised to include expenditures for travel insurance coverage; and
    - A category was added for expenditures to obtain a written recommendation for products or services from a person authorized under the laws of a province to practise medicine in that province.
- The following categories of reimbursable expenditures for surrogate mothers have been revised or added, and they may be reimbursed when the expenditures are in relation to her surrogacy:
    - An existing category was expanded to include expenditures for the care of pets;
    - An existing category was revised to include expenditures for travel insurance coverage;
    - A category was added for expenditures to obtain a written recommendation for products or services from a person who is authorized under the laws of a province to assess, monitor and provide health care to a woman during her pregnancy, delivery or the post-partum period;
    - A category for expenditures for the services of a midwife or doula was added;
    - A category for expenditures for groceries, excluding non-food items, was added;
    - A category for expenditures for telecommunications was added; and
    - A category for expenditures for prenatal exercise classes was added.
- The coming-into-force provision was revised so that the Regulations come into force on the day that section 12 of the AHRA comes into force.

Administration and Enforcement (Assisted Human Reproduction Act) Regulations

- The title of the Regulations was revised so that it is more consistent with the titles of the other regulations under the AHRA, as well as with Department of Justice guidelines on the format of regulatory titles.
- The definition of common-law partner has been amended such that, rather than referencing the definition of common-law partner in subsection 10(5) of the AHRA, the revised definition in the Regulations instead duplicates the wording of the definition in the Act. A definition of common-law partner is required in these Regulations as the definition in subsection 10(5) only applies to section 10 of the AHRA, and this revision is needed because these Regulations come into force earlier than subsection 10(5) comes into force, so a reference to subsection 10(5) will not suffice.
- The period of time only after which the designated officer may direct an inspector to dispose of sperm, ovum or in vitro embryo that was forfeited, when it is impossible to obtain consent of the donor, has been amended from 60 days to 180 days.
- The coming-into-force provision was revised, such that the Regulations come into force on the day that section 45 of the Act comes into force, or, if they are registered after that day, the Regulations come into force on the day they are registered.

Regulations Amending the Assisted Human Reproduction (Section 8 Consent) Regulations

- Subsection 2(1) and section 4 of the Amending Regulations, which set out replacement provisions for subparagraph 3(d)(ii) and paragraph 5(2)(b) of the Consent Regulations, have been revised to take into account the timing of donor consent and third party acknowledgement during IVF cycles.
    - These revisions pertain to the point in time before which notification of the withdrawal of the donor’s consent to use must be provided in order for the withdrawal of consent to be effective. The original amendments stated that the withdrawal of consent must take place before the third party acknowledges in writing that the material has been obtained for their

reproduction use. The revisions add an alternate point of time, where the withdrawal of consent must take place for it to be effective. A withdrawal is also effective if it takes place before the third party acknowledges in writing that the material is to be used for their reproductive use. The alternate point of time would be appropriate for IVF cycles, where it is typical practice for consent forms to be signed prior to the retrieval of gametes and onset of the IVF cycle.

- In subsection 2(1), this revision has been done by moving part of the new subparagraph 3(d)(ii) into a clause 3(d)(ii)(A), and by adding a new clause 3(d)(ii)(B), which describes a second scenario regarding consent and the removal or collection of material. The same revisions were made in section 4, by moving part of the new paragraph 5(2)(b) into a subparagraph 5(2)(b)(i), and by adding a new subparagraph 5(2)(b)(ii), which describes a second scenario regarding consent and the removal or collection of material.

- Section 12 of the Amending Regulations, which revises the opening wording of the transitional provision in subsection 16(2) of the Consent Regulations, has been revised to add section 13.2 to the “despite” list, to reflect changes in numbering as a result of the Amending Regulations.

Regulatory cooperation

Though regulatory alignment is not the purpose of the initiative, it increases alignment between Canada and the United States, the source of the majority of donor sperm and ova used in Canada. Donor sperm and ova in the U.S. are regulated under Title 21 of the *Code of Federal Regulations*, part 1271, entitled Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps). The registration scheme in the *Safety of Sperm and Ova Regulations* will be similar to what is in place in the U.S. U.S. regulations require that all establishments that process or distribute donor sperm and ova for use in the U.S. must register with the Food and Drug Administration (FDA). Establishments located outside of the U.S. that import, or offer for import, donor sperm and ova into the U.S. are also required to register with the FDA. [22]

The *Safety of Sperm and Ova Regulations* will closely align the screening and testing requirements for sperm and ova donors with those in the U.S. Specifically, compared to the current requirements in the Semen Regulations, the initiative will result in greater alignment of infectious disease testing requirements, test kit requirements, and donor deferral requirements. For example, this includes permitting the use of test kits licensed in the U.S. as well as better aligning infectious disease testing intervals with those currently required in the U.S. In addition, the U.S. regulations place certain record requirements on establishments regarding donors and donations, including a retention period of 10 years.

The areas where the Regulations will not align with federal regulations in the U.S. include genetic screening and most requirements under quality management, aside from certain record requirements as noted above. It is typical industry practice, however, for donors to undergo genetic testing that will satisfy the regulatory requirements of genetic screening. While the HCT/Ps regulations have Current Good Tissue Practice requirements that are similar to the *Safety of Sperm and Ova Regulations*’ quality management requirements, donor sperm and ova and the establishments that process them are not required to meet them. However, due to the absence of federal regulations related to quality management for assisted reproductive technologies in the U.S., as well as considerable variation in state-level requirements, professional guidelines and good practice protocols play an important role in overseeing assisted reproductive technology practice. The guidelines and standards established by the American Society of Reproductive Medicine and the American Association of Tissue Banks are aligned with Current Good Tissue Practice requirements, as well as the requirements in the *Safety of Sperm and Ova Regulations*. Moreover, these professional standards also serve as the foundational requirements for the assisted reproductive technology laboratory certification program operated by the Centers of Disease Control and Prevention (CDC), which authorizes U.S. states to set up certification programs to use accreditation organizations to certify and inspect laboratories. While the certification program is voluntary, there is a high level of participation within the program, with the CDC reporting in 2016 that 436 out of 463 fertility clinics operating in the U.S. were certified or

pending certification under the program. [23] This indicates that the U.S. AHR industry standards typically include quality management measures.

In Europe, sperm and ova donors are required to be screened and tested similarly to the requirements in the *Safety of Sperm and Ova Regulations* including screening for genetic diseases prevalent in their ethnic background and other inherited conditions known to be present in the family, as outlined in the European Union Tissue and Cells Directives (EUTCD). While the EUTCD defines overarching mandatory requirements for donors of reproductive tissues, it also allows for European Union member states to adopt their own specific screening and/or testing requirements on a national basis to address local epidemiological risk factors and to ensure a higher level of safety. As well, the quality management requirements in the *Safety of Sperm and Ova Regulations* align with similar provisions related to establishing and maintaining a quality program, SOPs, personnel, facilities, environmental controls, equipment, process controls, labelling, storage, records, complaints, and reporting errors, accidents, and adverse reactions in the European Good Tissue Practice guidelines developed by the European Commission. Overall, the Regulations will result in Canadian requirements being better aligned with typical industry practice in Europe than is the case under the current regulatory requirements in the Semen Regulations.

The existing Consent Regulations are consistent with typical industry practice in the U.S., and the amendments will resolve concerns of sperm and ova banks, including those in the U.S., that the Regulations could unintentionally compromise the anonymity of donors. As payment for sperm and ova donation and surrogacy is not prohibited in the U.S., there are no regulatory requirements in the U.S. with respect to reimbursement of expenditures. However, Canadian regulations with respect to reimbursement are necessary to bring into force the reimbursement provisions of the AHRA, and having different regimes on this matter is not expected to pose any issues regarding regulatory alignment.

Rationale

Protecting Canadians who use donor sperm and ova in AHR

The *Safety of Sperm and Ova Regulations* will help protect the health and safety of Canadians who use donor sperm and ova and the children born through AHR by updating the screening and testing requirements for donor sperm and by introducing screening and testing requirements for donor ova. This includes modernizing the requirements for donor sperm by updating donor screening criteria to reflect advances in the understanding of disease pathology, and by changing donor testing requirements, including expanding test kit eligibility and increasing testing intervals. The framework will also increase oversight of the establishments that supply donor sperm and ova to better support the use of sperm and ova that meet safety requirements.

While the Regulations have a present value cost of $11,256,703 over a 10-year period, with a $4,579,273 cost to industry and the remainder to the federal government, the qualitative benefits in human health and safety, including reducing the risk of disease transmission to recipients of donor sperm and ova as well as children born of AHR, warrant the requirements.

Permitting reimbursements to donors and surrogate mothers

The *Reimbursement Related to Assisted Human Reproduction Regulations* will provide clarity on the permitted expenditures that may be reimbursed to sperm and ova donors and surrogate mothers, as well as to persons involved in maintaining and transporting IVEs. This will provide needed clarity to those offering and receiving reimbursements related to these AHR activities so they can undertake those transactions without concerns that they could be contravening the Act.

Increasing alignment and improving accessibility of donations

The *Safety of Sperm and Ova Regulations* will better align with U.S. FDA regulations as well as typical U.S. industry practice in its requirements for donor screening and deferrals, infectious disease testing, including testing intervals, and test kits. Further, directed donation processing will make it

easier for Canadians who know their donor to proceed with building their families.

Implementation, enforcement and service standards

The coming into force of the regulations will be gradual to provide time for stakeholders to plan for and adjust to the new regulatory requirements, and to give Health Canada time to update its processes. Transitional provisions will provide regulated parties that process, import, or distribute donor sperm or ova with a 90-day period after the coming into force of the *Safety of Sperm and Ova Regulations* to comply with the registration and notification provisions. Health Canada will also be publishing guidance documents to provide assistance to the AHR industry and others on how to comply with the regulations. Concurrently with final publication of the regulations, draft guidance documents on the *Safety of Sperm and Ova Regulations* and the *Reimbursement Related to Assisted Human Reproduction Regulations* will be published for a 30-day consultation period. Final guidance documents will be made available in advance of the coming into force of the regulations, to support regulated parties in bringing their operations into compliance.

Compliance and enforcement activities in support of the new regulatory requirements may begin after publication of the regulations in the *Canada Gazette*, Part II. Health Canada's compliance approach to the *Safety of Sperm and Ova Regulations* will be in line with the approach currently used for the Semen Regulations and other regulatory regimes. With regard to service standards for responding to registrations from primary establishments, it is expected that, after the transitional period, 90% of decisions will be made within 90 calendar days from the receipt of a complete application.

Compliance and enforcement activities may include the following: monitoring establishment compliance through a risk-based inspection program; compliance verification and investigation activities based on complaints or identified non-compliance with the regulations; and education, consultation and information sharing through the development of documents and other compliance promotion activities.

Performance measurement and evaluation

Health Canada will implement the program evaluation requirements of the Treasury Board Policy on Results with respect to certain elements of this initiative (i.e. safety of semen and ova, reimbursement) through the Health Product Performance Measurement Strategy, the result-based management tool that measures, monitors and reports on expected results of the Health Products Program. As part of this strategy, Health Canada will incorporate proactive compliance promotion, monitoring and data collection following the implementation period to determine whether there are any trends associated with non-compliance that could suggest that sections of the regulations are not understood by all or particular groups of regulated parties.

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Small Business Lens Checklist

1. Name of the sponsoring regulatory organization:

Health Canada

2. Title of the regulatory proposal:

Regulations under the *Assisted Human Reproduction Act*

3. Is the checklist submitted with a RIAS for the *Canada Gazette*, Part I or Part II?

☐ *Canada Gazette*, Part I ☑ *Canada Gazette*, Part II

A. Small business regulatory design

I	**Communication and transparency**	**Yes**	**No**	**N/A**
1.	Are the proposed regulations or requirements easily understandable in everyday language?	☑	☐	☐
2.	Is there a clear connection between the requirements and the purpose (or intent) of the proposed regulations?	☑	☐	☐
3.	Will there be an implementation plan that includes communications and compliance promotion activities, that informs small business of a regulatory change and guides them on how to comply with it (e.g. information sessions, sample assessments, toolkits, websites)?	☑	☐	☐
4.	If new forms, reports or processes are introduced, are they consistent in appearance and format with other relevant government forms, reports or processes?	☑	☐	☐
II	**Simplification and streamlining**	**Yes**	**No**	**N/A**
1.	Will streamlined processes be put in place (e.g. through BizPal, Canada Border Services Agency single window) to collect information from small businesses where possible?	☐	☑	☐
The information collection has been designed to reduce burden on businesses where possible, including placing fewer requirements on regulated parties that perform lower-risk activities. The requirements do not require the services provided by BizPal, the Single Window Initiative, or similar streamlined processes.				
2.	Have opportunities to align with other obligations imposed on business by federal, provincial, municipal or international or multinational regulatory bodies been assessed?	☑	☐	☐
3.	Has the impact of the proposed regulations on international or interprovincial trade been assessed?	☑	☐	☐

4.	If the data or information, other than personal information, required to comply with the proposed regulations is already collected by another department or jurisdiction, will this information be obtained from that department or jurisdiction instead of requesting the same information from small businesses or other stakeholders? (The collection, retention, use, disclosure and disposal of personal information are all subject to the requirements of the *Privacy Act*. Any questions with respect to compliance with the *Privacy Act* should be referred to the department's or agency's ATIP office or legal services unit.)	☐	☐	☑
The specific information that would be collected under the regulations is not being collected by another department or jurisdiction.				
5.	Will forms be pre-populated with information or data already available to the department to reduce the time and cost necessary to complete them? (Example: When a business completes an online application for a licence, upon entering an identifier or a name, the system pre-populates the application with the applicant's personal particulars such as contact information, date, etc. when that information is already available to the department.)	☐	☑	☐
Health Canada's long-term plan will be to accommodate the above scenarios; however, there are currently no processes in place to support this.				
6.	Will electronic reporting and data collection be used, including electronic validation and confirmation of receipt of reports where appropriate?	☑	☐	☐
7.	Will reporting, if required by the proposed regulations, be aligned with generally used business processes or international standards if possible?	☑	☐	☐
8.	If additional forms are required, can they be streamlined with existing forms that must be completed for other government information requirements?	☑	☐	☐
III	**Implementation, compliance and service standards**	**Yes**	**No**	**N/A**
1.	Has consideration been given to small businesses in remote areas, with special consideration to those that do not have access to high-speed (broadband) Internet?	☑	☐	☐
2.	If regulatory authorizations (e.g. licences, permits or certifications) are introduced, will service standards addressing timeliness of decision making be developed that are inclusive of complaints about poor service?	☑	☐	☐
3.	Is there a clearly identified contact point or help desk for small businesses and other stakeholders?	☑	☐	☐

B. Regulatory flexibility analysis and reverse onus

IV	**Regulatory flexibility analysis**	**Yes**	**No**	**N/A**

1.	Does the RIAS identify at least one flexible option that has lower compliance or administrative costs for small businesses in the small business lens section? Examples of flexible options to minimize costs are as follows: • Longer time periods to comply with the requirements, longer transition periods or temporary exemptions; • Performance-based standards; • Partial or complete exemptions from compliance, especially for firms that have good track records (legal advice should be sought when considering such an option); • Reduced compliance costs; • Reduced fees or other charges or penalties; • Use of market incentives; • A range of options to comply with requirements, including lower-cost options; • Simplified and less frequent reporting obligations and inspections; and • Licences granted on a permanent basis or renewed less frequently.	☑	☐	☐
2.	Does the RIAS include, as part of the Regulatory Flexibility Analysis Statement, quantified and monetized compliance and administrative costs for small businesses associated with the initial option assessed, as well as the flexible, lower-cost option?	☑	☐	☐
3.	Does the RIAS include, as part of the Regulatory Flexibility Analysis Statement, a consideration of the risks associated with the flexible option? (Minimizing administrative or compliance costs for small business cannot be at the expense of greater health, security or safety or create environmental risks for Canadians.)	☐	☐	☑
The flexible option introduces no additional risks.				
4.	Does the RIAS include a summary of feedback provided by small business during consultations?	☑	☐	☐
V	**Reverse onus**	**Yes**	**No**	**N/A**
1.	If the recommended option is not the lower-cost option for small business in terms of administrative or compliance costs, is a reasonable justification provided in the RIAS?	☐	☐	☑
N/A, as the recommended option is the lower cost option.				

Footnotes

a S.C. 2004, c. 2

b S.C. 2012, c. 19, s. 737

1 SOR/2007-118

2 SOR/96-254

3 Bushnik, T. Cook, J. Hughes, E., and Tough, S. 2012. Seeking medical help to conceive (http://www.statcan.gc.ca/pub/82-003-x/2012004/article/11719-eng.htm). Statistics Canada Health Reports, Vol. 23, No. 4.

4 Canadian Assisted Reproductive Technologies Registry (CARTR) Plus. 2017. Preliminary treatment cycle data for 2016. Better Outcomes Registry & Network Ontario. (CARTR Plus 2017 Report — powerpoint presentation (https://cfas.ca/cartr-annual-reports.html)).

5 Bushnik, T., Cook, J. L., Yuzpe, A. A., Tough, S., and Collins, J. 2012. Estimating the prevalence of infertility in Canada (https://doi.org/10.1093/humrep/der465). Human reproduction, 27(3), 738–746.

6 Royal Commission on New Reproductive Technologies. 1993. Proceed with care — final report of the Royal Commission on New Reproductive Technologies (http://publications.gc.ca/site/eng/9.699855/publication.html).

7 Department of Justice. Assisted Human Reproduction (Section 8 Consent) Regulations (http://laws-lois.justice.gc.ca/eng/regulations/SOR-2007-137/page-1.html). 2007.

8 The AHRA defines human reproductive material as “a sperm, ovum or other human cell or a human gene, and includes a part of any of them.”

9 Mroz, J. 2012. In Choosing a Sperm Donor, a Roll of the Genetic Dice (https://www.nytimes.com/2012/05/15/health/in-sperm-banks-a-matrix-of-untested-genetic-diseases.html). The New York Times.

10 Sheldon, T. 2002. Children at risk after sperm donor develops late onset genetic disease (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1122572/). British Medical Journal.

11 Khamsi, R. 2006. Children with gene disorder share sperm donor dad (https://www.newscientist.com/article/dn9208-children-with-gene-disorder-share-sperm-donor-dad/). New Scientist.

12 Ahmad, A. 2012. Danish sperm donation law tightened after donor passes on rare genetic disease (https://www.bionews.org.uk/page_93799). BioNews.

13 Prohibitions related to Purchasing Reproductive Material and Purchasing or Selling In Vitro Embryos (https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/legislation-guidelines/assisted-human-reproduction/prohibitions-purchasing-reproductive-material-selling-vitro-embryos.html) and Prohibitions related to Surrogacy (https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/legislation-guidelines/assisted-human-reproduction/prohibitions-related-surrogacy.html).

14 Fake it Till You Make it: Policymaking and Assisted Human Reproduction in Canada (PDF) (http://www.jogc.com/article/S1701-2163(15)30566-1/pdf) and Breaking the Law (http://www.dal.ca/sites/noveltechethics/projects/human-reproduction/breaking-the-law.html).

15 “Material” is defined in section 45 of the AHRA as “an embryo or part of one, a foetus or part of one or any human reproductive material outside the body of a human being, or any other thing.”

16 When this document refers to “Regulations,” it is in reference to specified regulations under discussion; when the document refers to “regulations” that is in reference to multiple regulations or to regulations generally.

17 Canadian Cost-Benefit Analysis Guide: Regulatory Proposals (PDF) (https://www.tbs-sct.gc.ca/rtrap-parfa/analys/analys-eng.pdf)

18 O’Reilly, Daria, et al. Feasibility of an altruistic sperm donation program in Canada: results from a population-based model (https://reproductive-health-journal.biomedcentral.com/articles/10.1186/s12978-016-0275-0). Reproductive Health, BioMed Central, 14 Jan. 2017.

19 Gunby, Joanne. CARTR Annual report – 2012 (https://cfas.ca/report-2012.html). Canadian Fertility & Andrology Society, IVF Directors Group of the Canadian Fertility and Andrology Society, 2012.

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21 Myers, R. P., Krajden, M., Bilodea, M., Kait, K., Marotta, P., Peltekian, K., Ramji, A., Estes, C., Razavi, H., Sherman, M. 2014. *Burden of disease and cost of chronic hepatitis C virus infection in Canada*. Canadian Journal of Gastroenterology and Hepatology, 28(5):243–250.

22 Tissue Establishment Registration (http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/default.htm)

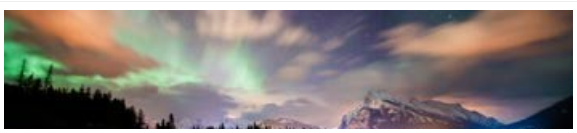
23 Centers for Disease Control and Prevention. 2016. 2016 Assisted Reproductive Technology Fertility Clinic Success Rates Report (https://www.cdc.gov/art/reports/2016/fertility-clinic.html), pages 539–577

Government of Canada activities and initiatives

#YourBudget2018 – Advancement

(https://www.budget.gc.ca/2018/docs/themes/advancement-advancement-en.html?utm_source=CanCa&utm_medium=Activities_e&utm_content=Advancement&utm_campaign=CAbdgt18)
Advancing our shared values

#YourBudget2018 – Reconciliation



(https://www.budget.gc.ca/2018/docs/themes/reconciliation-reconciliation-en.html?utm_source=CanCa&utm_medium=%20Activities_e&utm_content=Reconciliation&utm_campaign=CAbdgt18)
Advancing reconciliation with Indigenous Peoples

#YourBudget2018 – Progress

(https://www.budget.gc.ca/2018/docs/themes/progress-progres-en.html?utm_source=CanCa&utm_medium=Activities_e&utm_content=Progress&utm_campaign=CAbdgt18)
Supporting Canada's researchers to build a more innovative economy