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# Compliance and enforcement policy for the *Assisted Human Reproduction Act*



POL-0100

June 26, 2019

Canada 

**Compliance and enforcement policy for the *Assisted Human Reproduction Act* (POL-0100)**

Author: Regulatory Operations and Enforcement Branch

Date issued: June 26, 2019

Date implemented: June 26, 2019

Replaces: New

**Disclaimer**

This document does not constitute part of the *Assisted Human Reproduction Act* (the Act) or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

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# 1. Introduction

The *Assisted Human Reproduction Act* (Act) and its regulations establish the framework to help protect the health, safety, dignity and rights of individuals who use or are born of assisted human reproduction (AHR) in Canada. This framework includes a set of prohibitions and penalties, provides for the oversight of processing donor sperm and ova used for the purpose of AHR and the reimbursement of donors and surrogates, and establishes regulatory requirements at the federal level on how such activities must be conducted to help protect public health and safety.

## 2. Purpose

As part of its regulatory responsibilities, Health Canada monitors compliance, undertakes enforcement activities and works towards preventing non-compliance. This policy describes Health Canada's national compliance and enforcement approach with respect to the Act and its regulations.

The following table shows the types of icons used in this document, and the way they are intended to be used:



**Important:** Key or cautionary information you want people to know.



**Information:** Supplementary information like quotes and legal references.

## 3. Background

Established on April 4, 2016, the Regulatory Operations and Enforcement Branch (ROEB) is a dedicated compliance and enforcement Branch within Health Canada. ROEB brings together Health Canada compliance and enforcement functions within one organization.

The current regulatory environment for AHR is characterized by a global supply of donor sperm and ova used; rapid scientific innovation and technological advancements; changing consumer behaviours; and increased demands for transparency regarding regulatory decision-making.

Canadians may be increasingly exposed to donor sperm and ova originating from jurisdictions that may not have a regulatory regime comparable to Canada.

It has become increasingly important to have a strong and dynamic compliance and enforcement function to protect the health of Canadians through modern legislation and effective compliance and enforcement actions supported by strong border oversight and international cooperation.

ROEB's mission is to lead compliance and enforcement activities and complementary scientific programs to inform and protect Canadians from health risks associated with products, substances and their environment. ROEB is also the centre for regulatory and policy expertise related to compliance and enforcement activities.

## 4. Scope

This policy applies to Health Canada's compliance and enforcement activities conducted in relation to material and activities that fall under the Act.

The regulated material under this Act includes:

- donor sperm used for the purpose of AHR
- donor ova used for the purpose of AHR
- *in vitro* embryos

The regulated activities under this Act include:

- providing consent for the use of donated human reproductive material for the purpose of creating an embryo
- processing donor sperm or ova for the purpose of AHR
- distributing donor sperm or ova for the purpose of AHR
- making use of donor sperm or ova for the purpose of AHR
- importing donor sperm or ova for the purpose of AHR
- reimbursing sperm and ova donors for expenditures
- reimbursing persons for expenditures related to the maintenance or transport of an *in vitro* embryo
- reimbursing surrogate mothers for expenditures and loss of work-related income

The prohibited activities under this Act include:

- knowingly creating a human clone or a chimera
- knowingly creating a hybrid for the purpose of reproduction
- knowingly performing procedures for the purpose of creating a human being that would ensure or increase the probability that an embryo will be of a particular sex or that would identify the sex of an *in vitro* embryo, except to prevent, diagnose or treat a sex-linked disorder or disease
- knowingly altering the genome of human cells or *in vitro* embryos in a manner that the alteration is capable of being transmitted to descendants
- paying surrogates or any other person to arrange the services of a surrogate
- purchasing or selling *in vitro* embryos
- purchasing sperm or ova from a donor or a person acting on behalf of a donor
- using human reproductive material without consent for the purpose of creating an embryo or using an *in vitro* embryo without consent for any purpose

## 5. Guiding principles

The work of Health Canada serves to advance the purpose of the Act, which is to protect and promote the health, safety, dignity and rights of Canadians who use or are born of assisted human reproductive technologies. [Health Canada’s Compliance and Enforcement Policy Framework](#) identifies a number of principles that guide Health Canada in carrying out its compliance and enforcement activities. Health Canada emphasizes the following guiding principles in the application of the Act under its mandate.

### a. Evidence-based

Health Canada’s compliance and enforcement actions and decisions are based on the best available evidence, information and science. Evidence is assessed objectively and is based on the [Health Canada Decision Making Framework for Identifying, Assessing and Managing Health Risks](#). Where relevant evidence is incomplete or inconclusive, a precautionary approach may be taken. As new information becomes available, the risk may change and require a different approach to compliance and enforcement.

### b. Risk-based approach

Health and safety risks can emerge from a number of sources, such as diverging from quality and safety requirements when processing donor sperm and ova or by making use of donor sperm or

ova that is contaminated. Providing financial compensation beyond expenditures associated with donation procedures or surrogacy crosses ethical boundaries and may put the safety and well-being of Canadians at risk through exploitation and the commodification of persons born through the application of AHR technologies. The 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.

When a regulated material or activity does not comply with the law, Health Canada makes an assessment to determine the most appropriate type of intervention. This assessment takes into account the characteristics of the material or the activity that may pose a risk to the health or safety of Canadians such as:

- the significance of the deviation from prescribed standards in the conduct of a regulated activity
- the severity of harm, real and potential, that may result from the non-compliance
- the complexity of the regulated activities conducted in relation to the material
- the regulatory status of the party conducting the regulated activity
- the exposure of Canadians to the material

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. For example, Health Canada will take into consideration:

- the behaviours of the regulated party conducting the activity, such as whether the regulated party acted with indifference, recklessness or premeditation
- the compliance history of the regulated party and previous compliance issues, including the regulated party's past and recent actions to comply with the law
- the degree of co-operation and responsiveness offered by the regulated party
- the likelihood of repeat compliance issues
- the likelihood of the enforcement action being effective in bringing the party into compliance or in mitigating the risk

Depending on the issue, additional factors may be taken into consideration, reflecting the unique circumstances of particular instances of non-compliance.

## c. Preventing exploitation and commodification

In Canada, sperm and ova donors cannot be paid – their donation must be altruistic. Exploiting the reproductive capabilities of children, women and men for commercial ends is strictly forbidden for health and ethical reasons.

The Act also prohibits the buying and selling of *in vitro* embryos in Canada, no matter the purpose, recipient or seller. This prohibition includes the exchange of property or services as a means of buying or selling an *in vitro* embryo. These prohibitions reflect concerns about the potential exploitation of donors and the potential commodification of human reproductive material and persons born through AHR.

As well, the Act also prohibits commercial surrogacy, including the payment of a female person to be a surrogate, as it raises concerns about the commodification and exploitation of the surrogate, the commissioning parent(s) and any person born as a result of the commercial surrogacy arrangement.

Despite these prohibitions, Health Canada recognizes that donors and surrogates should not be out of pocket for expenditures they incur because of their altruistic donation or surrogacy. While the donor cannot be paid in any way (money, gifts, services, etc.) for the donation of their sperm or ova, out-of-pocket expenditures directly related to their donation that are prescribed in the regulations may be reimbursed.

That said, the Act does not prohibit buying sperm or ova from a person other than a donor, if the person is not acting on behalf of the donor and the sale of sperm or ova. This means that the Act does allow fertility clinics and sperm banks to charge a fee for their services, which may include the storage, transfer and use of donated ova or sperm.

Similarly, while the purchase and sale of *in vitro* embryos are prohibited by the Act, the Act also recognizes the costs involved in the maintenance and transfer of an *in vitro* embryo and allows for reimbursement of such expenditures.

Although there is no obligation to reimburse, the Act allows the reimbursement of such expenditures, provided the reimbursement is done in accordance with the regulations. The purpose of the regulations is to set broad categories of expenditures eligible for reimbursement and to establish a verifiable process by which these expenditures can be reimbursed.



## d. Fairness, consistency and impartiality

Health Canada works to apply the Act in a fair, consistent and impartial manner. Qualified and authorized personnel are trained to carry out compliance and enforcement activities in a professional, unbiased and unprejudiced manner.

Health Canada follows a national approach to compliance and enforcement, regardless of where or by whom donor sperm or ova is processed, distributed, or imported, or where the reimbursement of expenditures or loss of work income occurs. To promote national consistency in compliance and enforcement activities, Health Canada personnel are trained on the relevant policies, guidelines and standard operating procedures.

Health Canada staff are guided by the [Values and Ethics Code for the Public Sector](#) and the *Health Canada Values and Ethics Code*.

## e. Transparency

Health Canada strives to make information about compliance and enforcement activities public. By making policies and guidance documents public, information on the decision-making process is clear and understandable to everyone. The Department provides access to information regarding compliance and enforcement actions while respecting its legal obligations under applicable privacy laws. For example, Health Canada makes available the results of establishment inspections so that persons using AHR technologies in Canada can make informed choices in selecting their source for donor sperm and ova.

Regulated parties can expect to see an increase in the type and scope of compliance and enforcement decisions made public. This approach is consistent with the Government of Canada's [Open Government](#) commitment to make government decisions, data and information more accessible to everyone.

Health Canada adheres to the [Directive on Open Government](#).

# 6. Role of Health Canada

ROEB is the organization in Health Canada responsible for the delivery of a national compliance and enforcement program for all material and activities regulated under the Act.

ROEB carries out inspections and other compliance and enforcement activities that follow applicable laws, policies and guidance documents. ROEB staff includes enforcement officials,

such as trained inspectors and laboratory analysts, as well as advisors and analysts providing subject matter and regulatory expertise.

Inspectors' powers are set out in sections 47, 48 and 50 of the Act. Section 47 states that "an inspector may, for a purpose related to verifying compliance or preventing non-compliance with any of sections 8, 10 and 12, enter any place or conveyance in which the inspector has reasonable grounds to believe that there is any activity, material or information in respect of which any of those sections applies." Under section 48, the inspector may also enter dwelling houses for inspection purposes with consent of the occupant or under the authority of an administrative entry warrant.

During an inspection, an inspector may, among other things, examine any material or information that is relevant to the purpose of verifying compliance or preventing non-compliance with any of sections 8, 10 and 12, take samples for laboratory analysis, conduct any test or analysis of any material, make copies and open packages. As well, under section 50, an inspector has the authority to seize and detain material or information by means of which, or in relation to which, the inspector believe on reasonable grounds the Act has been contravened. The Act also contains provisions for having seized information or material restored and provides for the automatic forfeiture of seized material or information within 60 days after the date of the seizure if no order of restoration is applied for or made.

Through guidance documents, ROEB provides general guidance to regulated parties, persons making use of AHR technologies and other stakeholders with respect to the legislation governing health products in Canada, including the consequences associated with non-compliance.

## 7. Roles and responsibilities of other parties

It is against the law to distribute, make use, or import donor sperm or ova for the purpose of AHR unless processed in accordance with the Act by a primary establishment registered with Health Canada. Anyone conducting a regulated activity under the Act has clearly defined responsibilities for the health and safety of Canadians using AHR technologies and persons born through the application of AHR technologies.

Other parties may also be subject to the Act although they may not require an authorization from Health Canada to perform certain activities. For example, while persons reimbursing expenditures incurred by donors or surrogates are not required to register or notify Health Canada to conduct their activity, they are subject to section 12 of the Act that prohibits the reimbursement of expenditures unless done in accordance with the regulations.

The primary responsibility of a regulated party is to understand its obligations under the Act and to comply with these requirements. Regulated parties who fail to comply will be subject to compliance and enforcement actions.

## a. Regulated parties

Regulated parties have **mandatory** responsibilities under the Act. Any place or conveyance where an inspector has reasonable grounds to believe that any activity, material or information related to sections 8, 10 or 12 of the Act is located can be inspected. Regardless of where donor sperm or ova is processed, if it is to be distributed, imported, or made use of for the purpose of AHR in Canada, it must be processed in accordance with applicable requirements under Canadian law.

The owner or person in charge of a place entered by an inspector designated under the Act as part of an inspection, and every person found in that place, are required to provide all reasonable assistance and information that may be reasonably required. For example, during an inspection, an inspector may request that a regulated party provide evidence that its facility, equipment, practices and procedures meet the applicable requirements. Obstructing or hindering, or knowingly making any false or misleading statement, either orally or in writing, to an inspector who is carrying out their duties under the Act is an offence.

Regulated parties are expected to:

- understand the relevant law and their obligations
- ensure their materials, activities and processes comply with the applicable laws
- provide all reasonable assistance to inspectors during an inspection as required by law

## b. Health professionals

Professional bodies regulate health professionals under provincial law. However, they may also have obligations under the Act if they conduct a regulated activity.

The *Safety of Sperm and Ova Regulations* define the term “health professional” as “a person who is authorized under the laws of a province to make use of sperm or ova in that province and who

- makes use of sperm or ova or distributes sperm to a recipient for their personal use;
- prepares, quarantines, labels or stores sperm or ova for the purpose of their use by that person; or,
- prepares, quarantines, labels or stores sperm for the purpose of its distribution by that person to a recipient for their personal use.”

According to that definition, health professionals include physicians and clinicians working directly in the healthcare field.

Physicians and other health professionals are responsible for the donor sperm or ova that they use or provide to patients. Under the Act, donor sperm or ova that is used or distributed by health professionals for the purpose of AHR must be processed in accordance with Canadian requirements. As such, health professionals must ensure that the donor sperm and ova they make use of for the purpose of AHR are processed according to Canadian law.

Among other requirements, health professionals must investigate any errors or accidents that occur during an activity they conduct. They are also required to report on any investigations they conduct that could result in an adverse reaction to Health Canada. Health professionals that have reasonable grounds to believe that an adverse reaction has occurred must notify the primary establishment responsible for processing the implicated sperm or ova immediately so that they may conduct an investigation. They should also inform Health Canada of any suspected adverse reaction related to donor sperm or ova. For more information on how to report an error, accident or an adverse reaction to Health Canada, you can consult Health Canada's [Adverse Reaction and Medical Device Problem Reporting](#) website.

Where a health professional conducts any activity that is subject to the Act and regulations other than those listed in the definition of a health professional, **that person would be considered an establishment** and subject to the relevant establishment requirements that correspond to the activities being carried out. Furthermore, where a health professional has incorporated their practice, **that corporation is considered an establishment** and is subject to the relevant regulatory requirements.

## 8. Compliance and enforcement actions and tools

Health Canada manages the risks posed to Canadians using AHR technologies and persons born through the application of AHR technologies through various types of compliance and enforcement activities. Health Canada chooses the actions and tools that are most appropriate for the situation, based on a number of factors. Some activities are designed to help regulated parties better understand their responsibilities under the Act. Others are designed to induce or compel compliance with the law. [Health Canada's Compliance and Enforcement Policy Framework](#) provides an illustration of the different levels of compliance and enforcement actions and shows how the different types of actions and tools are used.

Informed by the assessment of available evidence and risks pertaining to the situation of non-compliance, Health Canada will decide to use these actions and tools individually or together. Health Canada officials will also decide if the seriousness of the non-compliance and the risk

posed to the health and safety of Canadians warrants an immediate, strong and unequivocal response such as a registration suspension or a referral for prosecution. In other circumstances, a compliance and enforcement response proportionate to the identified risk will provide the regulated party with an opportunity to come into compliance. When the risk changes or considerations related to risk management evolve, Health Canada will adapt the type of enforcement response and the type of actions to the situation. If the situation of non-compliance persists, additional actions will be taken and these will escalate towards stronger compliance and enforcement actions.

The compliance and enforcement activities include:

- active prevention of problems through compliance promotion
- targeted oversight of risks through proactive compliance monitoring
- rapid response and enforcement to address detected public health risks

## a. Compliance promotion

Health Canada strives to support regulated parties in actively preventing problems from occurring in the first place. Compliance promotion focuses on raising awareness and educating regulated parties about their obligations under the Act. Health Canada publishes policies and guidance documents so that regulated parties understand Health Canada's interpretation of the legislation, the processes to follow and the scientific standards or principles that apply. Health Canada raises awareness amongst regulated parties regarding the range of compliance and enforcement actions available in cases of non-compliance. Compliance promotion also includes providing information to Canadians to help them make informed choices with respect to AHR.



### Intended Parents

Intended parents that are using donor sperm or ova or that are providing reimbursements to donors and surrogates have matters to consider and rules to follow. For example, intended parents that reimburse donors or surrogates must adhere to the requirements set out in the Act and regulations.

Intended parents also have a responsibility to educate themselves when selecting donor sperm and ova and to be careful when selecting donor sperm and ova from the Internet. Intended parents can recognize material authorised for distribution and use in Canada by the primary establishment's registration number that must accompany any material being distributed.

These registration numbers are assigned to primary establishments in accordance with the relevant regulations. Intended parents can check information about a primary establishment's registration on Health Canada's website.

Intended parents can also find [recall and safety alerts](#) on Health Canada's website. They are also encouraged to report any problems they encounter with donor sperm or ova through Health Canada's [Adverse Reaction and Medical Device Problem Reporting](#) website. This will help Health Canada to identify safety concerns.

## b. Compliance monitoring

Health Canada proactively carries out compliance monitoring activities to verify compliance with the Act, to respond to issues of non-compliance and to address the risk posed to the health of Canadians. Monitoring activities vary by product and activity and may include inspections to verify compliance and prevent non-compliance with sections 8, 10 and 12 of the Act, laboratory analysis of donor sperm, ova or other material and the review of reimbursement records. Inspections for activities related to sections 8, 10 and 12 of the Act may involve, but are not limited to, actions such as:

- visual examination of a facility, inventories, equipment, packaging, labelling and websites
- collection and review of documents and records
- collection of samples for laboratory analysis

The frequency, intensity and nature of compliance monitoring activities may vary according to the risks identified. Health Canada uses the information gathered through compliance monitoring to determine if further regulatory action is required. In particular, Health Canada:

- administers registrations for primary establishments
- gathers and analyzes a range of information, such as complaints and adverse reaction reports sent to Health Canada and compliance and enforcement information shared by foreign regulators
- carries out activities to verify compliance in response to information regarding known or suspected non-compliance with the applicable requirements of the Act

- conducts planned information-gathering projects that may focus on specific areas of the regulations or target specific regulated parties that will help determine if there are additional problems or areas of non-compliance that require enforcement actions
- collaborates with other Canadian (i.e. provincial and territorial governments) or foreign regulatory agencies as appropriate
- consults with additional subject matter experts, as needed

## c. Enforcement

Enforcement actions include any actions ROEB takes to compel or induce compliance in order to mitigate the risk resulting from non-compliance with the Act.

Based on the severity of the risk posed by regulatory non-compliance, Health Canada determines the most appropriate level of intervention. In alignment with the [Health Canada Compliance and Enforcement Policy Framework](#) and informed by the specifics of each case, Health Canada will choose the most appropriate tool to achieve compliance and mitigate any risks to health.

Regulated parties who are subject to a regulatory action or a decision will be provided with a reasonable opportunity to be heard when required by law.

### Enforcement Responses

Contravention of the provisions under the Act, whether intentional or unintentional, is unacceptable. When Health Canada identifies a contravention of the Act, it has a number of enforcement powers available to compel or induce compliance, to prevent or address non-compliance, or to address an issue of public health and safety. These include:

- sending letters to non-compliant regulated parties requesting that the regulated party submit a plan for corrective measures
- sending letters to non-compliant regulated parties requesting that the regulated party cease activities
- issuing public advisories or other forms of risk communication
- requesting a recall of regulated material that does not meet the requirements of the Act
- recommending the refusal or seizure of imports at the border
- requesting an importer take corrective measures on material under certain conditions, consent to its removal from Canada or to its seizure

- refusal, suspension, or cancellation of a registration
- seizure, forfeiture and disposal

## Taking measures

Section 44 of the Act contains provisions that enable Health Canada to take, or order any person to take, all reasonable measures that Health Canada considers necessary to mitigate the effects of a contravention of the Act or to prevent a contravention when there are reasonable grounds to believe that the Act has been or is likely to be contravened.

### Section 44



- (1) If the Minister has reasonable grounds to believe that this Act has been, or is likely to be, contravened, the Minister may take, or order any person to take, all reasonable measures that the Minister considers necessary to mitigate the effects of the contravention or to prevent the contravention.
- (4) No person who takes measures under this section, or who takes measures specified in an order made under this section, is personally liable either civilly or criminally in respect of any act or omission in the course of taking those measures unless it is established that the person acted in bad faith.
- (5) Subsection (4) does not apply to a person who has committed a contravention of this Act.
- (6) For greater certainty, orders made under this section are not statutory instruments within the meaning of the [Statutory Instruments Act](#).

*Note: subsections (2) and (3) were repealed in 2012.*

This authority may be used to take measures, or order a person to take measures that – based on the best available evidence, information and science objectively assessed – are expected to address an existing contravention or to mitigate the effects of the contravention. As well, measures may be taken if, based on knowledge, experience, expert advice or other information from a reliable source, the Minister has reasonable grounds to believe that a contravention is likely to occur and the measures are considered necessary to prevent the contravention.

Measures that may be taken, or ordered to be taken, include:

- ordering a person to stop conducting a regulated activity
- refusing the importation of regulated material at the border that do not meet the requirements of the Act



- ordering a person having possession, care, or control of imported regulated material that does not meet the requirements of the Act, or was imported in contravention of the Act, to remove it from Canada
- ordering a recall of regulated material that does not meet the requirements of the Act, or ordering such regulated material to be sent, or cause it to be sent, to a place specified in the order
- ordering a person to modify the label of regulated material or modify or replace its package if the label or packaging does not meet the requirements of the Act

## Seizure

Seizure is an enforcement tool that may be undertaken by an inspector to address a non-compliance. The objective of seizure to address non-compliance is to control or mitigate a risk to the health or safety of the Canadian public because of information or material deemed to be in contravention of the Act.

The powers to seize material or information rests with the inspector. Seized material or information may be stored on site or in another location. Where seized sperm, ovum or *in vitro* embryos are seized on site, identification methods would be used to segregate seized material, such as seizure tags, from inventory available for distribution.

A person from whom material or information are seized may apply to a provincial court judge within whose jurisdiction the seizure was made for an order of restoration within 60 days after the date of seizure. If no application for restoration is made, or if an application is made but no order of restoration is made, the seized information or material is automatically forfeited to the Crown 60 days following the seizure.



In order to apply for an order of restoration, the applicant must send a notice to the Minister at least 15 days before the day on which the application is to be made that specifies:

- the provincial court judge to whom the application is to be made
- the date, time and location of where the application is to be heard
- the seized material or information that is the subject of the application

- the evidence that will be relied on to establish that the applicant is entitled to possession of the seized material or information

If the judge is satisfied that the applicant is entitled to be in possession of the seized material or information and it will not be required as evidence in any proceedings under the Act, then the judge may issue an order of immediate restoration or, if the seized material or information will be used as evidence in a any proceeding under the Act, an order of later restoration. This order would return the seized material or information back to the applicant.

The designated officer within Health Canada must make reasonable efforts to preserve any viable sperm, ova, or *in vitro* embryos that are seized under the Act or the *Criminal Code of Canada*. If that seized sperm, ova, or *in vitro* embryos is forfeited to the Crown, then any further measures taken must be consistent with the consent of the donor – which can include the original consent to use from the donor or any consent provided to a clinic by the donor – for the destruction of the sperm, ova or *in vitro* embryo. However, if it is impossible to obtain the consent of the donor for further measures, any further measures must be in accordance with the *Administration and Enforcement (Assisted Human Reproduction Act) Regulations*, which only permit the designated officer to direct the disposal of donor sperm, ova or *in vitro* embryos 180 days after it had been forfeited.

## Investigation and prosecution

In certain circumstances, Health Canada’s regulatory enforcement responses are not sufficient to achieve compliance. In these instances, Health Canada may conduct an investigation into potential offences under the Act or make a referral to law enforcement.

### Investigation

An investigation involves collecting evidence under the authorities available in the *Criminal Code of Canada* (e.g., search warrant and production order). Health Canada will prioritize contraventions by parties who:

- demonstrate a disregard for the legislative and regulatory requirements
- have a history of contravening the Act
- are engaging in activities that could cause serious harm, such as
  - prohibited activities
  - intentional avoidance of the law

- o the distribution, making use of, or importation of donor sperm and ova that has not been processed in accordance with Canadian law

## Prosecution

Health Canada may refer the results of its investigation to the Public Prosecution Service of Canada recommending prosecution in relation to offences under the Act and the *Criminal Code of Canada* where applicable.

Sections 60 and 61 of the Act contain offence provisions that provide for a fine, a term of imprisonment, or both.

### Section 60



A person who contravenes any of sections 5 to 7 and 9 is guilty of an offence and

- (a) is liable, on conviction on indictment, to a fine not exceeding \$500,000 or to imprisonment for a term not exceeding ten years, or to both; or
- (b) is liable, on summary conviction, to a fine not exceeding \$250,000 or to imprisonment for a term not exceeding four years, or to both.

### Section 61



A person who contravenes any provision of this Act — other than any of sections 5 to 7 and 9 — or of the regulations or an order made under subsection 44(1) is guilty of an offence and

- (a) is liable, on conviction on indictment, to a fine not exceeding \$250,000 or to imprisonment for a term not exceeding five years, or to both; or
- (b) is liable, on summary conviction, to a fine not exceeding \$100,000 or to imprisonment for a term not exceeding two years, or to both.

## Notifying interested authorities

Health Canada administers the Act in a manner that complements the important role that the provincial and territorial governments play in the delivery of healthcare in Canada.

Section 64 of the Act enables Health Canada to inform provincial and territorial medical regulatory authorities of the identity of any person who is charged with an offence under the Act

or who Health Canada has reasonable grounds to believe may have acted in breach of any professional code of conduct.

#### **Section 64**



The Minister may notify any interested authority, such as a professional licensing or disciplinary body established under the laws of Canada or a province, of the identity of a person who is charged with an offence under this Act or who there are reasonable grounds to believe may have acted in breach of any professional code of conduct.

In addition, if any identified issues are not within the scope of the Act, Health Canada may refer those matters to the appropriate authority.

# Appendix A – Glossary

## Acronyms

**AHR:** assisted human reproduction

**ROEB:** Regulatory Operations and Enforcement Branch

## Terms



These definitions explain how terms are used in this document. If there is a conflict with a definition in the *Assisted Human Reproduction Act* or associated regulations, the definition in the Act or regulations prevails.

**Accident** – An unexpected event that is not attributable to a deviation from standard operating procedures or applicable laws that could compromise human health and safety or the safety of sperm or ova.

**Adverse reaction** – 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.

**Chimera** – An embryo into which a cell of any non-human life form has been introduced or an embryo that consists of cells of more than one embryo, foetus or human being.

**Compliance** – The state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or a product with a legislative or regulatory requirement.

**Compliance monitoring** – Actions planned to maintain regular surveillance in order to evaluate compliance with applicable requirements of the Act and its associated regulations. This includes a wide variety of fact gathering and assessment activities such as inspections, market surveys and a product-sampling program.

**Compliance promotion** – Actions taken to educate about roles and responsibilities prescribed by the Act.

**Donor sperm and ova** – Sperm or ova that is obtained from a donor and that is meant for the use of a female person other than a spouse, common-law partner or sexual partner of the donor, or ova that has been obtained from a donor and that is meant for the donor's use as a surrogate.

**Embryo** – A human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended and includes any cell derived from such an organism that is used for the purpose of creating a human being.

**Enforcement** – Actions that may be taken to compel or induce compliance in order to mitigate the risk identified by non-compliance with the Act and its associated regulations.

**Error** - a deviation from standard operating procedures or applicable laws that could compromise human health and safety or the safety of sperm or ova.

**Foetus** – A human organism during the period of its development beginning on the fifty-seventh day following fertilization or creation, excluding any time during which its development has been suspended and ending at birth.

**Human clone** – An embryo that, as a result of the manipulation of human reproductive material or an *in vitro* embryo, contains a diploid set of chromosomes obtained from a single — living or deceased — human being, foetus or embryo.

**Hybrid** – The combination of human and non-human genetic material:

- a human ovum that has been fertilized by a sperm of a non-human life form;
- an ovum of a non-human life form that has been fertilized by a human sperm;
- a human ovum into which the nucleus of a cell of a non-human life form has been introduced;
- an ovum of a non-human life form into which the nucleus of a human cell has been introduced; or
- a human ovum or an ovum of a non-human life form that otherwise contains haploid sets of chromosomes from both a human being and a non-human life form.

**Information** – Information that is recorded in any form.

**Inspection** – With respect to verifying compliance or preventing non-compliance with sections 8,10 or 12, monitoring and assessment against the applicable requirements of the Act and its associated regulations. Inspections may also be routinely conducted based on risk to assess compliance.

**Inspector** – Any person designated as an inspector under section 46 of the Act.

***In vitro* embryo** – An embryo that exists outside the body of a human being.

**Material** – 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.

**Precautionary Approach** – An approach to risk management decision-making that is applied in circumstances of scientific uncertainty, reflecting the need to take action in the face of a potentially serious risk without awaiting the results of scientific research. Cost-effective action must be taken when there are threats of serious or irreversible damage to human health, even if some cause and effect relationships are not fully established scientifically.

**Primary establishment** – 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.

**Processing** – in respect of sperm or ova, means performing the donor suitability assessment, obtaining the sperm or ova from a donor, preparing, identifying, testing, preserving, assessing quality, labelling, quarantining, or storing.

**Surrogate** – a female person who – with the intention of surrendering the child at birth to a donor or another person – carries an embryo or foetus that was conceived by means of an assisted reproduction procedure and derived from the genes of a donor or donors.

# Appendix B – References

## Laws and regulations

### *Criminal Code of Canada*

[laws-lois.justice.gc.ca/eng/acts/C-46/](https://laws-lois.justice.gc.ca/eng/acts/C-46/)

### *Assisted Human Reproduction Act*

[laws-lois.justice.gc.ca/eng/acts/a-13.4](https://laws-lois.justice.gc.ca/eng/acts/a-13.4)



Regulations made under the *Assisted Human Reproduction Act* include:

- Consent for Use of Human Reproductive Material and In vitro Embryos Regulations
- Safety of Sperm and Ova Regulations
- Reimbursement Related to Assisted Human Reproduction Regulations
- Administration and Enforcement (Assisted Human Reproduction Act) Regulations

All regulations made under the Act can be accessed by clicking on the link attached to the *Assisted Human Reproduction Act*.

## Other related documents

### [Directive on Open Government](https://tbs-sct.gc.ca/pol/doc-eng.aspx?id=28108)

[tbs-sct.gc.ca/pol/doc-eng.aspx?id=28108](https://tbs-sct.gc.ca/pol/doc-eng.aspx?id=28108)

### [Health Canada Decision-Making Framework for Identifying, Assessing and Managing Health Risks](https://canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/health-products-food-branch/health-canada-decision-making-framework-identifying-assessing-managing-health-risks.html)

[canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/health-products-food-branch/health-canada-decision-making-framework-identifying-assessing-managing-health-risks.html](https://canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/health-products-food-branch/health-canada-decision-making-framework-identifying-assessing-managing-health-risks.html)

### [Health Canada's Compliance and Enforcement Policy Framework](https://canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-does-as-regulator/compliance-enforcement-framework.html)

[canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-does-as-regulator/compliance-enforcement-framework.html](https://canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-does-as-regulator/compliance-enforcement-framework.html)

### [Values and Ethics Code for the Public Sector](https://tbs-sct.gc.ca/pol/doc-eng.aspx?id=25049)

[tbs-sct.gc.ca/pol/doc-eng.aspx?id=25049](https://tbs-sct.gc.ca/pol/doc-eng.aspx?id=25049)



## Websites

[Assisted human reproduction](#) on Health Canada's website

[canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/legislation-guidelines/assisted-human-reproduction.html](http://canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/legislation-guidelines/assisted-human-reproduction.html)

[Compliance and enforcement](#) on Health Canada's website

[canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement.html](http://canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement.html)

[How to report an adverse reaction to Health Canada](#)

[canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html](http://canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html)

[Recalls and safety alerts](#)

[healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php](http://healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php)

[The Government of Canada's Open Government Initiative](#)

[open.canada.ca/en](http://open.canada.ca/en)